

# Establishing a Lot through Sanitation Clean Breaks in Produce Packing Facilities<sup>1</sup>

Taylor L. O'Bannon, Angela M. Valadez, Matthew D. Krug, Benjamin Chapman, and Michelle D. Danyluk<sup>2</sup>

## What is a lot?

A lot is a distinct portion of a crop, such as all of the commodity harvested on the same day. Many produce packers establish lots for traceability reasons and to limit risk to their business in the event of a food-safety contamination event. Whether a packer determines a lot by date, grower, field, buyer, or some other means, a clean break is needed before and after the production of that lot for it to be considered separate from other production.

## Why establish a clean break?

Clean breaks define the quantity of produce that must be recalled in the event of a recall or outbreak. Establishing a clean break requires both food safety considerations and business considerations. Implementing clean breaks more frequently reduces the quantity of produce in a recall but also requires time and labor to implement. As has been noted in a number of previous produce outbreaks and recalls, the lack of a defined clean break can expand a food safety event to cover an entire production season and beyond.

This document is intended to highlight the importance of sanitation clean breaks in produce packing facilities and identify what is needed for a clean break to be established.

## What is a sanitation clean break?

A sanitation clean break, commonly referred to as simply a "clean break," is a defined production break that involves a documented, verified, and validated cleaning and sanitation process of food contact surfaces. Under the Food Safety Modernization Act's (FSMA) Produce Safety Rule (PSR), food contact surfaces are defined as "...those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations." These surfaces include the food contact surfaces of equipment and tools used during harvest, packing, and holding.

## What is the difference between cleaning and sanitizing?

Cleaning is commonly defined as the removal of physical soil or debris from a surface. Soil in a packing facility may include plant debris, earth, mud, dust, rust, or other mineral deposits, wax buildup, PLU stickers or adhesives, biofilms, etc. Cleaning can be divided between wet cleaning and dry cleaning.

Sanitizing is commonly defined as the reduction of microorganisms on a cleaned surface. A surface must first be cleaned to sanitize it effectively. Soil and organic matter remaining on the surface interacts with organic compounds inactivating the sanitizing agent.

Before implementing a cleaning and sanitation program, it is important to determine which approach is best for your operation. Dry cleaning and wet cleaning is a process that is chosen based on the environment of the facility and the food commodity that is harvested, packed, and held. Some facilities require dry cleaning, as the introduction of water will rehydrate dusts and provide moisture for bacterial growth. Once microorganisms grow, cross contamination and microbial movement in the facility can follow. Dry cleaning often occurs with the use of limited compressed air, vacuuming, towel wiping, use of non-abrasive scrub pads, use of dry steam, UV-C radiation, brushing, sweeping, or scraping followed by using an alcohol-based sanitizer step.

Wet cleaning involves the use of water to aid in removal of organic matter, followed by a water-based or liquid-based detergent. This process is often followed by a water rinse before a water-based sanitizer is added. Wet cleaning can include the use of a foamer, water hose and nozzle, steam cleaner, mop and bucket.

It is important to evaluate your facility, equipment, and commodity to determine which cleaning approach is best. Some operations use a combination of dry and wet cleaning to effectively clean food contact surfaces and establish clean breaks.

## Establishing a Clean Break

The recommendations below are drawn from Good Agricultural Practices (GAPs), Best Management Practices (BMPs), Good Manufacturing Practices (GMPs), and the scientific literature.

All food contact surfaces (often described as Zone 1 in food processing and manufacturing) should have a sanitary design and be constructed in a way that they can be cleaned and sanitized. This includes hard surfaces that are impervious and nonabsorbent, easily cleanable, have smooth surfaces that are resistant to wear and corrosion, and can withstand cleaning action with the use of chemicals.

Sanitation standard operating procedures (SSOPs) for cleaning and sanitizing need to be in place at a facility and specifically designed for that facility. These SSOPs should:

- Identify the exact surfaces or area to be cleaned and sanitized and defined by the packer as a food contact surface and specify protocols by which different surfaces will be cleaned.
- Specify the frequency at which each procedure will be conducted and identify the employee responsible for the procedure.
- Evaluate the condition of the food contact surfaces to ensure that they can be cleaned and sanitized.
- Identify compounds used and how they are used (may include concentration, mixing procedure and water source; pH, contact time, and temperature; and rinse procedure, if applicable).

All detergents used for the purpose of cleaning food contact surfaces should be complementary to the organic matter and equipment it is intended for. Sanitizers must be EPA registered and labelled for their intended use as a sanitizer on a food contact surface.

Records that support the SOPs must be completed and available. They should include time/date of cleaning/sanitation activity, a log of compound concentration, and the individual(s) who carried out the tasks.

Following any issues, Corrective Action records should be kept that indicate steps were taken to restore sanitary conditions, rework or divert any product that may have been processed under unsanitary conditions, and document actions taken to prevent this issue from occurring in the future.

A lot size should be determined by the packer based on when complete clean breaks are conducted (a clean break, as described above, would be required before and after a lot). A documented clean break between lots serves as a break in continuity between affected lots in the occurrence of a food safety event.

## Validating a Clean Break

Visual inspection is often the minimum practice to verify a surface is cleaned. The use of rapid, real-time methods for soil detection can be used to verify a clean break was effective. Swab testing collects samples from the equipment surface and are tested for specific contaminants. Microbiological testing and ATP testing often are used to test for total organic soil residue. Swab testing can provide more accurate and reliable results compared to a visual inspection.

## Quick Facts about Clean Breaks

- Food contact surfaces need to be able to be cleaned and sanitized.
- Procedures for cleaning and sanitation should be documented and include location, frequency, and chemicals used.
- Chemical compounds for cleaning and sanitation should be validated for their intended use and employed according to the manufacturer's directions.
- Documenting when, how, and why cleaning and sanitation occurred is necessary to establish a lot.
- When there is a change in equipment, cleaning and sanitation chemicals, production frequency, or an addition of new product types, a review of your SSOPs is warranted to ensure the food contact surfaces can still maintain their desired cleanability.

<sup>1</sup>This document is FSHN13-10, one of a series of the Department of Food Science and Human Nutrition, UF/IFAS Extension. Original publication date August 2013. Revised June 2020 and February 2025. Visit the EDIS website at <https://edis.ifas.ufl.edu> for the currently supported version of this publication.

<sup>2</sup>Taylor O'Bannon, state specialized Extension agent, food safety, UF/IFAS Extension Southwest District, UF/IFAS Citrus Research and Education Center; Angela M. Valadez, PhD, alum; Matthew D. Krug, former state specialized agent II, food science, UF/IFAS Southwest Florida Research and Education Center; Benjamin Chapman, assistant professor, Department of 4-H Youth Development and Family and Consumer Sciences, North Carolina State University; Michelle D. Danyluk, professor, Department of Food Science and Human Nutrition, UF/IFAS Citrus Research and Education Center; UF/IFAS Extension, Gainesville, FL 32611.

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