

White paper: Lower the Risk of Food Recalls with Pneumatic Systems Audits and Upgrades

FESTO



Upgrading pneumatic systems is one of the fastest and most cost-effective ways of meeting cGMP and FSMA guidelines.

By Steve Bain, Industry Segment Manager for Food and Beverage, Festo.

The Grocery Manufacturers Association (GMA) said in a 2011 report¹, “A recall, particularly a ‘Class I,’ or health and safety recall, is usually a significant event for a food, beverage, or consumer products company. For companies that have faced a recall in the past five years, 77% of respondents estimated the financial impact to be up to \$30 million dollars; 23% reported even higher costs.”

The impact of tainted food on the overall economy is even larger. Forbes magazine reported² in 2016 that the annual expenses of medical treatment, lost productivity, and illness-related mortality from the 48 million Americans stricken by food-borne pathogens tops \$55 billion.

¹ Capturing Recall Costs: Measuring and Recovering the Losses, GMA October 2011

² America’s food industry has a \$55.5 billion safety problem. Forbes May 6, 2016

The Food Safety Modernization Act (FSMA) was signed into law in 2011 to prevent the health and economic impacts of badly processed foods. Current Good Manufacturing Practices (cGMPs) under FSMA CFR Title 21 117.40 is the cornerstone of this effort. Title 21 details the cleanability and cross contamination standards that plants must meet so that food is deemed safe and companies avoid recalls.

Cleanability and cross contamination prevention features as detailed by FSMA and cGMPs should be strongly considered when purchasing new equipment, but what about the current installed base of older systems? How do plants cost effectively and quickly upgrade these older systems?

Many electromechanical components are cost effective to audit and replace as required to improve food safety.

Reduce contamination through better component selection

There are many potential sources of contamination in food production. Some of these issues can be eliminated through employee training, but some are inherent to the design of the machine. Furthermore, the components used in the equipment must meet wear and cleanability standards to maintain the utmost in food and packaging safety.

Unlike complete pieces of equipment, many electromechanical components are relatively cost effective to audit and replace as required to improve food safety. Here are eight steps for improving air quality and reducing potential sources of biologic, allergen, and particle adulteration:

1. Ensure compressed air intended for food contact does not contaminate food.
2. Evaluate additional potential contamination points with compressed air.
3. Ensure that pneumatic tubing is approved by the Food and Drug Administration (FDA) and is resistant to cleaning processes.
4. Eliminate fittings that are difficult to clean.
5. Eliminate components that easily corrode and are not designed for the food environment.
6. Ensure that components can be easily cleaned and are properly rated for cleaning processes.
7. Ensure that actuators utilize food-safe grease.
8. Conduct audits at scheduled intervals.

Ensure compressed air does not contaminate food

Ambient air contains a host of impurities and in food plants adulterating and allergenic particles are added to the mix. Compressed air systems that are used in direct food contact and in motion control increase the density of these contaminants. It is vital that compressed air intended for direct contact with food and used at the end of the packaging line is made as clean as possible through filtration. For this reason, air filtration efficiency is the first line of defense for maintaining food safety.

However, cGMPs under CFR Title 21 117.40 do not define a required compressed air quality for direct contact with food and primary packaging, which means the required filtration level must be determined by the end user. While many end users have determined their own air quality requirements, others may be unsure of recommended purity. Organizations such as British Compressed Air Society (BCAS), 3A Sanitary Standards, VDMA Mechanical Engineering Industry, and Safe Quality Food (SQF) have published recommendations for specific air quality requirements. SQF recommends, for example, a final filtration stage of 0.01 micron with a filtration efficiency of 99.999% to be located at the point of use for direct food contact. If a plant has not created its own risk assessment, operations personnel may consider meeting the SQF standard.

The compressed air preparation unit, shown below, has a filtration cascade meeting SQF. Assuming 7:4:4 air quality from the compressor, the resulting air quality of 1:4:2 also meets the ISO 8573-1:2010 standard that specifies purity classes of compressed air with respect to particles, water, and oil.



Festo MS Series air filter offers compressed air quality with 99.9999% efficiency.

➤ **It is vital that compressed air intended for direct contact with food and used at the end line is made as clean as possible through filtration.**

Evaluate additional potential contamination points with compressed air

While compressed air intended for food contact is often addressed with proper filtration, there are several additional ways that compressed air can come into contact with food. For example, leaking fittings and tubing will allow compressed air to exhaust in unexpected areas, which can often include areas directly over the food production. This means not only checking air nozzles and cylinders, but also finding and stopping leaks.

Preventive maintenance in terms of ongoing leak detection makes food safety and operational sense, i.e. leak detection lowers the risk of indirect contamination and reduces energy costs. The Festo MSE6-E2M module is an automated component for detecting leaks in a machine. Once a baseline of air usage is developed, the E2M module alerts plant personnel when too much air is consumed. This module also automatically lowers pressure when a machine is idle to further save energy. By monitoring compressed air usage, leaks can often be discovered soon after they occur and prevent potential contamination issues.

➤ **Leak detection lowers the risk of indirect contamination and reduces energy costs.**



The Festo MSE6-E2M module detects leaks and lowers compressed air consumption on a machine.

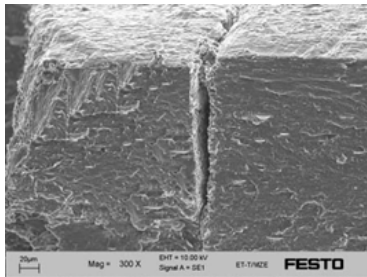
Another unintentional contamination source is the exhaust from valves controlling pneumatic components. Often, valves are mounted near or above the food zone, and the air exhausting from the valve therefore poses a contamination hazard. Distance exhaust as much as possible from food and packaging and eliminate leaks that may blow contaminants into the atmosphere. If the valve cannot be moved, then the exhaust should be ducted to a safe area.

Besides air being exhausted from a valve, a quick exhaust located on a pneumatic actuator will also vent compressed air. As quick exhausts are generally mounted to the actuator that controls part of the process, this means quick exhausts are generally exhausting near the food zone. Quick exhausts should be avoided if possible by installing the controlling valve closer to the application. By utilizing an IP69K valve manifold such as the Festo MPA-C, the tubing lengths can be significantly reduced, which improves machine speed and often eliminates the need for a quick exhaust. If quick exhausts still are required, the exhaust should be ducted to a safe area.

➤ **Plastics and elastomers that come into direct contact with food must comply with the directives of the FDA. The material must not give off or absorb any hazardous substances.**

Ensure that pneumatic tubing is FDA-approved and resistant to cleaning processes

Plastics and elastomers that come into direct contact with food must comply with the directives of the FDA. The material must not give off or absorb any hazardous substances. Plastics and elastomers must also resist stress and be cleanable. Pneumatic tubing is at risk from various environmental influences as shown by the microscopic crack in the micrograph below – a crack that can house contaminants.



Scanning Electron Microscope micrograph shows cracking in incorrectly applied polymer tubing.

Approximately 90% of the defects on pneumatic tubing are traced to chemical, microbiological, or physical influences. Proper tubing selection and upgrade can minimize or eliminate failures due to these influences. Hydrolysis-resistant polyurethane, PUN-H, and Polytetrafluoroethylene, PTFEN, tubing from Festo are ideally suited for use in the food industry. Both are resistant to cleaning agents, microbes, and hydrolysis and are FDA compliant. PUN-H is more flexible and economical, while PTFEN is ideal for the harshest environments.

Eliminate fittings that are difficult to clean

Exposed threads provide the perfect breeding ground for contaminants as the small spaces between the threads are difficult to clean. Any threads that cannot be avoided should therefore be closed off with suitable blanking caps and sealed.

➤ Exposed threads provide the perfect breeding ground for contaminants.

There are several thread types used in pneumatic connections. BSPP, also known as G-thread, left in the image below, is a parallel thread that features a clean design that eliminates exposed threads by sealing flush to a gasket. Utilizing G-threads wherever possible is an easy choice for improved FSMA compliance.

Tapered threads such as R-thread and NPT, center and right, seal by wedging threads together and through the use of sealing tape. These tapered threads risk contamination, not only through exposed threads, but also from metal fragments or flaking tape. For this reason, tapered threads should be avoided for equipment in the food industry.



Parallel threads such as G-threads, left, secure to a sealing gasket and eliminate exposed threads. R-threads, center, and NPT, right, require sealing tape and seal by wedging the threads together.

Eliminate components that corrode easily

Many potential sources of contamination in food production such as bacteria, chemical influences, or corrosion particles can be eliminated by utilizing a few basic design considerations. To ensure that cleaning is safe, the materials used must not react with the cleaning agents or disinfectants. Machine parts must be resistant to corrosion and be mechanically and chemically stable. The image below shows the incorrect choice of materials for a pneumatic cylinder based on the amount of corrosion.



Rusted parts illustrate an incorrect choice of materials.

Contrast the components above with the actuator made of stainless steel shown below. Its design rigorously conforms to cGMP criteria. For example, there are no threads on the bearing cap and thus a reduced possibility of trapping contaminants. Its self-adjusting end position cushioning system is designed without contaminant susceptible adjusting screws. The actuator also utilizes NSF-H1 grease and FDA approved seals.

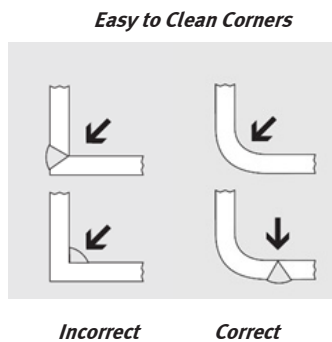
➤ **Small radii and corners pose a hygiene risk because flow velocities of the cleaning agents and disinfectants are substantially reduced in tight spaces.**



Stainless steel clean design pneumatic actuator (Festo CRDSNU)

Ensure components can be easily cleaned

Small radii and corners pose a hygiene risk because flow velocities of the cleaning agents and disinfectants are substantially reduced in tight spaces and the required cleaning effect isn't achieved. Components should have a minimum radius of 3 mm on parts as the following illustration shows.



A high gloss surface finish is essential on components that come into contact with the food product in order to reduce microbial contamination. This can be achieved by using a mean peak-to-valley height of 0.4 to 0.8 μm within the food zone. High-quality surface finishes and large radii, such as those found on the pneumatic actuator shown below, make cleaning the actuator quick and easy.

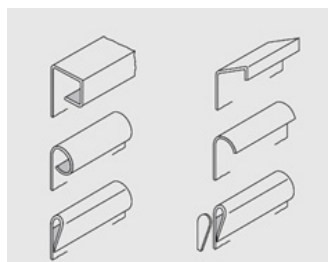


Easy clean Festo DSBF cylinder

➤ **Components must be designed to eliminate dead spaces.**

All machines and system components must be designed to eliminate dead spaces. Product remnants in dead spaces are difficult if not impossible to remove. Components must therefore be designed to be either completely open or completely sealed as shown in the following illustration.

Designed for cleaning processes



Incorrect

Correct

Cleaning processes often employ the use of high-pressure hoses. Equipment and components must be designed to withstand these processes. Resistant surfaces and a high IP protection class, such as the Festo MPA-C IP69K rated valve terminal, are designed to operate effectively in harsh environments.



Designed for washdown, the Festo MPA-C valve manifold meets IP69K rating. Note the rounded design which eliminated dead spaces.

Ensure that actuators utilize food-safe grease

The U.S. has the strictest regulations on the use of lubricants and additives used in the food industry. Lubricating greases and oils must comply with CFR 21 178.3570. For equipment and components that will unavoidably come into occasional contact with foods and primary packaging, approved lubricants such as NSF-H1 must be used.

➤ **It is imperative to audit cylinders for the NSH-H1 grease and replace those that do not have it.**

One potential food contaminate often overlooked is the lubricant in pneumatic cylinders. Close examination in the packaging area sometimes shows that unsafe grease is actually leaking from the nose of cylinders onto the food or primary packaging. It is imperative to audit cylinders for the NSH-H1 grease and replace those that do not have it.

In the washdown area, intensive cleaning can wash lubricating grease out of the cylinder. Not only does this pose a contamination problem, but also serves to impair cylinder operation. In the washdown area, utilize cylinders that feature FDA-approved dry-running seals, such as the Festo A3 seal. This will ensure clean, optimum operation even when the grease has been washed from the cylinder. Eliminating the use of components that fail because lubrication can be washed away is an example of how cleanability and cGMPs can improve uptime.



Festo A3 dry-run seals are designed to continue operating smoothly when grease is washed out due to intensive cleaning processes. (Clean design cylinder)

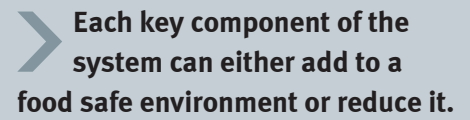
Conduct audits at regular intervals

Pneumatic systems are not static. Components wear out and vibrations can loosen fittings. New components become available that are not only easier to clean, but also more rugged, performing better in harsh environments. It is not cost effective to replace every older machine, but it is worthwhile in terms of clean operation and overall equipment effectiveness (OEE) to maintain and upgrade pneumatics and automation components through regular audits.

The organizing principle of this white paper was to trace compressed air into, through, and out of the pneumatic system.

Each key component of the system can either add to a food safe environment or reduce it. Use this beginning, middle, and end layout to organize pneumatic system audits.

Festo has a collection of downloadable educational materials on sanitary design that both OEMs and end users can benefit from. Links to these materials are found at www.festo.com/foodsafety



Each key component of the system can either add to a food safe environment or reduce it.

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