



## A Systematic Approach to Developing a Sanitation Program

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### Overview

This document will cover the importance of cleaning and sanitizing food contact surfaces and how operations can use a systematic approach to develop a sanitation program through the step-by-step process outlined below.



Image 1. Steps involved in a systematic approach to developing a sanitation program.

### Cleaning and Sanitizing

Sanitation is composed of two parts: cleaning and sanitizing. Cleaning is essential to remove food sources for bacteria, prevent cross-contamination, minimize biofilm formation, and prepare surfaces for the effective application of sanitizers. An unclean (“dirty”) surface cannot be sanitized because most sanitizers are impacted by residual debris that prevents them from contacting microorganisms. You want a sanitizer to reduce the number or activity of microorganisms, not sanitize or bind debris; therefore, you should always clean before you sanitize. Sanitizers should contain a label approved by the Environmental Protection Agency (EPA) for how you intend to use it (for example, food contact) and reduce the levels of microorganisms. Sanitizing can also extend the shelf-life of food products by improving product quality.

### Why Establish Clean Breaks?

A clean break, or sanitation clean break, is a planned stop in production to clean and sanitize food contact surfaces (Krug et al. 2020). Clean breaks are an effective way to separate production lots when they are carefully documented, monitored, and verified. A lot, or production lot, refers to a specific batch of product, identified by information like harvest date, supplier, field, or buyer.

Clean breaks limit the impact of recalls or outbreaks by helping to trace designated lots throughout the supply chain quickly. They can also limit the amount of product that may need to be recalled. For example, the 2020 *Salmonella* Newport outbreak linked to red onions demonstrated the consequences of insufficient clean breaks (US FDA, 2021a and b). In this outbreak, over 1,600 illnesses occurred, and three months’ worth of onions were recalled because of potential cross-contamination from inadequately cleaned food contact surfaces. Cross-contamination involves the unintentional movement of contamination from a contaminated surface to an uncontaminated one. When food contact surfaces are not effectively cleaned and sanitized, cross-contamination can occur. Since the producer was not able to show effective sanitation to delineate a clean break, more onion lots needed to be recalled.

### Systematic Sanitation Process

To establish a systematic (step-by-step) sanitation process, it is important to validate, monitor, and verify cleaning and sanitizing protocols. These steps ensure that the process is effective, consistent, and documented. Each facility, commodity, and food contact surface have unique needs, so it is important to approach sanitation with this in mind. These needs may include different types of debris, microorganisms, operational requirements (for example, clean-in-place), among others. There is no one-size-fits-all approach to sanitation, so this systematic process provides steps to consider.

## Validation

Validation is an important part of developing a sanitation program because it (1) identifies science-based parameters to follow and (2) shows that you can meet those parameters in your own operation. These parameters may include sanitizer contact time, sanitizer concentration, mechanical action (for example, scrubbing), temperature, and others. Often EPA-approved labels on sanitizer products provide guidance on these parameters, such as “follow with a potable water rinse” or “allow to air dry completely”. Research and real-world testing may also show parameters will work to reduce microorganisms or prevent cross-contamination.

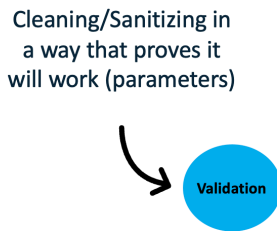


Image 2. The validation is the foundation of the systematic process of developing a sanitation.

## Monitoring

Monitoring confirms that cleaning and sanitizing procedures follow validated parameters. Monitoring activities include checking sanitizer concentrations, allowing sufficient contact time, and inspecting surfaces to confirm they are visibly clean. If monitoring shows that these parameters are not being met (for example, surfaces are not visibly clean before sanitizing), these errors must be corrected through appropriate activities, such as recleaning the surface or retraining employees on what is considered “visibly clean”.

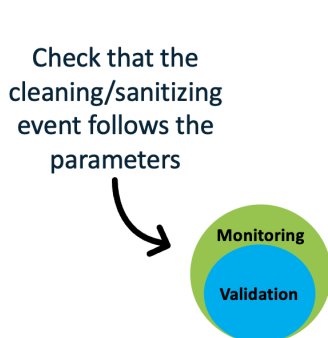


Image 3. The monitoring step in the sanitation systematic process checks that validated parameters are followed.

## Verification

Verification confirms that the cleaning and sanitizing process adheres to the sanitation plan. This step involves using tools to assess the environment and documenting the effectiveness of procedures. Regulatory requirements emphasize the need to clean and sanitize food contact surfaces as frequently as necessary to prevent contamination. Types of verification may include visual inspections, biochemical assays (e.g., ATP), aerobic plate counts, indicator organisms, and pathogen testing.

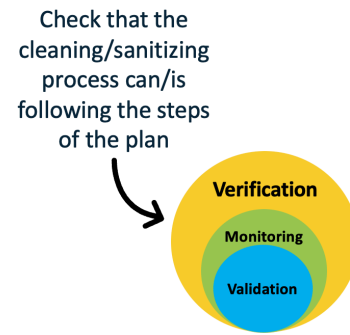


Image 4. The verification step in the sanitation systematic process checks the sanitation process can/is following the steps of the plan.

## Recordkeeping

Recordkeeping confirms sanitation activities were performed correctly. It is essential to have written documentation that cleaning and sanitizing activities are conducted for audits and inspections. If a record does not exist showing that sanitation occurred correctly, you cannot prove these activities occurred when inspected or audited. For example, the FSMA Produce Safety Rule requires a record showing the date, method of cleaning, and signature or initials of the person performing the activity. These must be kept for at least two years and reviewed.

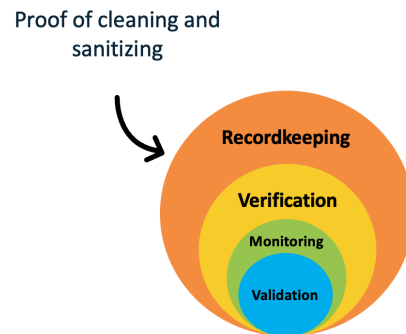


Image 5. The recordkeeping step in the sanitation systematic process is the proof of adequate cleaning and sanitizing activities.

## Sanitation Standard Operating Procedures (SSOPs)/Training

Sanitation Standard Operating Procedures (SSOPs) provide clear instructions for cleaning and sanitizing procedures. SSOPs may not be required for every operation, but they are often expected by buyers and may be a requirement of third-party audit schemes. Training personnel on proper protocols and Personal Protective Equipment (PPE) use is critical for successful implementation.

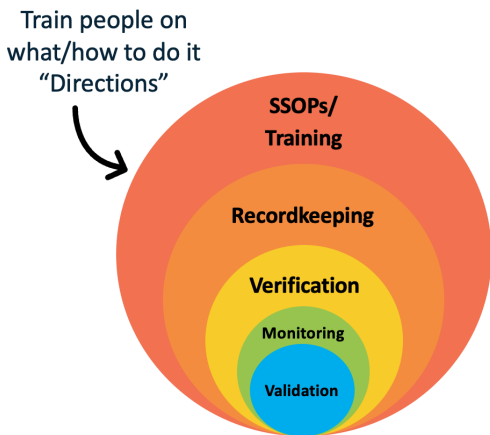


Image 6. The SSOPs/Training step in the sanitation systematic process trains people on what and how to follow “the directions step-by-step”.

## Sanitation Programs

Sanitation programs can be wet, dry, or both. Wet sanitation uses water and often includes detergents to remove soil and debris or sanitizers mixed with water. Dry sanitation avoids water and may involve sweeping, vacuuming, steam to remove debris, or alcohol-based sanitizers. Dry cleaning is common between wet cleanings and may occur in between clean breaks.

A master sanitation schedule outlines routine, deep, and end-of-season cleaning events. Not every surface may need daily cleaning, but scheduling ensures surfaces are cleaned and sanitized as necessary. This helps maintain effective sanitation practices over time. A master sanitation schedule can also help establish clean breaks.

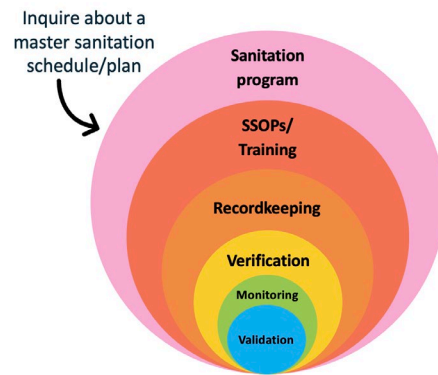


Image 7. Once a validated, monitored, and verified step-by-step sanitation protocol has been developed, a master sanitation schedule can ensure all surfaces are cleaned and sanitized as necessary according to the sanitation program.

## References

Krug, M.D., B. Chapman, and M. D. Danyluk. 2020. Establishing a Lot through Sanitation Clean Breaks in Produce Packing Facilities. Available at: <https://journals.flvc.org/edis/article/download/122020/125407>. Accessed Jan 3, 2025.

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