How Clean is Clean?

Understanding the Role of Testing to Assure Proper Sanitation in the Food Industry

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Table of Contents

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What You'll Learn From this Paper

This paper is the third in a series focused on testing. The first paper provided an overview of raw material, finished product, and environmental testing, with a focus on pathogen testing. The second one was focused on issues specific to allergens. This paper will give more detail on how testing can verify and validate sanitation procedures. Cleaning and sanitation are major activities in all food processing operations, with many facilities having dedicated shifts that perform these functions. But how clean is clean? There are several types of testing that can help answer this question. This paper is designed to:

- Explain methods to assure that surfaces are free of contaminants
- Understand which aspects of sanitation are considered "preventive controls" by FDA versus prerequisite programs
- Explain how verification of sanitation is addressed within GFSI schemes
- Describe the considerations when determining the best way to include testing in your food safety program

At the end of this paper, we trust you will have a better understanding of the role testing can play in verifying sanitation within the food industry, the various methods available, and the way sanitation is proposed to be handled by FDA.

Is it Clean?

In most of the food industry, cleaning occurs on a regular schedule. There may be specific elements of cleaning that occur during each shift, each day, or on a less frequent schedule. Depending on the facility, products, and equipment, there may be wet cleaning or dry cleaning; the equipment may be amenable to clean in place (CIP) or may need to be disassembled and cleaned out of place (COP). Regardless of the mode and type of cleaning, a major objective of cleaning is to make sure that product integrity is maintained including quality and safety during processing and packaging.

Inadequate cleaning and sanitation can jeopardize product safety. Pathogens present in the environment and on unclean food contact surfaces can contaminate food products. Those food products can potentially cross contaminate other products as they are being processed. Preventing cross contact of allergens is a major issue that was discussed in detail in the previous paper.

But how can you tell if something is really clean? There are several ways to quantify the degree of cleanliness and verify cleaning and sanitation in order to ensure compliance with regulations and more importantly, make sure the food produced is safe.

Environmental Monitoring

Environmental testing provides verification of sanitation standard operating procedures (SSOP). One way to check on the effectiveness of all cleaning and sanitation activities is to implement an environmental monitoring program that includes a pre-operation program. There are several types of monitoring tools that can be employed for that purpose. One of the most popular methods is through

the use of an ATP sanitation monitoring system. These systems measure the presence of adenosine tri-phosphate (ATP), a chemical produced in every living cell, to measure the amount of organic residue that remains on a surface after cleaning. A positive result can't tell you exactly what kind of biological or allergenic material remains, but it serves as a warning that cleaning to a validated standard was not achieved. An ATP sanitation monitoring system is comprised of three parts – an electronic instrument, called a luminometer, swabs or sampling devices, and software for tracking and trending the results. Users sample a surface after it has been cleaned, activate the swabs or samplers and place them into the luminometer for reading. A relative light unit (RLU) score is produced based on the amount of ATP that was present on the surface and is compared to thresholds the user has established. These thresholds are established through a validation process and are typically incorporated within a facility's SSOPs. Three threshold levels are typically established – pass, indicating that the cleaning process was executed successfully relative to the established standard; marginal, indicating that the cleaning process fell outside of the successful range but within a range of acceptable variation; and fail, indicating that some or all components of the cleaning process were not executed correctly.

ATP tests cannot tell you if pathogens, or even bacteria, are present. A fail ATP test can result if material of plant or animal origin is detected above the established standard. Regardless of the reason for a fail ATP test, the result means that cleaning was inadequate. A major benefit of using ATP tests is that the result is obtained nearly instantly. ATP testing provides an opportunity to verify that sanitation was adequate before production operations resume. This form of monitoring allows for immediate feedback and can pinpoint problem areas that need more thorough attention.

Facilities can test directly for environmental pathogens such as *Listeria* and *Salmonella* spp. to complement and complete a robust environmental monitoring program.

Are Pathogens Lurking?

When considering environmental monitoring, environmental testing for pathogens is a hot topic.
As you will read in the regulatory requirements section FSMA suggested that environmental monitoring could be a preventive control, although FDA has not required it in the proposed rule, if a facility finds that is Reasonably Likely to Occur (RLTO) in their facility or products. Pathogens can be introduced into the environment through a number of ways personnel, raw materials, pests, etc. Once into a facility it can be transported throughout the facility in a number of ways. For example, equipment such as fork lift and pallet jacks are used all throughout the facility; personnel or utensils move from one area to another. Pathogens and allergenic contaminants can travel through dust and aerosols .

Pathogens in the environment can be transient or resident. Transient pathogens are those that pass through and do not become established in the facility. They are brought in by one means or another and are eliminated through the normal effective SSOPs. Those pathogens that are residents have found their way into a niche or biofilm, which are more likely to form in hard-to-clean places. Biofilms are more resistant to typical sanitation measures..

Salmonella spp. are recognized as being an environmental pathogen in facilities producing dry products and employing dry cleaning. *Listeria monocytogenes* is a common wet and cold environmental pathogen. When evaluating the hazards in the facility it is critical to know what will survive in the facility's environment and in the products produced. This information will assist building an effective environmental program to seek and destroy.

Seeking Indicator Organisms vs. Pathogens

In addition to pathogen monitoring in the environment another good way to verify sanitation is through monitoring levels of appropriate indicator organisms. Indicator organisms can provide insight to the overall level of contamination in the facility or on product contact surfaces. Indicator organisms are non-pathogenic and can be an overall indicator of cleanliness. One way to monitor for overall cleanliness is to test for total aerobic plate count (APC). Another approach is to monitor for the family of enterobacteriacea. These two indicator tests can be effective to ensure SSOPs are effectively executed. *Listeria monocytogene*s can be monitored using *Listeria* spp. as an indicator. Per the FDA proposed rule there is not an indicator that was identified as acceptable for *Salmonella* spp. Similar to the pathogens in the environment, indicators should be selected with the facility environment and the products produced in mind to ensure they are appropriate. The right testing and results will drive the right cleaning and sanitation behaviors.

Getting in the Zone

Now that we know it takes a combination of approaches, ATP, indicators and pathogens to monitor for effective sanitations it's important to consider where to test. It is becoming common practice to use a zoned approach.

- Zone 1: product contact surfaces (e.g., conveyor belt)
- Zone 2: surfaces adjacent to product contact surfaces (e.g, leg of equipment)
- Zone 3: other areas and surfaces in the vicinity where food is produced (e.g., floor)
- Zone 4: areas where food is not produced (e.g., locker room)

Using ATP swabs, and perhaps examining total aerobic plate counts, is appropriate to gauge the effectiveness of the cleaning and sanitation process in zone 1. Depending on the product, the risk, and other factors, zone 1 areas are seldom tested for pathogens (facilities testing zone 1 for pathogens should follow a test-and-hold process until results are obtained). Instead, zones 2 and 3, and perhaps zone 4, are more typically the subject of environmental pathogen testing. Facilities need to be prepared for finding a positive, since that is the goal of the program, and know the approach they will take to eradicate a pathogen before it has the potential to contaminate the food product.

Regulatory Requirements

Sanitation is part of cGMPs and through the proposed update to cGMP's, FDA intends to require that "all food contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against the contamination of food, food-contact surfaces, and food-packaging materials". The most substantial difference between this expectation and existing GMPS

that are in force today is the special attention given to allergen cross contact, which was discussed in the second white paper in this series.

However, FDA is requiring industry to do more in the area of sanitation if it functions as a preventive control. And for good reason. In the proposed rule the FDA reviewed cGMP-related recalls during 2008-2009. They found that a lack of sanitation controls was a contributing factor in 17% of recalls. In some instances this can be assumed it was due to inadequate sanitation. Which could also be from the inadequate implementation of cGMPs. This shows cleaning and sanitation have a direct impact on the safety of the food produced.

FDA has identified sanitation controls as preventive controls to address cross-contamination and cross-contact from insanitary objects and product surfaces. They are requiring those facilities to consider if environmental pathogens are reasonably likely to occur (RLTO) if they produce ready-to-eat (RTE) products. RTE foods that are exposed to the environment post-processing and prior to packaging may have a risk of environmental contamination. For example, a baked breaded product with a cheese or other filling generally will have to cool prior to packaging. In this example, the environment where the product is exposed prior to packaging could result in cross-contamination. A second type of hazard is exposure to pathogens due to employee handling, such as for products like deli style sandwiches or salads. Facilities should also consider if there are any food allergen cross-contact hazards. In considering these hazards in a facility or for a specific product, if the hazard evaluation finds they are RLTO then those key sanitation activities could be considered a preventive control.

Doing this would elevate the documentation, recordkeeping and monitoring associated with these components of sanitation. While sanitation has always been an important part of the operations of a food facility, there is the potential for the rigor associated with sanitation- particularly the documentation that it's being done consistently and effectively, to increase with the proposed Preventive Controls rule.

While FDA isn't proposing to require that cleaning be validated, there are approaches to validate or verify cleaning, including testing for allergens, testing for indicator organisms, and using ATP tests.

Although lack of environmental monitoring was a factor in 9% of GMP-related recalls, the economics of environmental testing for pathogens prevented FDA from including a requirement for environmental pathogen testing in the proposed preventive controls rule. However FDA included a substantial discussion of the merits of environmental pathogen testing in an appendix that accompanied the proposed rule.

Industry Requirements: GFSI

Increasingly, GFSI has become a major force within much of the food industry. GFSI set forth a guidance document outlining expectations of food safety management systems and different audit schemes have

been benchmarked against the GFSI standard. Every GFSI scheme has a section that identifies the requirements for sanitation.

British Retail Consortium (BRC) lists cleaning and sanitizing as the first bullet on the list of prerequisite programs, noting that the control measures and monitoring procedures need to be documented and are a key foundation of a HACCP plan. Prerequisite programs including cleaning are within the scope of the required BRC audit. In addition, an inspection program that assesses "cleaning and housekeeping performance" is required on at least a monthly basis. If cleaning is contracted, there must be a process to approve and subsequently monitor such contractors. Further, BRC requires a "scheduled program of testing" that includes the processing environment. It is up to facilities to develop the details of the program.

Safe Quality Foods (SQF), requires that facilities develop criteria to ensure the effectiveness of prerequisite programs including cleaning and sanitation, and has procedures in place to verify the effectiveness of monitoring those PRPs. In Module 11, section 2.13, SQF has detailed requirements for sanitation. Facilities must document:

i. What is to be cleaned;

ii. How it is to be cleaned;

iii. When it is to be cleaned;

iv. Who is responsible for the cleaning;

v. Methods used to confirm the correct concentrations of detergents and sanitizers, and

vi. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

The verification of sanitation achieved by the types of tests described in this paper is relevant to the last point about verifying effectiveness, and SQF is clear that an environmental pathogen or indicator monitoring program is required in high risk areas. In Module 2, SQF also specifies that product contact surface cleaning between line changeovers shall be effective to sufficiently remove all potential target allergens from subsequent product contact.

The treatment of sanitation by FSSC 22000 is most similar to the approach proposed by FDA. FSSC 22000 asks facilities to identify which elements of sanitation, if any, are considered operational prerequisite programs (which is similar in concept to preventive controls) versus prerequisite programs. Verifying the effectiveness of the sanitation program is required by FSSC 22000.

Summary

Sanitation has always been, and will continue to be, a key component of an effective food safety system. Deficiencies in sanitation have resulted in outbreaks and recalls, prompting FDA to require facilities to consider if elements of sanitation need to be elevated to the status of a preventive control.

Our recommendations:

- Evaluate the risks of pathogen contamination or allergen cross contact due to sanitation, considering
    - The type of cleaning used
    - The type of product being produced (e.g., ready to eat or not?)
    - The status of the facility, and clean-ability of equipment and surfaces
- Determine if aspects of cleaning should be designated as “preventive controls”
- Critically evaluate how you verify that something is “clean” today
    - Have you validated the cleaning process?
    - Do you verify cleaning using ATP swabs, testing for indicator organisms, etc.?
    - Is an environmental pathogen testing program in place?

The changes in regulatory requirements as well as customer requirements demand that now, more than ever, facilities demonstrate that they are implementing robust food safety practices. Cleaning and sanitation is a key part of a food safety program and warrants attention.

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About The Acheson Group

Established in 2013 as an independent venture of Leavitt Partners Global Food Safety Solutions, The Acheson Group, LLC (TAG), led by Dr. David Acheson, is a strategic consulting firm for food and beverage companies and those providing technical support to the food industry. With a focus on strategic risk management, TAG provides the latest food safety consulting insights in a global environment in

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