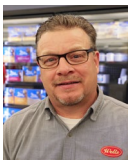
Verification of Control of an Environmental Contamination to Product or Product Contact Surface

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"There's always another story. There's more than meets the eye."
— **W.H. Auden**

The ability to verify and even validate cleaning and sanitation practices is imperative to mitigating risk when it comes to bacteria, allergens, and the health of your consumers. Active environmental monitoring provides a level of assuredness and peace of mind that your food production facility is as clean as it looks before you start your next production cycle. Though visual inspections remain an industry standard of providing initial verification of clean, it is best practice to create and implement a more robust verification process to ensure the production environment is in a complete sanitary condition. The following are additional tools which support the initial visual verification inspection.

ATP Testing

(Adenosine triphosphate testing) is an effective way to spot check your cleaning/sanitation practices. ATP provides energy in all living cells and therefore is present in all organic matter. The use of ATP swabs and ATP readers allow the user to swab product contact surfaces of a production facility and provide a general sense of cleanliness by detecting organic matter generally. ATP is measured in RLU (Relative Light Units) and the higher the number, the more organic matter is remaining following the sanitation process which would indicate that additional cleaning is necessary. ATP testing is easy to execute with an inexpensive cost per test. The food industry uses ATP testing as a general indicator test, but it is important to note that the test does not test for specific allergens, bacteria, or pathogens.

Protein Testing

Protein Testing is another easy and inexpensive test to conduct when verifying the efficacy of the cleaning/sanitation process. Protein swabs are a next level of rigor in verifying that the product contact surface is clean and for the detection of the presence of protein residue rather than just organic matter. All allergens are proteins. Therefore, while protein swabs do not identify an actual allergen (e.g., milk, egg, peanut) the detection of a protein residue left on the cleaned product contact surface may indicate that an allergen protein may remain, and additional cleaning is required.

Conducting a validation study where you pick an allergen of concern (e.g., milk) and conduct side by side swab testing with both the allergen swab (e.g., LFD (Lateral Flow Device – see next section)) and protein swabs helps to ensure that the protein swab is detecting the milk protein allergen. This validation step adds additional layer of robustness to your cleaning verification process.

Allergen Testing

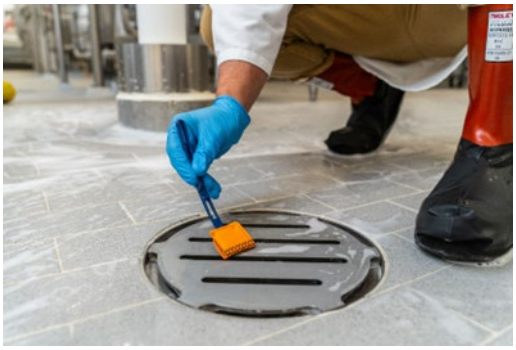
Allergens require more specific testing and isolation of specific allergen targets. Though ATP testing may indicate the presence of organic residue, and protein swabs may indicate the presence of a protein residue, allergen testing kits provide specific ways to test for allergens of concern within a food production facility. Preventative controls, based upon your facility and potential allergens, demand that production methods assure there is no detection of allergens in the air or on product contact surfaces that look clean. Allergen tests are designed to detect specific allergens and can be both qualitative and quantitative. Qualitative allergen test kits indicate the presence or absence of a specific allergen and are referred as or known as lateral flow devices (LFDs). Qualitative test (LFDs) are relatively easy to use after receiving some initial training and the test can be conducted right on the production line. However, Qualitative test kits (e.g., LFDs) are a bit more expensive than protein swabs Quantitative allergen test kits not only indicate the presence or absence but can also quantify the amount of allergen present to its limit of detection and are known as ELISA (Enzyme-linked immunosorbent assay) test kits. Quantitative allergen testing (e.g., ELISA tests) requires a laboratory setting with an extensively trained lab technician and are thus more expensive to conduct.

Air Testing

One of the most easily overlooked sources of potential contamination is facility environmental air and compressed air. Air testing is a preventive measure that takes testing beyond just the surfaces in your food production facility. Air (factory air and compressed) sampling provides an additional layer of protection by measuring levels of bacteria, yeasts, and molds that are present in the air. Various kinds of samplers and plate agars can be used in accordance with a baseline sampling standards to assess potential contamination of product by facility environmental air and compressed air.

General Microbiological Testing

The food production environment is not a sterile environment. As a result, the presence of various bacteria not visible to the human eye is possible. Therefore, it is beneficial to include environmental swab sampling and testing for “indicator” bacteria in your cleaning/sanitation verification procedures. Indicator bacteria (e.g., coliforms or *Enterobacteriaceae*) provide proof that the production environment has been cleaned to a microbiological level.



Environmental Pathogen Testing

As previously mentioned, the food production environment is not a sterile environment and may have the presence of various bacteria that are not visible to the human eye. Unfortunately, some of these bacteria are harmful and could result in a human foodborne illness if the product produced is contaminated with the environmental pathogen (*Listeria monocytogenes, Salmonella, or* pathogenic *E.coli)*. Therefore, it is required in the FDA Rule, 21 CFR 117, that anytime there is an exposed ready-to-eat food product to the production environment prior to packaging, the production facility must have a pathogen environmental monitoring program (PEMP). A PEMP is a program put in place to monitor for the presence of the aforementioned environmental pathogens in the production environment. Additionally, the PEMP is a verification of the efficacy of cleaning/sanitation process. The PEMP should be modeled after a Seek and Destroy methodology of continually assessing data to determine if the control system is impactful for the control of the pathogen of concern. (e.g., *Listeria monocytogenes*). The basis of a "Seek and Destroy" methodology is to aggressively look for the pathogen (e.g., *Listeria monocytogenes*) or look for the indicator to the pathogen of concern (*Listeria spp.* for *Listeria monocytogenes* or *Enterobacteriaceae* for *Salmonella*) through thorough and aggressive environmental swabbing. The PEMP uses an indicator bacterium rather than the pathogen itself to verify the control. And when the indicator is found, aggressive actions are taken to eliminate the indicator organism from the environment. Eliminating the indicator then provides an environment where the pathogen cannot grow. Due to the complexity of designing a monitoring program, you may want to bring in an expert. Working with an expert or an accredited testing lab will help you learn: What to test for, Where and How often to test, How to use indicator organisms, How to take samples and What to do when you find something.

For more in-depth guidance on best practices for pathogen control, be sure to read the Controlling Pathogens in Dairy Processing Environments for the U.S. Dairy Industry which can be found at **www.usdairy.com/foodsafety**.