The Importance of Cleaning Validation in Allergen Management

White Paper

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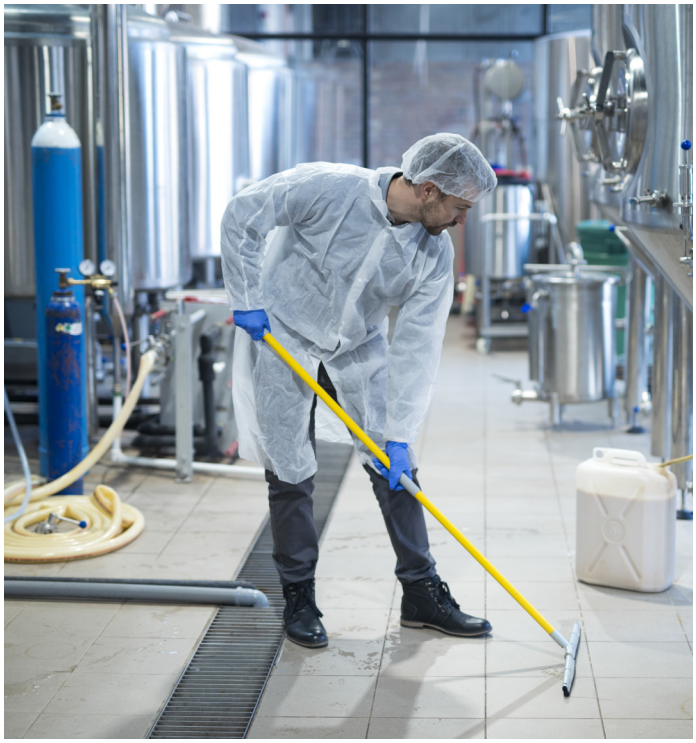
Introduction

When we think about cleaning in the food industry, we usually consider its function in terms of hygiene. However, when using equipment that is shared between multiple recipes, cleaning is also a vital control in product changeover (whether that is a tray used to carry ingredients or the whole production line). This is especially true when the cleaning provides a break between the changeover of recipes with different allergen profiles. To assess whether there is any carry over of allergens after cleaning, it is important to have scientific evidence that the cleaning procedures are effective and are sufficient at removing all traces of allergens from the shared equipment, therefore reducing the risk of carry-over into the next made product. By gathering this evidence, food manufacturers can confidently avoid the use of Precautionary Allergen Labelling (PAL) on their products.



The role of cleaning validation

The validation of cleaning procedures is about obtaining evidence to prove that the cleaning process works and can be shown to be effective repeatedly. Validation shouldn't be confused with the similar sounding verification, or with monitoring. Cleaning verifications are periodic assessments which show that the procedure is still effective after the validation. An example of verification tools that are sometimes used, are qualitative Rapid Lateral Flow Devices (RLFDs). RLFDs are best suited to environmental samples like rinse waters and surface swabs. It is important to remember that if these are used, they are properly validated for the factory's specific contaminants. Monitoring activities are the checks that are carried out every single time the clean is done and often involve visual inspections and signoffs.

A cleaning validation study is a quantitative assessment of cleaning methods to ensure that they are sufficient to minimise the risk of unintentional allergen presence in the next produced product, that could occur from using shared equipment. This process is a formal requirement of HACCP, as well as being incorporated into GFSI standards such as BRCGS and FSSC 22000.

The validation of the cleaning process should be planned, rigorous and thorough, and is often a large piece of work. Once the validation has been completed and it has shown that the cleaning procedure is acceptable, the validation should not need to be repeated, unless there is a change to the manufacturing process, the method of cleaning or the ingredients that are used.

In the cases where the cleaning is shown not to be sufficient, the analytical results should indicate either where improvements need to be made and the validation should be repeated, or that it is not practical to clean the equipment to an acceptable level. In the latter case, an investment in new or dedicated equipment may need to be investigated or where this is not feasible, the cleaning validation has provided evidence that precautionary allergen labelling should be used.

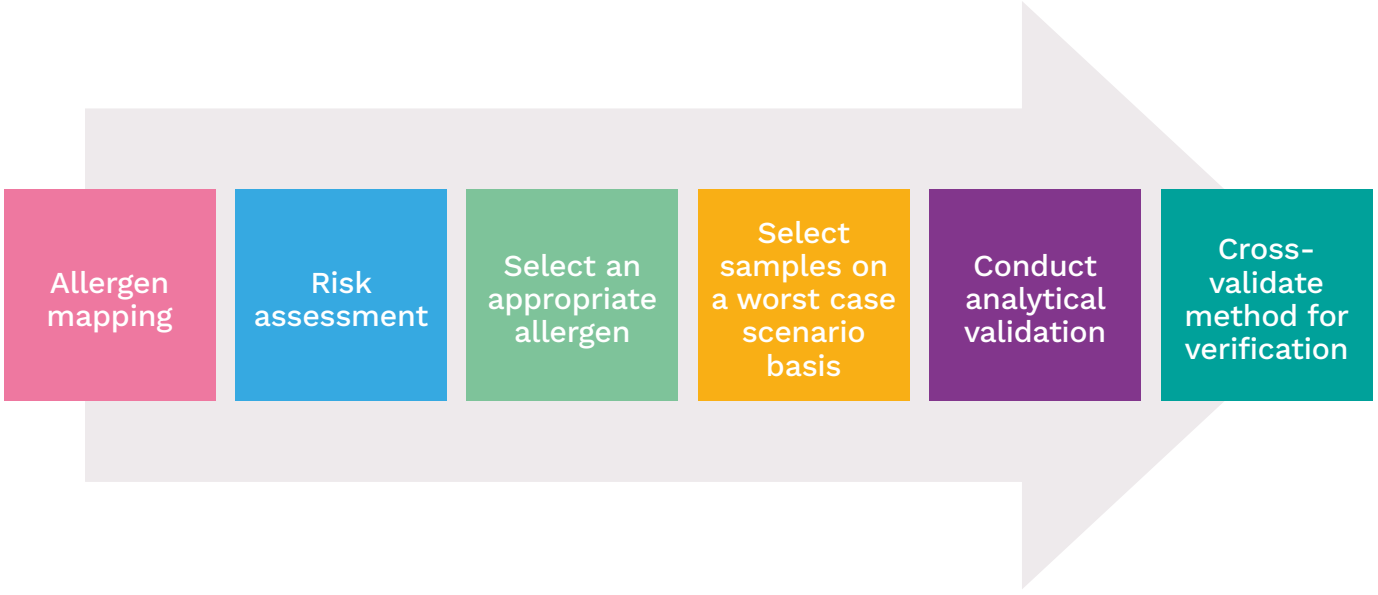


Figure 1: Process flow of conducting a cleaning validation

Designing a cleaning validation programme

The key to a successful cleaning validation study is planning. It is important to take the best samples for the specific production process, as there is no “one size fits all” solution, and careful planning should allow for saving on time and cost. It is not about the quantity of swabs and samples that are taken and sent for analysis, but the quality of them.

The process of conducting a cleaning validation begins with allergen mapping and thinking about what allergens there are on site. In some cases, there may only be one or two allergens and depending on the layout of the factory it might be possible to map out where they travel, how they are moved and what equipment they are used on during the production process. In this assessment, consideration should be given not only to which allergens are used on site, but also to the physical form they are in. For example, a powder is likely to be a higher risk than a solid that is potentially easier to contain.

The next step, doing a risk assessment, will identify all the processes and areas where there is a potential for unintentional allergen presence in a product that does not contain that allergen. Not all the risks and processes identified are going to be managed by cleaning - for example, risks like mislabelling of materials in a warehouse will be managed through other measures. However, where there is shared equipment between allergen and non-allergen ingredients or products and cleaning has been identified as a control measure, this will need to be subjected to a cleaning validation plan. The risk assessment exercise should highlight which equipment is shared and which allergens are involved.

When planning the cleaning validation, consideration should be given to which equipment in the production should be chosen and which target allergens can be used to demonstrate that the cleaning has been effective at removing the risk of carry-over. A cleaning validation should include the most high-risk pieces of equipment and by watching a clean take place this will help identify difficult to clean or reach areas, including where product is likely to get held up. If there are multiple lines and the equipment layout is similar and the cleaning process is identical, then a site does not need to conduct a cleaning validation on every line for every allergen. A target allergen can be selected to show the cleaning is effective for other allergens, if one is chosen that is present in sufficient quantity, has a high protein level, is hard to clean off the equipment and which has a suitable detection method. If the target allergen can be shown to be removed successfully, then easier to clean allergens in lower quantities will also be removed using the same cleaning procedure.

It is also good practice that if the equipment is made from a variety of different materials, that these are all included in the cleaning validation. A piece of equipment that is made from stainless steel is going to be easier to clean compared to something that is made of rubber.

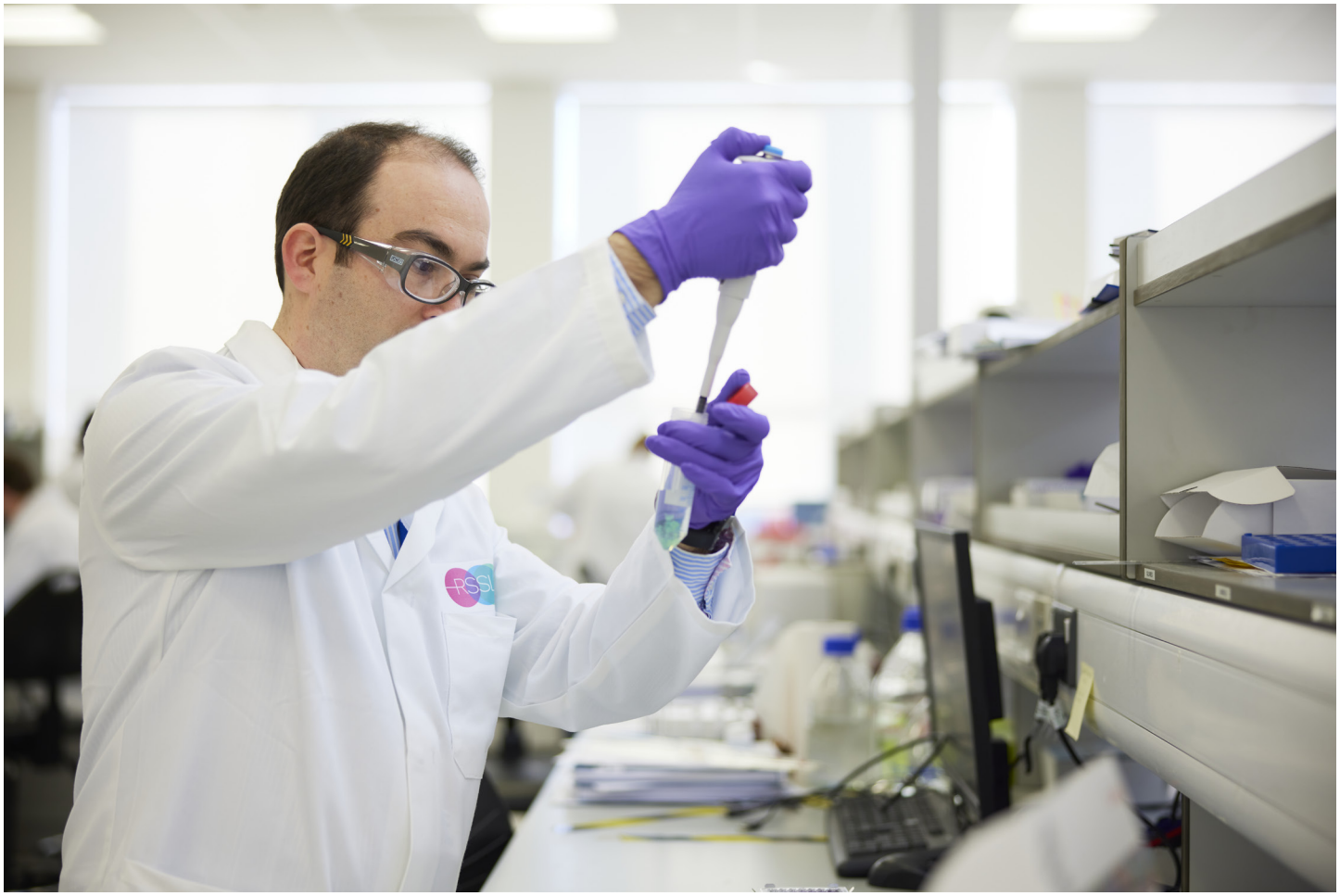
Figure 2: Diagram showing (from left to right) progression from materials that are typically easier to clean to those that are more difficult to clean.

Sampling and analysis

When designing a cleaning validation programme, the sampling that takes place needs to be considered, both in terms of what type of sample to collect as well as what to test those samples for. A key point to base these decisions on, which should be helped by the risk assessment and allergen mapping, is choosing the worst-case scenario allergen, as discussed above.

There are multiple types of samples that should be taken. These are spilt into product samples (pre-clean product containing the allergen of concern and post-clean product made after the clean) and environmental samples (surface swabs, purge samples, rinse waters from a CIP system and air monitoring system / settle plate testing). Typically, a cleaning validation will require a combination of these types of samples, but this will vary depending on the type of factory and line.

Choosing the right analytical method to use for the testing is also hugely important. Ideally the testing should be done using an ELISA method, as they are quantitative and specifically look for the protein in the sample making them more clinically relevant. The method chosen should not only be validated itself, but also validated for the specific sample collected, otherwise there is a risk of false negative or false positive results, potentially leading to lengthy and costly recalls or investigations. False positive or negative results can occur because food is generally a complex matrix and can cause different types of interferences with biological assays. It is not feasible when doing the initial validation of an ELISA kit to test every single combination of ingredients. Therefore, when a laboratory hasn't tested a specific food type before, it is important that they do this extra level of validation, usually in the form of spike recovery testing, to ensure that the results are accurate and reliable.



Testing of positive controls is critical and will not only show that a good target allergen has been chosen, but also that the test method is suitable for the sample collected. There are lots of different tests out there for each allergen and all of them are going to perform slightly differently and it is not just a case of choosing the most sensitive test. A good example of this is when testing for egg allergen, some ELISA tests on the market are designed to detect raw egg and are actually very poor at detecting cooked egg. Therefore, if the contaminant is cooked egg, the test chosen needs to be one that is specifically designed to detect this. Testing a positive control, the pre-clean product containing the allergen of concern, will show whether the test chosen is good at detecting the factory's specific contaminant. If the test can't detect the allergen of concern when it is supposed to be there in large quantities, then it is not going to be able to detect the allergen when it is only present at trace levels.

Documentation

Maintaining good records of the results and outcomes of the cleaning validation is a given but it is also important to document all the decisions made before starting the cleaning validation. This includes everything from the reasons behind which allergen to target, to the decisions on where to take swabs. This is useful for not only demonstrating the business has done everything reasonably practicable to ensure the cleaning is effective but also, if the person who previously conducted the cleaning validation has left the business or is unavailable, there are documented reasons for the decisions made which will allow others to understand what has been done.

Part of the documentation will also be the recording and maintenance of training records, as the compliance and understanding from the staff undertaking the cleaning procedures is essential in effectively managing a facility with non-dedicated equipment.

All this documentation makes up part of a site's due diligence and will be vital if an incident did occur, proving that there is a system and importantly, that the system works.

Conclusion

Demonstration of the effectiveness of cleaning through validation programmes is an essential process for a food business to undertake, but only when based on thorough planning, taking into consideration allergen mapping, risk assessments and considering the specific risks from that site. With the use of suitable quantitative analytical methods, using the worst-case scenario products and being backed up by verification and monitoring practices, this all provides evidence of the continued effectiveness of the cleaning procedures in place.

Whilst cleaning is a control measure used to reduce allergen contamination, it must be remembered that it should never be used in isolation. Instead, effective cleaning should be seen as an important part of the broader picture of allergen management.

How RSSL can help

RSSL is an established expert in cleaning validation and the management of allergens throughout the food production process. We can provide support with analytical testing, allergens training as well as manufacturing consultancy.

To find out more, please contact us on: **+44 (0)118 918 4076**, email **enquiries@rssl.com**, or visit **www.rssl.com**

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Leyla is a biologist and the newest consultant in RSSL's Food Safety and Quality team, where her focus is on allergen management and supporting clients from different areas of the food industry. Leyla's projects range from general allergen advice to practical on-site training for manufacturers, retailers and food service businesses.

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