



## Application Note #65

# Establishing a Clean Break in Production

Scheduled production downtime is often perceived as a loss of profit. In actuality, scheduled maintenance events can produce fewer mechanical breakdowns, resulting in a more efficient operation. They can also provide time for a more thorough sanitation process resulting in a “clean break.” By definition, a clean break is a production break that involves a documented, verified, and validated cleaning and sanitation process to ensure sterility upon completion. In practice, a clean break is a damage limiting event that defines the maximum quantity that could be recalled in case of a contamination. It assures microbial contamination cannot overlap from one production run to another. Financially, a clean break is like an insurance policy, money spent on something you hope gives you no return on investment. Emotionally, a clean break is peace-of-mind.

Clean breaks are an important component of an effective traceability program. The tangible benefit is only felt when a microbial disaster strikes. If a recall were to occur, the recalls will include all product that was packed since the last FULL cleaning and sanitizing event. The product that is processed between clean breaks is called a lot. The more frequently clean breaks are established, the smaller the lot. If a facility’s clean break cannot be defended during a recall, then as far as an investigator is concerned, that company did not have one. When that happens, the recall will only grow. In October 2018, McCain Foods recalled 63 different products back to a shipped date of January 1, 2016 because they did not have a more recent clean break.

Because of the nearly constant stream of products passing through these facilities, defining a clear production break can be difficult. Consequently, if a contamination is detected, the question of how far back to recall is painstaking, especially if the decontamination process utilized has limitations. Typical cleaning and sanitization methods can have difficulty guaranteeing that all organisms have been contacted or contacted with the proper effective dosage. Therefore, these techniques cannot be trusted to eliminate all of the organisms, and cannot be used for a true clean break. Even ozone, which is an effective gaseous sterilization method, does not hold the concentration very long, which makes it difficult to do larger areas. Other fumigation methods, such as use of chlorine dioxide gas, can completely eliminate all of the organisms and thereby “reset” a facility. Chlorine dioxide gas is able to achieve a complete 6-log sporicidal decontamination of all surfaces within a space, including hard-to-reach areas such as cracks and crevices, because it is a true gas above -40 degrees and its molecule size is smaller than the smallest virus. Once the gas has been removed, the area is safe and does not require additional cleanup.

A dairy powder processing plant decide to amend their strategy utilizing chlorine dioxide gas to save time and money in establishing their clean break. This processing plant had been decontaminating their production environment annually for the past few years with chlorine dioxide gas. Over this time, the facility made improvements to its equipment and the building itself in order to mitigate some of the issues that were uncovered after resetting the plant's microbiome. In one instance, the facility was able to trace a new contamination to a minor water leak into their plant. This year, it was determined that the environment was in much better control than in previous years as no pathogens were found in the environment. With that information, ClorDiSys Solutions entered discussions with the facility to amend the scope of the decontamination. Instead of treating the entire production environment, the decontamination would focus on the tanks and piping system up through to the packaging equipment. This strategy enabled the facility to save both time and money as the treatment volume was dramatically reduced, while still acting as a true clean break by sterilizing the product contact surfaces. With a cost savings of over 60%, the facility is now considering this treatment plan twice a year to provide further provide peace of mind in case of a product contamination.

Similar to a firebreak in a forest, a clean break provides companies with a defined and defensible line of safety. The strategic use of preventive scheduled downtime leads to a safer, more reliable, more efficient operation. By using chlorine dioxide gas routinely for decontaminating a facility before an issue arises, the chance of a contamination and/or a recall declines drastically, potentially saving money, disruptions to business, and perhaps lives.