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Cleaning: Considerations and Testing Tools for a Strong Cleaning, Sanitation and Allergen Monitoring and Verification Program

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Relevance of Cleaning as a Prerequisite for Food Safety

Establishment of food safety plans have an objective to prevent the introduction of physical, chemical and microbiological risks in the food supply chain. Management systems like Hazard Analysis Critical Control Points (HACCP) enable physical, chemical and biological risks from raw materials, product distribution and consumption to be addressed by implementing controls through risk analysis. Principles of HACCP are also in alignment with the requirements of the Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) rule for food processors — Hazard Analysis and Risk-Based Preventive Controls (HARPC). The HARPC rule enables identification of potential risks associated with foods and processes in order to implement controls to minimize the hazards.

Systems like HACCP and HARPC will only be effective if good manufacturing practices (GMPs) and prerequisite programs, including pest-control, traceability and recall, hygiene and sanitation are correctly developed and implemented.[1] Among these prerequisites the need to implement standardized procedures for cleaning and sanitizing of the plant and food processing equipment are of great importance for the success of any robust food safety management system.[2,3,4]

Cleaning for Hygiene and Cleaning for Allergens

Cleaning is the process of removing food and other types of debris from a surface. It involves the application of physical, chemical and thermal energies, or a combination of them, to remove food residues.[5] The combination of these energies will determine the effectiveness and rate of the cleaning method. An effective cleaning process should balance cleaning effectiveness, food safety and cost.

The process of cleaning will be specific to the equipment, surfaces, utensils or rooms in a facility, but overall it includes: the removal of gross soil or debris, rough clean, pre-rinse, clean, post-rinse and inspection.[6]

General cleaning is often done with the objective of eliminating food and debris from a surface for efficient sanitation. Without effective cleaning, sanitation will be compromised.[7] Together, cleaning and sanitation can prevent the development of niche sites, where microorganisms can establish, develop and become a focus of contamination for pathogenic or spoilage microorganisms.

Allergen cleaning is considered a preventive control to minimize the risk of cross-contact contamination and it is required where an allergen is not an intentional ingredient of the food that is going to be produced. Allergen cleaning has the specific objective of removing food allergens (usually proteins) from surfaces and equipment to eliminate the risk of cross-contamination. *Cleaning procedures may be satisfactory for hygiene purposes but may not be sufficient for the removal of allergens from surfaces.*[5]

Cleaning Validation

Cleaning validation consists of proving and documenting that a cleaning regimen or procedure will lead to the expected results (removal of food residues or removal of allergens), and thus meets the cleaning objective of the hazard to be controlled.[3] During a cleaning validation study there are several aspects to be considered.[3,4] One of the key elements is the need of selecting analytical methods that provide the evidence that the cleaning regime has met a defined acceptance criteria that is practical, achievable and verifiable.

Analytical methods used for cleaning validation should be specific for detecting the risk to be evaluated; such as, one or a group of microorganisms, a specific allergenic food protein or chemical residue. Before selecting a method, it is important to verify that it is fit for purpose[8] and it can detect the target analyte with the specificity and sensitivity at an accepted established criterion.

Analytical Methods for Validation for Cleaning and Sanitation

After a product run, the validation of a Sanitation Standard Operation Procedure (SSOP) for cleaning should be performed. In the case of cleaning for hygiene, validation may be performed to assess cleaning and sanitation, to demonstrate that the process is effective in removing soil, food debris and that the sanitizer is effectively eliminating microorganisms. To assess the effectiveness of this process various analytical methods can be considered in relevant test points:

A. Visual Inspection: Visual clean is an expectation after a cleaning process has been carried out and before sanitation is performed. This method enables an overall assessment of the equipment and surfaces. Visual inspection does require training for inspectors assessing the cleaned equipment, areas or surfaces to ensure that the assessment occurs with the same criteria. Visual inspection may benefit with the use of UV light, flashlight or backlight. This procedure has limitations, as it is still subjective and imprecise, even with trained personnel. Attached proteins and microorganisms may be present even in a visually pristine surface; thus *visual inspection should be considered as an expectation but not as a method to assess cleanliness, and it is not sufficient for a validation study.*

B. Microbial Quantification: Sampling relevant test points with swabs for direct enumeration of microorganisms enables the collection of data (microbial counts) to validate that the SSOP can remove microorganisms to an acceptable level. When utilizing microbial counts, it is important to 1) perform the sampling after the sanitizer has been rinsed; 2) ensure that the sample collection device is appropriate for the surface to be tested; and 3) that it contains a neutralizing solution to minimize residual sanitizing effect on microorganisms. Another point of consideration is the microbial target to be selected and detected. Pathogenic microorganisms, in general, should not be present and if they are, their presence may be in levels below the limit of quantitation of most enumeration methods.

The use of indicator organisms, such as total aerobic count, helps to provide information about where the total population of bacteria present and capable of growing may create a niche, thus it is a valuable target to validate sanitation procedures,[9] and could be considered as an analytical method during validation. Other microbial groups such as *Enterobacteriaceae* may also be utilized as a target.

C. ATP: Detection of adenosine triphosphate is also a valuable resource during the validation process. ATP is considered a universal energy molecule for the cell, besides being present in all living cells, it is also present in residues from organic sources such as food debris, biofilms and surfaces touched by operators. ATP detection is often coupled to a light emitting reaction. In this reaction, the amount of light usually corresponds to the amount of ATP containing organic matter present. As it will be discussed later, ATP is a highly efficient tool for hygiene monitoring. However, it should also be considered as a tool for validation. During validation, it is possible to involve a higher testing frequency and more test points. The collected data will help to establish baseline levels.[10] An ATP value (often expressed in Relative Light Units) can be assigned to what a clean and sanitized surface should be and similarly to microbial counts, it offers numerical evidence about the efficiency of the SSOP. It is important to consider that ATP should not replace microbial enumeration methods; the amount of ATP is not necessarily correlated with microbial count results. *The use of both microbial and ATP quantification can provide a more robust set of data to support that the SSOP will be effective.*

Analytical Methods for Allergen Cleaning Validation

Similar to cleaning and sanitation, a validation study for an SSOP is performed to demonstrate that cleaning procedures being used are effective for the target allergens to prove that allergenic foods are removed or reduced to an acceptable established limit[11] (i.e., "Allergen Clean"). Allergens in the food industry refer to proteins from foods that have the capability to elicit an immune reaction in sensitive individuals.[12] Thus, analytical methods with the capability of detecting proteins are utilized during a cleaning validation process.

A. **Visual Inspection:** Like validation during cleaning and sanitation, visually clean is an expectation and should be the starting point but is not sufficient for a validation study.

B. **Antibody-based Assays:** Allergen specific methods like Enzyme-Linked Immunosorbent Assay (ELISA) enable the quantification of a specific food allergen (i.e., soy protein, milk protein, peanut protein, etc.). ELISA is based in the recognition of these proteins by specific antibodies that can recognize proteins and bind to them. The assay is coupled to a color-producing reaction so that there is a correlation between the color produced by a test sample and the amount of protein present in it. Lateral Flow Devices (LFDs) are also allergen-specific tests in which antibodies are also used to recognize specific proteins from foods. Different from ELISA, most LFDs are designed to generate a qualitative result (i.e., presence or absence of a protein). During a validation study, testing can be done pre-cleaning with a specific allergen test as it enables the establishment of an initial baseline of the level of allergenic foods present in an equipment or surface. Then the testing can be repeated after cleaning to confirm that the level of allergenic food is decreased (ELISA) or eliminated (i.e., below limit of detection; by ELISA or LFD) to an acceptable level. Some validation studies will include final product testing. This testing is usually the first production off the line after cleaning and sanitation and may be tested to verify the absence of an allergenic food as well as supplement the information generated on surfaces and equipment. There are several specific immunoassays used to detect proteins from allergenic foods, and the scope of the assay should be considered when selecting a method. Not all ELISA or LFD tests are designed for swabs or clean-in-place rinse water, and they may not all be suitable for food matrices. Thus, verifying the performance of the selected method before a validation study is critical. When evaluating cleanliness of a production line that contains several allergens, it may be possible to choose a single target allergen to represent all of the allergens by selecting the allergenic food in highest concentration in the product or the one that has been harder to remove. Often selecting the allergenic food in highest concentration in the product or the one that has been harder to remove may be an option.

C. **Non-specific Protein Testing:** Protein Swabs can be qualitative or quantitative colorimetric assays (e.g., biuret reaction or bicinchoninic acid [BCA]). These methods are capable of detecting proteins, however they lack specificity. These tests indicate the presence of protein on a surface, but will not differentiate specific proteins (i.e., milk protein vs. soy protein). In general, protein swabs may have a lower sensitivity than most antibody-based assays. Since the objective of a validation study is to demonstrate the removal of an analyte that was considered a risk for the production, the use of non-specific protein tests is not the ideal method for an allergen validation study. As ATP and general protein tests do not detect proteins from allergenic foods specifically, many auditing and certification firms now specifically request validation data conducted with specific-allergen testing.[13] For example, guidelines provided by the Safe Quality Food (SQF) only consider the use of specific allergen tests acceptable, as it provides specific evidence that the cleaning method is effective in removing a "specific allergen." Both ELISA and LFD methods have been accepted as recognized methods that meet the requirements for sanitation validation of the SQF Code.[14] Since non-specific protein assays may be used for routine verification, they may be included in the validation study to show that results obtained during the validation study with a specific-protein method are aligned with a protein assay.

A cleaning validation study is typically performed with acceptable results in 2–3 product runs. The process should be revalidated if a critical element has been changed, such as, major changes to product formulation, changes in detergents or sanitizers, different process schedules, cleaning procedures, etc. If there are no changes, a periodic revalidation is appropriate. The frequency and extent of the revalidation should be determined using a risk-based approach considering historical data that will be gathered during monitoring and verification.

Cleaning Verification

After an SSOP is validated and determined that it meets the requirements to effectively remove food, debris, chemicals and allergens, it is important to maintain the validated status. Verification shows that the implemented SSOP is working to monitor the risk to make sure it is under control. Analytical tools are required to provide ways for routine monitoring of the status of the equipment, surfaces or finished product after cleaning and sanitation have been performed. Like validation, relevant testing sites that are selected during the validation study can be tested for routine verification using a variety of different methods.

A. **Visual Inspection for Verification:** Can give a quick big-picture view about the effectiveness of cleaning and, as mentioned before, it is an expectation but, alone, it is not sufficient because trace levels of contamination cannot be seen by the naked eye. In addition, there may be surfaces on production equipment that cannot be visually inspected but may be contaminated. Visual inspection can be a precursor to ATP and allergen testing but it should not be a substitute.[15]

B. **ATP Monitoring for Verification:** Verifying cleaning of surfaces is the first basic step and it is usually done after cleaning and pre-operation. Hygiene Monitoring with ATP is a widely used approach because it is highly efficient as it quickly and easily provides results. Instead of quantifying specific microorganisms, it measures whether cleaning has been effective, and whether manufacturing can begin, or ATP levels may show that recleaning and retesting are necessary to minimize contamination before food processing starts. Hygiene monitoring with ATP generates a valuable reservoir of information as data is collected routinely. One advantage of ATP monitoring is that it can be trended and analyzed for hygiene management. By doing this, the collected data becomes information that goes beyond just immediate corrections (like reclean) and enables the identification of possible failures and allows for implementation of corrective actions that may be sustainable long term.

C. **Microbiological Enumeration for Verification:** Monitoring of microbial populations is still a valuable tool for verification, however different from ATP, cannot provide immediate results to the manufacturing sites, so it may not be done after every cleaning. However, the use of microbial enumeration for verification will establish verification of sanitation and thus should be performed periodically and on relevant testing points.[9,15] Both frequency and number of test samples should be selected based on a risk-based approach. Data trending allows continuous evaluation of the sanitation process and it enables continuous improvement for product safety and shelf life improvement.

D. **Verification of Allergen Cleaning:** Allergen cleaning should be verified after cleaning is done when product change-over has occurred to verify that the production line does not contain traces of foods from the previous run. This is with the objective of preventing cross-contact contamination. While ATP could be utilized as a first step to verify cleanliness, it should be considered that all cellular life contains ATP. For example, a positive ATP swab indicates that the surface requires additional cleaning but does not necessarily indicate the presence of protein. The use of ATP for allergen cleaning verification stands to reason that if a surface is cleaned sufficiently well to remove ATP to a low level, then the cleaning has been adequate to remove allergens.[16] While this may be true, it is important to consider that even if an ATP result is negative, protein may still be present that will not be detected with an ATP swab. Thus, the combination of ATP with a method that detects protein complement each other for a robust assessment of cleaning.

   The detection of protein is preferable to monitor the risk of proteins from allergenic foods. Two approaches may be considered; rapid protein specific methods or non-specific general protein-based methods. Lateral Flow Devices, also discussed as a tool for validation, are a rapid method to monitor specific proteins from allergenic foods. LFDs are a method that is easy to implement with minimal laboratory equipment and can determine within minutes if proteins from allergenic foods are present on a surface. In, addition, they are sensitive to detect traces of specific proteins.[13]

   The use of general protein-based methods may also be utilized for routine cleaning verification. The use of protein swabs can also enable rapid detection of protein. The assumption is that if protein is not detected, proteins from allergenic foods may be absent or are removed to very low levels. There are a variety of commercial protein swabs available to the food industry. However, it should be considered that the sensitivity of protein swabs is usually lower than protein-specific tests like LFDs. Certain swabs can be marked as high sensitivity, but still, it is important to verify that the level of detection is adequate to assess the risk of allergens on a surface. General protein test methods may be recommended in cases where proteins are highly hydrolyzed or processed, which may limit the performance of most immunoassays.

The combined use of specific and non-specific protein tests may also be considered for allergen cleaning verification. For example, the use of high sensitivity allergen swabs can be used after cleaning and before product change over in relevant testing points. These test points can be randomized for testing to ensure that cleaning is effective. Then the use of protein-specific LFDs can be incorporated periodically in critical testing points (that should also be randomized) to ensure that the cleaning regime keeps the actual risk under control.

The task of finding a cost-effective cleaning regimen can be problematic for food manufacturers. It is critical that all standard operating procedures that have been developed to achieve a clean state by effective environmental hygiene monitoring and/or allergen removal are thoroughly validated, monitored and verified regularly to ensure that the established procedures are working as intended. It is also critical to select appropriate methods for validation and routing verification to obtain adequate information about the effectiveness of an SSOP. It is as important that sampling points and sampling methods are thoroughly selected to assure that the results reflect the overall status of a surface or equipment. Trending and utilizing the data collected from various tests and risk targets will provide extremely valuable information about the sanitation and cleaning processes in a plant that may lead to long term and sustainable improvements within a food production plant and set up a good foundation for effective food safety plans.

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Dr. Gabriela Lopez Velasco, based in St. Paul Minnesota, has been a Global Technical Service Specialist at 3M Food Safety since 2015. She works as part of the global technical service and application engineer teams leveraging her expertise in food safety to provide technical training and application of 3M Food Safety portfolio. She currently oversees the 3M™ Allergen Testing platform. She received a degree in Food Chemistry from the National Autonomous University of Mexico (UNAM) and her doctorate in food science and technology from Virginia Polytechnic Institute and State University. She worked as a postdoctoral researcher at the University of California, Davis.

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