

Parker Hannifin Corporation
Filtration and Separation Division
242 Neck Road
Haverhill, MA 01835
phone: 800 343 4048 or 978 858 0505
fax: 978 556 7501

<http://www.parker.com/balston>

Reducing Contamination Risks of Compressed Air in Food Plants:

Benchmarking Good Manufacturing Practices

*A GMP Template for Food Plants
using risk-based systems:*

- *HACCP Procedures*
- *GFSI - SQF Code*

Lee Scott
LSCOTT@parker.com

November, 2012

Objective

The objective of this technical paper is to benchmark published Good Manufacturing Practices as they relate to compressed air use in a food processing facility in both a HACCP and/or Global Food Safety Initiative (SQF or BRC) environment.

Introduction

Any modern food manufacturing facility employs the use of compressed air extensively in the plant. As common as this is, the potential hazards associated with this powerful utility are not obvious and apparent. Food hygiene legislation to protect the consumer places the duty of care on the food manufacturer. For this reason, many companies often devise their own internal air quality standards based upon what they think or have been told is 'best practice'. This is no wonder, as the published collections of Good Manufacturing Practices (GMP) that relate to compressed air are nebulous and difficult to wade through. Understandably this has led to a significant difference in the quality of compressed air used throughout the industry, with major differences even existing in plants owned by the same company. The goal of this paper is to help make sense of it all.

Focus on Preventative Food Safety:

The recent focus on preventative food safety has been reinforced in the public sector in the US by the FDA's Food Safety Modernization Act (FSMA) as well as the private sector's Global Food Safety Initiative (GFSI). Both take aim at improving the knowledge of risk factors and preventative practices effectively raising the bar on food safety. The combination of improvements in food science and manufacturing processes provide the GFSI and FSMA a springboard for improved food safety and awareness regarding microbial contamination of food.

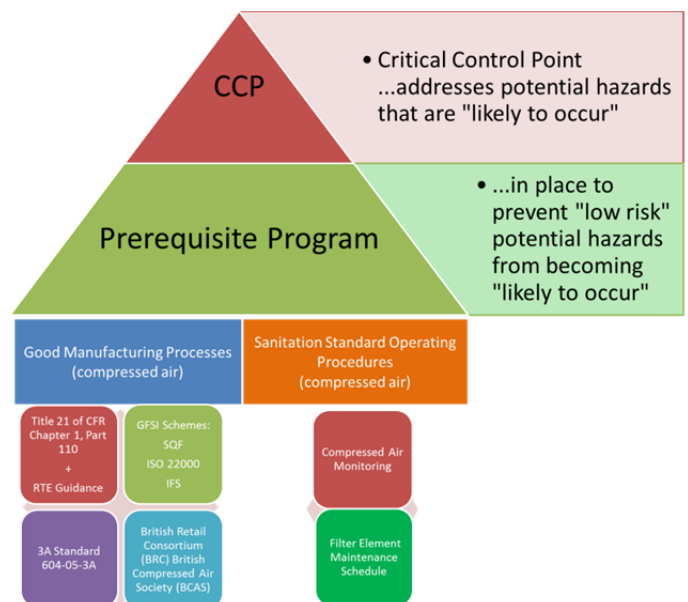
Whether it is one of the many voluntary schemes (GFSI) or mandated (FSMA), there are elements to these codes that put a heavy focus on risk-based (HACCP-like) food safety management programs. The USDA has mandated risk-based programs since the late 1990's. Risk-based food safety programs are unique to each facility and food product being manufactured and rely heavily upon the employment of GMPs and Sanitation Standard Operating Procedures (SSOPs).

The challenge with risk-based food safety systems is that they are not prescriptive. This works to the benefit of food manufacturers who are experts in their field of manufacturing and processes; however, it presents challenges with ancillary processes and procedures where the guidelines and GMPs are vague and non-specific.

The Risk-Based HACCP Environment:

When conducting a Hazard Analysis Critical Control Point (HACCP) analysis any point-of-use contact between the compressed air and food should be considered a potential risk point. Developing an effective HACCP Prerequisite Program (PRP) for compressed air to support Critical Control Points (CCP) is an effective way to mitigate those risks. As PRPs are generally founded upon GMPs and SSOPs this paper is intended to be an aid in deciphering best practices for compressed air.

HACCP In Food Processing



The GFSI/SQF Environment:

The number of Food manufacturing companies adopting GFSI endorsed food quality schemes is steadily growing. One of the most popular schemes in the US is the SQF Code. The 7th edition of the SQF code, released in July of 2012, now specifies in Modules 9, 10, 11, and 13 that:

- “compressed air used in the manufacturing process shall be clean and present no risk to food safety.”
- “compressed air used in the manufacturing process shall be regularly monitored for purity.”

Knowing the Potential Risks

Air is not as clean as it appears to be. Untreated compressed air contains many potentially harmful or dangerous contaminants which must be removed or reduced to acceptable levels in order to protect the consumer and provide a safe and cost effective production facility. Along with moisture and particulate matter, inlet air to a compressor generally carries 5 to 50 bacteria per ft³. A 75 hp compressor with a capacity of 300 SCFM therefore takes in 100,000 to 1 million bacteria each hour¹³. These bacteria get compressed along with the air and begin their journey through the compressed air system. Introducing this type of microbial contamination to food products is very risky and would be considered a lack of control by the facility. Understanding how to operationalize the treatment of compressed air in a facility will help ward off that risk.

Where the Air Contacts the Food:

Sometimes it is not apparent where the compressed air is contacting the food. Working surfaces like counters and conveyors are obvious and manageable contact points. The air is invisible. It leaves no visible trace where it contacts the food, other food contact surfaces, or the packaging. Without adequate hurdles and physical barriers in place the microbial, particulate, and (in some cases) compressor oil contamination is left behind after the air dissipates.

Some examples of direct and indirect contact points are:

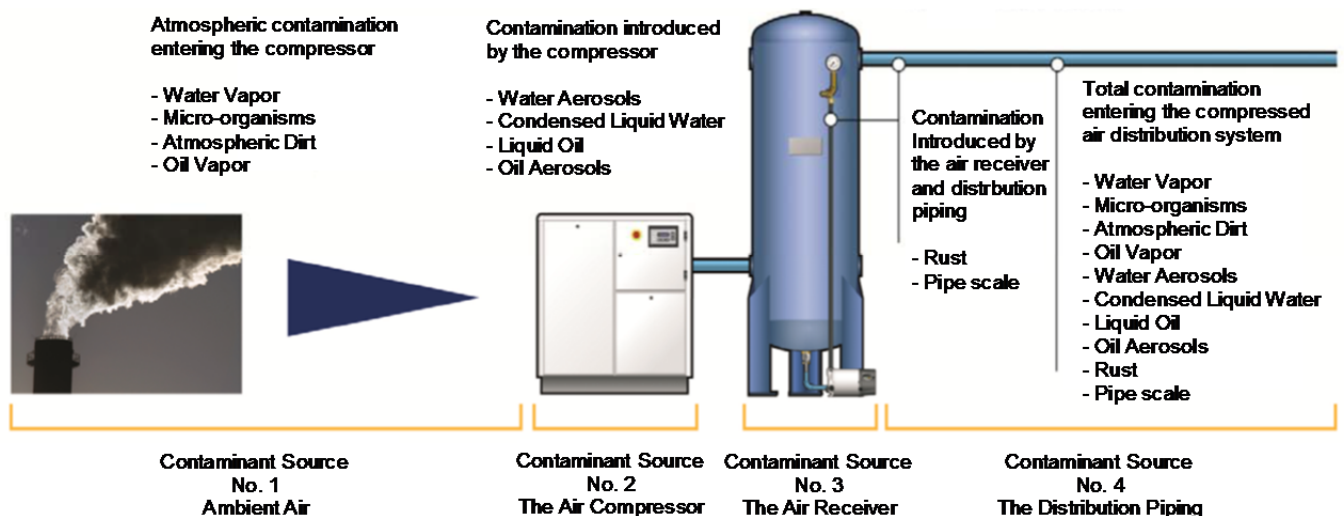
- Bagging
- Sparging/Mixing
- Drying
- Air Knives
- Pneumatic Exhaust (i.e., cylinder exhaust)

Managing the Risks:

Compressor room drying and filtration is good, but it's not enough for a food processing plant. System filtration can do a good job reducing the amount of contaminants that are introduced into the downstream distribution system; however, that alone does not meet the requirements of the published GMPs that address compressed air – nor is it fully effective. In this scenario the risk of food adulteration is still quite high. The warm, oxygen rich environment inside the downstream air reservoirs, piping, fittings, and controls are ideal harborage sites for microbial biofilm growth – especially when fed with food grade compressor oils that inevitably migrate downstream. For this reason a number of the published GMPs call for point-of-use filtration that should be in place for all points where compressed air either directly or indirectly contacts food.

The first line of defense to ward off potential microbial contamination of the food product from compressed air is to use point-of-use sterile air filtration. With a properly designed compressed air system employing the benchmarked GMPs (outlined later in this document) along with well-designed SSOP (Sanitation Standard Operating Procedure) maintenance and monitoring programs – the risk associated with compressed air at points of contact can be mitigated significantly. A system design employing sterile air filtration at point-of-use puts a physical barrier in the air stream guarding against microbial contamination of the food. Combining this system design with a HACCP Prerequisite Program (PRP) formalizing these GMPs and SSOPs makes a cost effective, efficient, and defensible risk management plan.

Compressed Air System Sources of Contamination



Ready-to-Eat Foods (RTE)

RTE foods are at high risk of contamination from sources such as compressed air. Any microbial contamination introduced in the later stages of RTE food processing can stay with the food all the way to the consumer, as few hurdles or barriers are generally in place to eliminate the hazards.

Point-of-use sterile air filtration is critical to ensuring RTE food safety at any point where compressed air can contact the food or food contact surfaces.

Microbes: Arrested Development – Benefits of Dry Air:

The warm, dark, moist environment inside a compressed air system is the perfect condition for microbes to flourish and grow. Drying the air to a low dew point is an effective way to inhibit this microbial growth. *Inhibit* – not kill. Microbes need food, water, and the right temperature to grow. Take one or two of those nutrients away, and the growth stops - temporarily. Some of the microbial pathogens that are hazards to food safety form spores and/or protect themselves by moving into a dormant stage when nutrients in the surrounding environment are depleted. These dormant spores resume propagation as soon as the missing nutrients (moisture) become available again through contact with the food.

*“Bacterial spores survive very dry conditions without any problem. Vegetative bacterial cells can survive dried states for a period of time. In fact, lyophilization (freeze drying) is a common way to preserve bacteria. Once conditions are favorable for growth (moisture, nutrients etc. , the bacteria can grow again. The foodborne pathogen Salmonella is notorious for surviving under water limited conditions.”*¹⁴

The best practice for food safety is to first dry the air and more importantly use point-of-use filtration to capture the microbes and spores so they never come in contact the food.

Good Manufacturing Practices – Industry Standards to Reference:

Identifying the risk and potential hazards with compressed air in a food plant is the easy part. Determining Good Manufacturing Practices for cleaning up the air is not so straightforward.

Below is a list of existing, published, and sanctioned Good Manufacturing Practices when it comes to compressed air in food manufacturing.

- US Code of Federal Regulations:
 - 21CFR, Chapter 1, Part 110, Section g
- FDA Guidance for Industry:
 - Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat (RTE) Foods
- 3-A Standards
 - 604-05 Accepted Practices for Supplying Air Under Pressure in Contact With Milk, Milk Products and Product Contact Surfaces
- British Compressed Air Society (BCAS)
 - Food Grade Compressed Air: Code of Practice
- British Retail Consortium (BRC): Issue 6
- SQF Code: 7th edition, July 2012
- International Featured Standards (IFS)
 - Version 6
- Global Red Meat Standard (GRMS): 4th ed.
- ISO 22000:2005
- British Standards Institute (BSI)
 - PAS 220:2008 Prerequisite Programs

Monitoring Compressed Air for Purity:

Whether it is specified or implied by the food safety scheme being employed in a plant, regularly testing the purity of compressed air coming in contact with food is a best practice. A single test at one point in time is not enough. Compressed air systems are dynamic and the compressor intake is subject to microbial, particulate, and moisture variations throughout the year as well as buildup of contamination in the system.

The table below outlines the compressed air testing specification for each of the standards/codes listed above:

Code or Standard	Verbiage relative to compressed air testing
IFS, ISO, GRMS	Compressed air is identified specifically as a potential risk to be evaluated and monitored as necessary.
USDA & FDA (21CFR), 3-A,	Compressed air monitoring is not specifically mentioned - it is implied by employing GMPs.
BCAS, BRC, SQF	Specific verbiage requiring test compressed air periodically.


The process and methods of compressed air testing for microbiological contaminant content is outlined very well in the ISO 8573-7:2003 document.

Benchmarking GMPs:

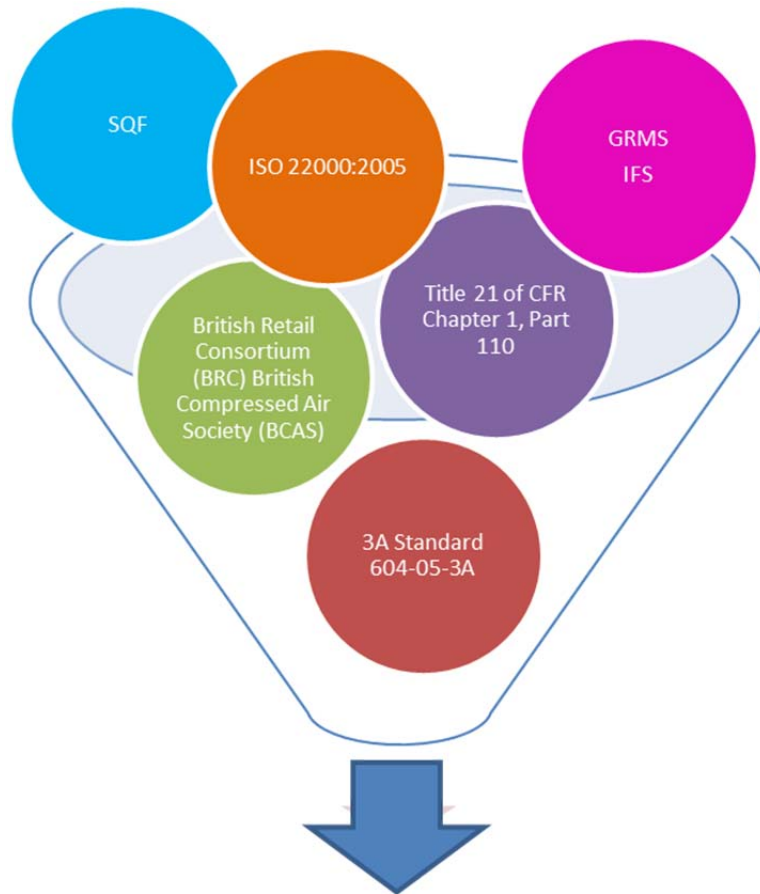
Employing the most critical elements from all of the published GMPs ensures that you have the bases covered for compressed air quality at the point of contact. Using filtration that meets the most discriminating industry standards ensures compliance with ALL of the published GMPs. An outline of published GMPs and standards is shown below:

Benchmarking of Compressed Air GMPs

Good Manufacturing Practices - Compressed Air in Food Plant	Dew Point	Oil Removal	Particulate Removal (includes microbiological particles)	Efficiency	Location of Filtration
FDA Code of Federal Regulations Title 21CFR, Part 110.40 (g) ¹		Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.			
FDA Guidance RTE foods ²			0.3 Micron		Point of use
FDA and the FSMA ¹² (Food Safety Modernization Act)		The FSMA does not introduce any specific regulations related to compressed air. It primarily requires companies under FDA jurisdiction to employ a risk-based (HACCP-like) food safety management scheme.			
3-A Standard 604-05-3A ³ Section: D6.6.1		Point of Use-Contact (sterile air): 99.999% ¹⁰ All other: 99% ¹⁰			
British Compressed Air Society (BCAS) ⁴ Section 6	-40° F/C	< 0.01 mg/m ³	0.1 - 0.5 Micron		
British Retail Consortium (BRC) ⁹		Compressed air used directly in contact with the product shall be filtered.			
Safe Quality Foods (SQF) 7th edition ⁵ . Section(s): 9.5.7; 10.5.7; 11.5.7; 13.5.4		Compressed air used in the manufacturing process shall be clean and present no risk to food safety.			
International Featured Standards (IFS) version 6 ⁶ . Section 4.9.10.2		Compressed air shall not pose a risk of contamination.			
Global Red Meat Standard (GRMS) ⁷		Hazards relevant to food safety shall be controlled in critical control points (CCP) and/or by GMP measures.			
ISO 22000:2005 ⁸ + Prerequisite Program (PRP) (like BSI PAS 220:2008 ¹¹)	ISO22000:2005 := Prerequisite Programs should be in place to address supplies of air (Section 7.2.3.C) BSI PAS 220:2008 Section 6.5 := (Summarized) Compressed air systems shall be constructed and maintained so as to prevent contamination. Requirements for filtration, microbiology, and humidity (RH%) shall be specified. Filtration of the air should be as close to the point of use as is practicable.				
Most discriminating filtration standard:		< 0.01 mg/m³	0.1 - 0.5 Micron	Point of Use-Contact: 99.999%	Point of use

 = Not Specified
 = Most critical standard

Let's boil it all down:



The *Best* Manufacturing Practices for compressed air in a food plant:

- Remove as much moisture as possible from the air before distributing it throughout the plant. A dew point of -40 F/C is ideal.
- Use point-of-use sterile air filtration wherever compressed air comes in contact directly or indirectly with food or food contact surfaces.
- Ensure the final stage of point-of-use filtration has a rating of 0.01 micron with a DOP efficiency rating that is equal to or better than 99.999%¹⁰.

Compressed air at 100 psig contains 8 times the amount of bacteria and contaminants as atmospheric air

Mesophilic Aerobic bacteria and fungi love the warm dark environment inside a compressed air system.

GMPs for Point-of-Use Compressed Air Filtration:

Point-of-use filtration is the best line of defense against microbial contamination of food in a compressed air system. Even the best of compressor room system filtration does not eliminate harborage sites and biofilm buildup in the downstream compressed air piping system.

Best Practices:

GMP: System Design

Point-of-Use Filtration:

Wherever the compressed air comes in contact with the food – either directly or indirectly - the following 3-stages of filtration will significantly reduce the risk of microbial contamination of the food.



- **Stage 1:** Remove bulk liquid and particulate matter down to 0.01 micron at $\geq 93\%$ DOP efficiency¹⁰. Automatic drain in filter.
- **Stage 2:** Remove oil and water aerosols and smaller particulate matter down to 0.01 micron at $\geq 99.99\%$ DOP efficiency¹⁰. Automatic drain in filter.
- **Stage 3:** Remove microbial contamination down to 0.01 micron at $\geq 99.9999\%$ DOP efficiency¹⁰ with a sterile air filter.

SSOP: Maintenance of Filters:

- **Stage 1:** Change filter element every 6-12 months.
- **Stage 2:** Change filter element every 6-12 months.
- **Stage 3:** Change filter element every 3-6 months – or sooner – as necessary based on point-of-use air quality test for microbial content.

Optional: Steam sterilize stage 3 (provided the filter is designed for CIP sterilization). Follow manufacturer's instructions.

- Note: Sterile air filters are designed to capture microbial matter larger than the nominal element rating. Microbial matter will not create a differential in pressure across the element. Therefore, measuring differential pressure across the element will not give an accurate reading of contamination. Air testing and/or regularly scheduled element changes are the best practice.

SSOP: Monitor Purity of Compressed Air:

- As a baseline - test compressed air at each food contact point periodically in accordance with ISO 8573-7:2003 standards. Determine test interval empirically based upon presence of microbial contamination.

SQF Code:

The 7th edition, published July 2012, has added the following verbiage to Module 11: Good Manufacturing Practices for Processing of Food Products:

11.5.7 Air Quality

- **11.5.7.1**
Compressed air used in the manufacturing process shall be clean and present no risk to food safety.
- **11.5.7.2**
Compressed air used in the manufacturing process shall be regularly monitored for purity.

Putting it into practice:

Implementing the GMP's and SSOP's shown to the left will fulfill the requirements of the new 11.5.7.1.

A periodic test (based on empirically derived test intervals) to confirm the absence of contamination should be performed at all points in the system where air could contact the food. This will fulfill the requirements of 11.5.7.2.

SQF Certification Levels:

- **Level 1**
The GMPs & SSOPs stated here will prepare the system design for future higher level certifications.
- **Level 2**
The GMPs & SSOPs stated here are very good foundations for a solid Prerequisite Program to support a plant's HACCP plan.
- **Level 3**
The Prerequisites from Level 2 combined with a formalized air quality testing program will provide the highest level of confidence in a safe compressed air system.

Notes

1

References

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=110&showFR=1&subpartNode=21:2.0.1.1.10.3>

2

<http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/foodprocessinghaccp/ucm073110.htm>

3

[3A Standard 604-05 may be purchased at: www.techstreet.com/3Agate.html](http://www.techstreet.com/3Agate.html)

4

<http://www.bcas.org.uk/compressed-air-codes-of-practice.php>

5

<http://www.sqfi.com/standards/>

6

<http://www.ifs-certification.com/index.php/en/ifs-certified-companies-en/ifs-standards/ifs-food>

7

http://www.grms.org/GRMS_standard.aspx

8

<http://www.iso.org/iso/home/search.htm?qt=22000&sort=rel&type=simple&published=on>

9

<http://www.brcglobalstandards.com/GlobalStandards/Standards/Food.aspx>

10

as measured by the Dioctylphthalate Fog Method (DOP) test - MIL-STD-282; method 102.9.1

11

<http://shop.bsigroup.com/en/ProductDetail/?pid=00000000030181317>

12

<http://www.fda.gov/food/foodsafety/fsma/default.htm>

13

[Camfil-Farr Food Processing Industry application brochure www.camfilfarr.com](http://www.camfilfarr.com)

14

McLandsborough, Dr. Lynne A., PhD, Associate Professor and Director of Undergraduate Food Science Program, Department of Food Science, University of Massachusetts, Amherst

Parker Hannifin Corporation

Filtration and Separation Division

242 Neck Road

Haverhill, MA 01835

Phone: 800 343 4048 or 978 858 0505

Fax: 978 556 7501

www.balstonfilters.com