Ensuring Food Safety with Food and Beverage Grade Compressed Air

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Contaminated Products From Hazards Found in Compressed Air is a Real Problem for Food and Beverage Manufacturers

A tour of any food and beverage manufacturing facility will see extensive use of compressed air in a variety of applications.

Compressed air often directly or in-directly contacts production equipment, ingredients and finished product. Additionally, compressed air is also used to automate processes, assist packaging of products and generate modified atmosphere gases on-site.

Irrespective of its use, a clean, dry, compressed air supply is essential to maintain consumer safety.

This powerful and versatile utility is not without safety risks. Users of compressed air will be familiar with the known hazards associated with using a pressurised gas on site, but those responsible for product quality and consumer safety are not always aware of the unseen hazards found in compressed air.

Untreated compressed air contains many potentially harmful or dangerous contaminants which must be reduced to acceptable levels in order to protect the consumer and provide a safe and cost-effective production facility.

Contaminants that may be a potential hazard for human consumption need to be controlled, as a lack of control could potentially result in a prosecution.

The subject of ensuring food safety is vast, complicated and well documented from a process point of view, however the compressed air system is an often overlooked source of biological, chemical and physical hazards that cannot be ignored.

The purpose of this white paper is to provide food & beverage manufacturers valuable information regarding potential hazards in their compressed air system that could lead to a quality incident and compromise consumer safety.

This White Paper will:

- Review the references to compressed air in the various global FSMS schemes, standards and best practice guidelines.
- Show how to integrate the compressed air system into the facilities food safety management system using the HACCP process.
- Provide advice for the hazard analysis team on the hazards to look for during the HACCP Hazard Analysis and the treatment technologies required to control the hazards (including those to avoid).
- Most importantly, provide a usable specification for Food & Beverage Grade Compressed Air.

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Protecting the Consumer

In order to protect consumers against ill health (or worse), most industrialised countries have strict regulations and laws governing hygiene of food and beverage products which must be adhered to during:

- **Preparation**
- **Packaging**
- **Distribution**
- **Processing**
- **Storage**
- **Handling**
- **Manufacturing**
- **Transportation**
- **Sale or supply**

Normally, hygiene regulations are strictly observed within the manufacturing and supply processes, however, through lack of awareness, they are not often applied to utilities.

The most overlooked utility being the compressed air which directly contacts manufacturing equipment, ingredients and finished products as well as powering many different manufacturing processes.

Hygiene Legislation & Duty of Care

In the United Kingdom and the European Union hygiene is covered by European Regulation (EC) 852/2004.

Other countries globally have their own national hygiene legislation.

Food and beverage manufacturers have a duty of care to adhere to national hygiene legislation or face legal consequences.

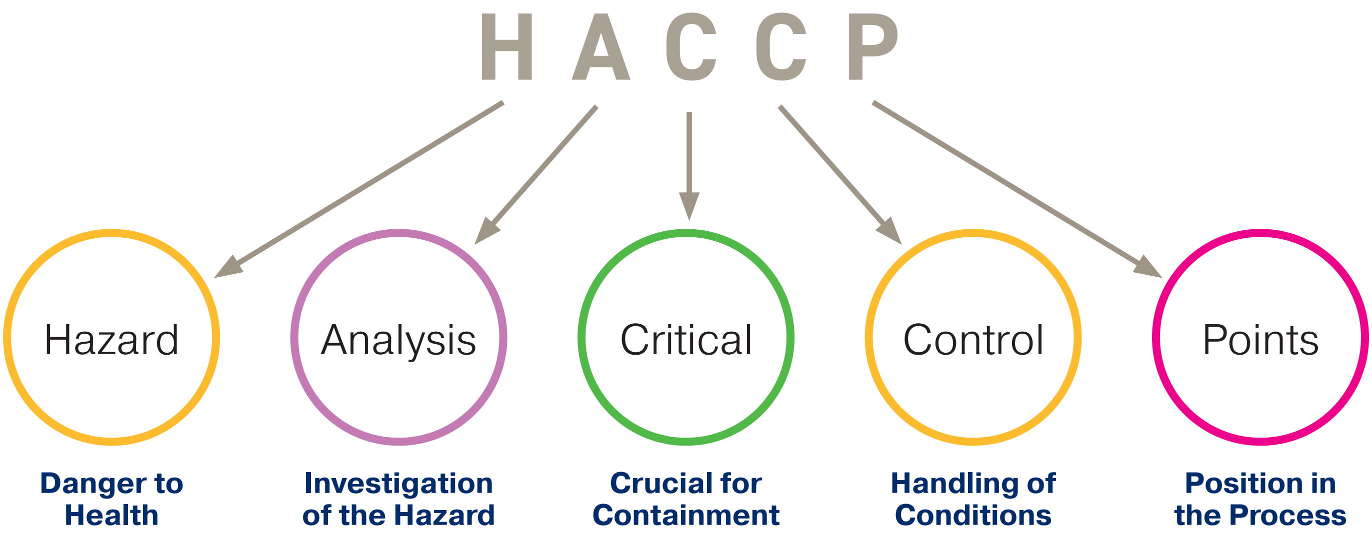
Hygiene legislation typically lays down the general rules for food business operators regarding the hygiene of foodstuffs, with a national law to enforce the legislation.

Hygiene legislation will have no direct reference to the compressed air system or the purity of compressed air used in the manufacture of food and beverage products.

However, in-directly, the compressed system and the purity of compressed air in the manufacture of food and beverage products does fall under the remit of hygiene legislation, because as we will see later in this document, compressed air is a source of biological, chemical & physical hazards that could harm the consumer.

Food Safety Management System (FSMS)

Typically, hygiene legislation requires food and beverage manufacturers to instigate a written Food Safety Management System based upon the principles of HACCP (Hazard Analysis Critical Control Points).



With regards to the Food Safety Management System, a food or beverage manufacturer has the option to develop their own ‘in house’ FSMS or use an FSMS developed by a 3rd party.

Should the FSMS be developed in house, the compressed air system and the purity of the compressed air used during manufacture must always be included.

Many manufacturers opt to implement a 3rd party FSMS. The added benefit of choosing this route is the access to 3rd party auditors trained on that particular FSMS. The audit allows a manufacturer to easily show compliance if required.

But how does a manufacturer know if the 3rd part scheme is adequate?

GSFI Recognised FSMS Schemes

The GSFI, or Global Food Safety Initiative is a coalition of food safety experts from independent companies who in simple terms, review the strength of separate FSMS schemes and where applicable grant recognition to the scheme.

Only FSMS schemes of the highest standard are granted recognition and are promoted by the Global Food Safety Initiative.

With regards to compressed air, some of the GSFI schemes directly reference the compressed air system, whilst some do not.

We will now review the GSFI approved FSMS schemes in relation to compressed air use and highlight any reference to compressed air in the scheme documents and also to any air purity specifications if available.

References to Compressed Air in GFSI Recognised FSMS Schemes

The following GFSI bench marked food safety standards have been reviewed in relation to any references within the scheme documents relating to compressed air use and compressed air purity specifications.

GFSI Accredited Scheme	Food / Beverage Sector	Direct Reference to Compressed Air	Includes a Usable Compressed Air Specification
Primus GFS	Agriculture	✗	✗
Global Seafood Alliance	Seafood	✗	✗
GlobalGAP	Agriculture & Livestock	✗	✗
CanadaGAP	Fresh Fruit & Veg	✓	✗
Global Red Meat Standard	Livestock	✗	✗
FSSC 22000	Process applicable to any sector	✗	✗
SQF	Process applicable to any sector	✓	✗
BRCGS Global Standard	Process applicable to any sector	✓	✗
IFS FOOD International Featured Standards	Process applicable to any sector	✓	✗
Japan Food Safety Management Association	Process applicable to any sector	✓	✗

Primus GFS

No direct reference to compressed air.

No compressed air purity specification included.

GlobalGAP

No direct reference to compressed air.

No compressed air purity specification included.

Global Seafood Alliance

No direct reference to compressed air.

No compressed air purity specification included.

CanadaGAP

Reference to compressed air: Extracts from - **Greenhouse-Manual-9.0-2021 & Fruit-and-Vegetable-Manual-9.0-2021**

“If compressed air is used in direct contact with product or food contact surfaces, the person responsible maintains compressed air equipment as per manufacturer’s instructions or according to a written procedure based on expert recommendations.”

No compressed air purity specification included.

GMRS Global Red Meat Standard

No direct reference to compressed air.

No compressed air purity specification included.

FSC22000

No direct reference to compressed air.

No compressed air purity specification included.

However, FSSC 22000 contains a complete certification Scheme for Food Safety Management Systems based on existing standards, including ISO 22000 series. ISO 22002-1 includes a reference to compressed air.

ISO 22002-1:2009

Reference to compressed air: Extracts from Prerequisite programmes on food safety - Part 1: Food manufacturing, **Section 6.5 Compressed air and other gases.**

'Compressed air, carbon dioxide, nitrogen and other gas systems used in manufacturing and/or filling shall be constructed and maintained so as to prevent contamination.

Gases intended for direct or incidental product contact (including those used for transporting, blowing or drying materials, products or equipment) shall be from a source approved for food contact use, filtered to remove dust, oil and water.

Where oil is used for compressors and there is potential for the air to come into contact with the product, the oil used shall be food grade. Use of oil free compressors is recommended. Requirements for filtration, humidity (RH%) and microbiology shall be specified.

Filtration of the air should be as close to the point of use as is practicable.'

No compressed air purity specification included.

SQF Food Safety Code: Food Manufacturing, Edition 9

Reference to compressed air: Extracts from PART B: The SQF Food Safety Code: Food Manufacturing – Module 11, section **11.5.5 Air and Other Gases**

'11.5.5.1 Compressed air or other gases (e.g., Nitrogen or carbon dioxide) that contact food or food contact surfaces shall be clean and present no risk to food safety.

11.5.5.2 Compressed air systems and systems used to store or dispense other gases that come into contact with food or food contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards. The frequency of analysis shall be risk-based and at a minimum annually.

Compressed Air Monitoring: A program that includes particles, water, oil, microbiological, and relevant gaseous testing in compressed air or other gases. A verification of the effectiveness of compressor maintenance and filtration that a management facility has in place.'

No compressed air purity specification included.

BRC Global Standard Issue 9

Reference to compressed air: Extracts from **4.5 Utilities - water, ice, air and other gases.**

- *'Utilities used within the production and storage areas shall be monitored to effectively control the risk of product contamination.*
- *4.5.3 Air and other gases used as an ingredient or that are in direct contact with products shall be monitored to ensure this does not represent a contamination risk. Compressed air that is in direct contact with the product shall be filtered at point of use.'*

No compressed air purity specification included.

IFS 7

Reference to compressed air: Extracts from **4.9.10 Compressed air and gases.**

- *'4.9.10.1 The quality of compressed air that comes in direct contact with food or primary packaging materials shall be monitored based on hazard analysis and assessment of associated risks. If gases are used, they shall demonstrate adequate safety and quality through a declaration of compliance and shall be suitable for the intended use.*
- *4.9.10.2 Compressed air shall not pose contamination risks.'*

No compressed air purity specification included.

Japanese Food Standards

Reference to compressed air: Extracts from JFS-B standard (guideline) Ver. 2.0 GMP 4 **Specifications of Manufacturing and Storage Area, and Utility Management - Compressed air, carbon dioxide, nitrogen and other gases.**

- *' Ensure that the gas equipment used for manufacturing and filling has specifications that do not pose a risk of contamination of food, and are properly maintained.*
- *Use approved gas for gases that come in contact with food.*
- *Ensure sure that dust, oil, and water are removed from air and gases that come into contact with food.*
- *Filter gases as close to the point of use as possible.'*

No compressed air purity specification included.

Other Regulations and Standards Relating to Food Safety & Referencing Compressed Air

In addition to the GSFI recognised FSMS schemes, there are other regulations and standards commonly in use globally that have an impact on compressed air system design and consumer safety.

Regulations / Standards	Food / Beverage Sector	Direct Reference to Compressed Air	Includes a Usable Compressed Air Specification
FDA Code of Federal Regulations Title 21CFR	Process Applicable to any Sector	✓	✗
FDA Guidance RTE Foods	Ready to Eat Foods	✓	✗
3-A Sanitary Standards 604-05	Dairy	✓	✗

FDA Code of Federal Regulations Title 21CFR

It is divided into 9 parts (1000+ pages)

In the 9 parts there are 7 reference to compressed air. The text relating to compressed air is common to all sections, with only references to the application changing – an example is shown below – this section relates to infant formula manufacture.

Reference to compressed air: Federal Regulations Title 21CFR Section 106.35 (G), Section 110.40 (G), Section 111.27 (7), Section 117.80 (G) & Section 507.22. **Extract below from - Section 110.40 (G)**

"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 in-direct food additives."

No compressed air purity specification included in any section other than Section 106.35 relating to infant formula.

"When compressed gases are used at product filling machines to replace air removed from the head space of containers, a manufacturer shall install, as close as practical to the end of the gas line that feeds gas into the space, a filter capable of retaining particles 0.5 micrometer or smaller."

FDA Guidance RTE Foods

"We recommend that you implement procedures to ensure that compressed gases or air used directly in or on RTE food, or on RTE food-contact surfaces, not become a source of L. monocytogenes. Examples of such procedures are drying and filtration. We recommend that dehydration be done at the source of gas or air supply and that filtration be done at the point of use, using a filter that can retain particles larger than 0.3 micron. You should take appropriate steps to maintain the filters"

No compressed air purity specification for other contaminants is included.

3-A Sanitary Standards

Supplying Air Under Pressure in Contact with Milk, Milk Products, and Product Contact Surfaces

Reference to compressed air: **Document 604-05-3A Section D6.6**

"Point of use – direct contact sterile air filter with 99.999% efficiency all other uses 99.99% efficiency"

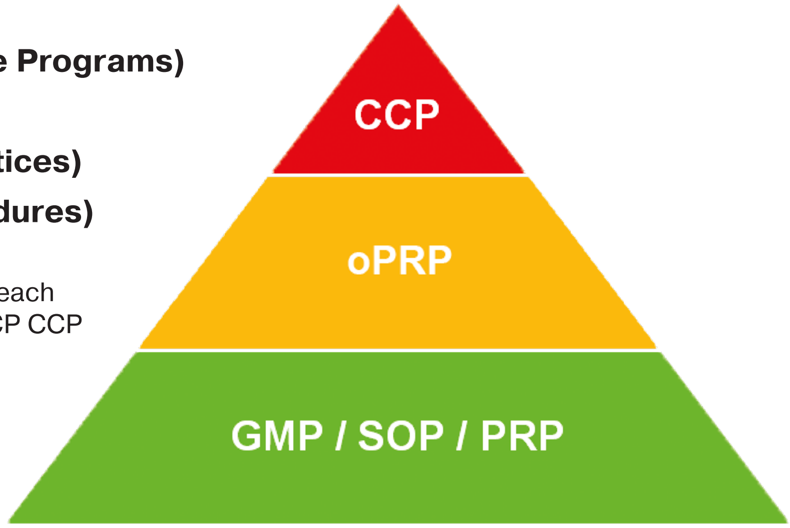
No compressed air purity specification for other contaminants is included.

Do the GSFI FSMS Schemes, Regulations and Standards Listed Offer Total Protection for Compressed Air Users?

Unfortunately not. However, these documents should not be ignored, as the GSFI FSMS scheme recommendations and other regulations and standards only form part of the food safety system and a good FSMS does not rely on a single point of control.

If the HACCP process is correctly implemented, it should also be underpinned by:

- **oPRPs (Operational Pre-Requisite Programs)**
- **PRPs (Pre-requisite Programs)**
- **GMPs (Good Manufacturing Practices)**
- **SOPs (Standard Operating Procedures)**



Each one is a layer in a security screen and at each layer, the level of security improves. The HACCP CCP being the final layer of protection.

If a CCP is required, then the first two defence layers are missing or inadequate. Therefore, when conducting the Hazard Analysis, if a CCP is identified, first ask "Can this CCP be eliminated by implementing a GMP, PRP or oPRP?"

The references from the various FSMS schemes only provide generic advice, i.e. "Don't allow the compressed air to contaminate the manufacturing process, ingredients of food" or "Treat the compressed air to prevent hazards entering the manufacturing process", however they do not provide specific guidance on what contaminants to treat or to what level. This is left to the HACCP process.

Therefore, the guidance provided by the FSMS schemes can be classified as a PRP or GMP and sits at the foundation of a good Food Safety Management System.

Important Note:

The recommendations provided by the GSFI FSMS schemes and other regulations and standards listed previously should not be the only guidance followed relating to the compressed air system.

Applying the HACCP Principle

Hygiene legislation requires a manufacturer to follow the principles of HACCP, as do the various FSMS schemes reviewed previously. So what can go wrong?

Applying the HACCP Process

No one understands a company's manufacturing process better than the people responsible for the day to day operation of that facility. The HACCP principle works very well when the team carrying out the Hazard Analysis fully understand the manufacturing processes and have clear industry guidelines, GMPs (Good Manufacturing Practice) or SOPs (Standard Operating Procedures) to follow.

The Problem with Risk Based Food Safety Management Systems

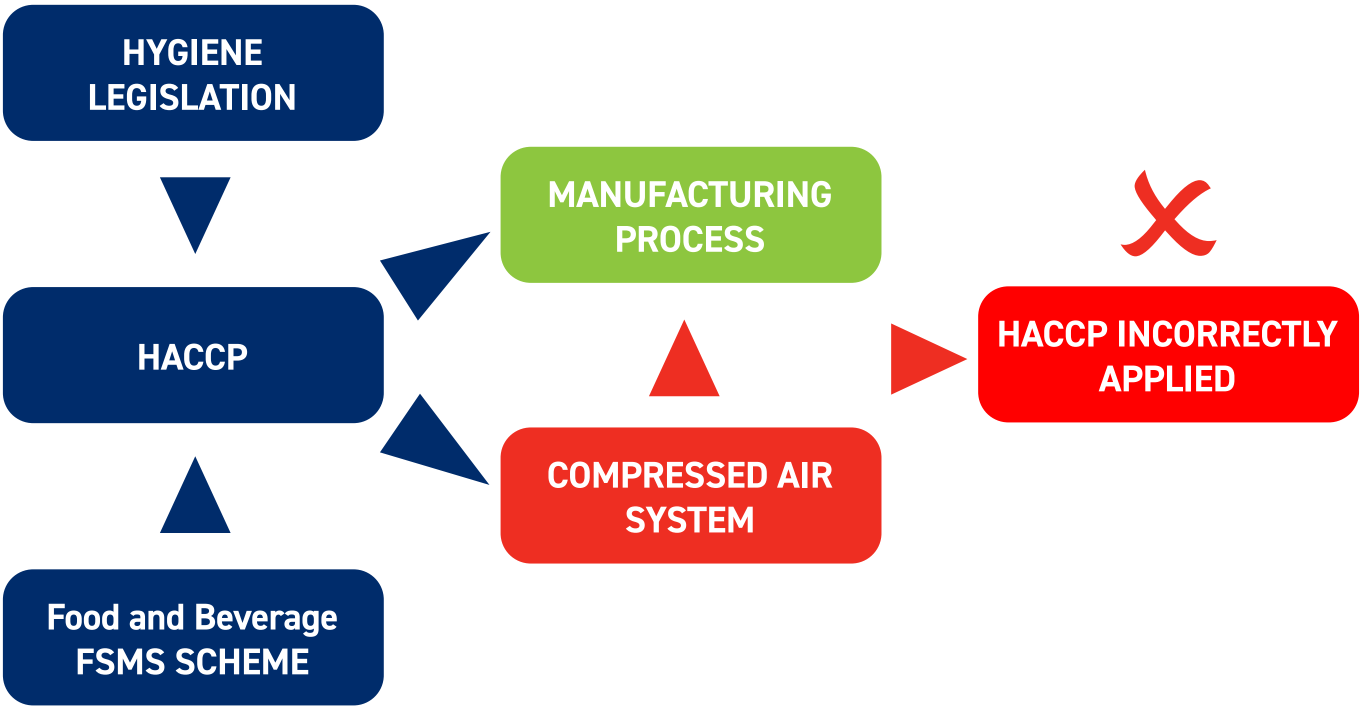
Unfortunately, when it comes to utilities such as compressed air, where industry guidelines, GMPs or SOPs provide very little guidance or do not exist, serious problems can arise.

Compressed air contains harmful, unseen hazards (contaminants), and as they are mostly invisible, many users of compressed air are unaware of their presence, the source of those hazards and most importantly, the problems those hazards can present to consumer safety.

For this reason, the compressed air system is commonly omitted from the Hazard Analysis (Risk Assessment) process.

Incorrect application of the HACCP principle

(Compressed air system omitted / no compressed air expert on HA Team)



- The HACCP process is applied only to the main manufacturing process
- Compressed air purification equipment being specified exactly the same as equipment used in a general industrial manufacturing plant, with no regards to the additional requirements of a food and beverage manufacturing facility
- Untreated / under treated hazards in the compressed air directly entering and contaminating the manufacturing process
- Potential for unidentified quality incidents and / or failure of quality audits

Risk-based food safety systems lack detail (due to the diversity and uniqueness of each manufacturing facility and process). Therefore, they either require a food & beverage manufacturer to be expert in all aspects of the manufacturing process and facility (including utilities) or to employ the use of 3rd party "experts". Often referred to as the "competent person".

What makes a "Competent Person" when it comes to compressed air treatment?

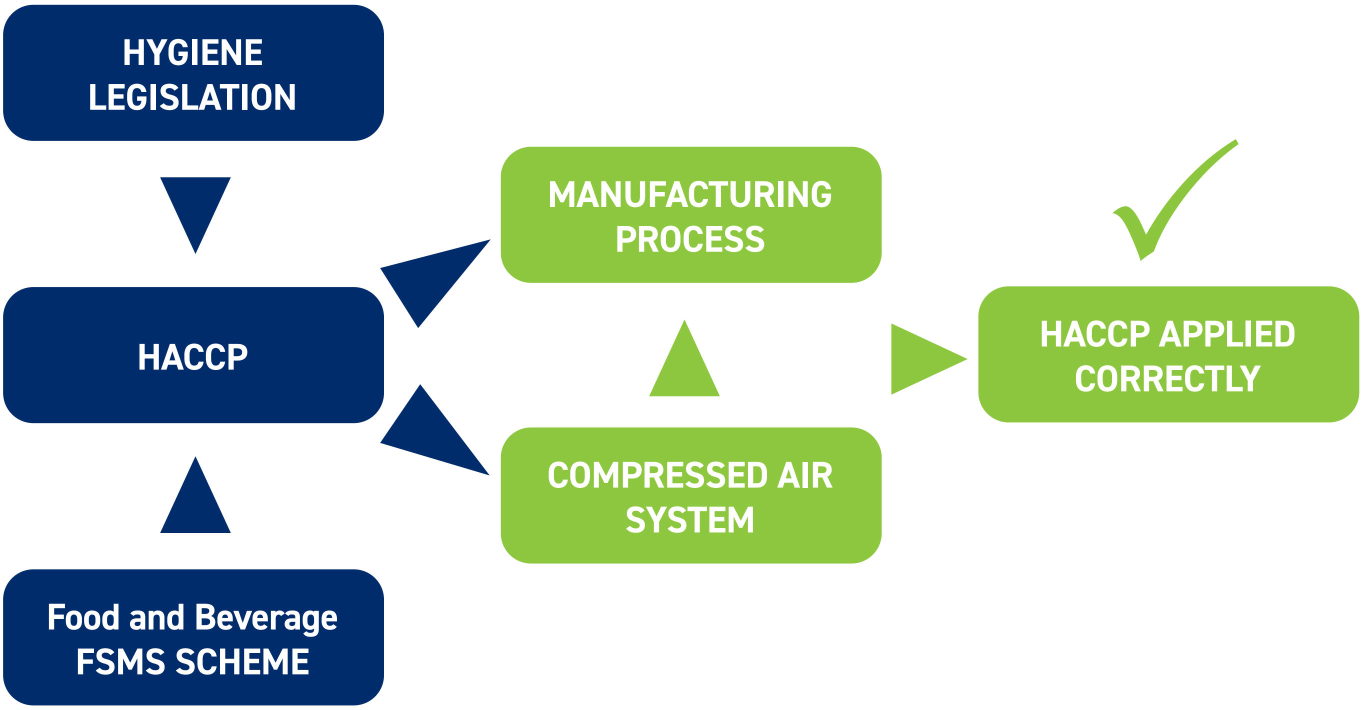
The person(s) carrying out the Hazard Analysis on the compressed air must have a good understanding of:

- Hazards associated with Compressed Air (Contaminants)
- The sources of contamination
- The problems compressed air contamination can cause
- All of the components that make up a compressed air system
- Compressed Air Treatment equipment
- International standards relating to compressed air purity / HACCP process / oPRPs / PRPs / GMPs
- Equipment and methodology used to test compressed air systems for contamination
- Air purity requirements specific to food / beverage grade compressed air applications

Important Note: When it comes to assessing the compressed air system for potential hazards, a 'competent person' should be part of the Hazard Analysis team.

Correct application of the HACCP principle

(Compressed air system included / compressed air expert included on HA Team)



- Compressed air system included as part of the Hazard Analysis
- Compressed air purification "experts" called in to assist with the hazard analysis
- All compressed air hazards (Contaminants) identified
- Compressed air Treatment system requirements specified correctly
- Hazards reduced to acceptable levels
- Manufacturing processes protected
- Consumer safety ensured

Including The Compressed Air System in The Hazard Analysis

Compressed air contains biological, chemical and physical hazards (referred to as contamination). These hazards must be treated before it can be used to supply food and beverage applications, especially if the compressed air directly or in-directly contacts manufacturing equipment, ingredients, finished products or product packaging.

Understanding the different sources of compressed air contamination, the specific contaminants present in compressed air and the different phases the contaminants are in, is a key factor when performing the hazard analysis.

To provide food and beverage grade compressed air and to ensure consumer safety, there are a minimum of TEN biological, chemical and physical contaminants originating from FOUR different sources that must be treated.

CONTAMINANT SOURCE #1
THE AMBIENT AIR

Contaminants

- Micro-organisms
- Water Vapour
- Atmospheric Particulate
- Oil Vapour

CONTAMINANT SOURCE #2
THE AIR COMPRESSOR

Contaminants

- Liquid Oil
- Oil Aerosols
- Liquid Water
- Water Aerosols
- Oil Vapour (from the compressor oil)
- Compressor Wear Particles

CONTAMINANT SOURCE #3
THE AIR RECEIVER

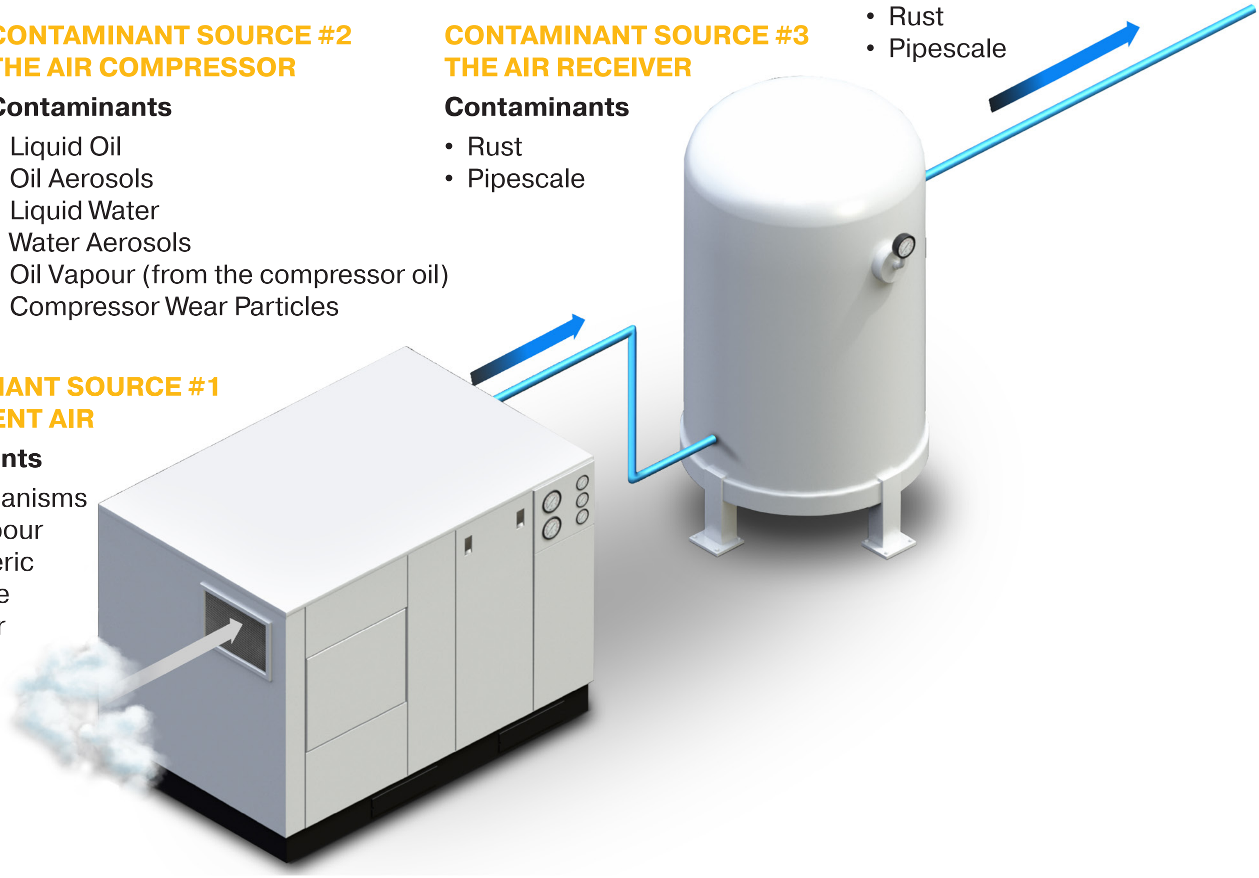
Contaminants

- Rust
- Pipescale

CONTAMINANT SOURCE #4
THE DISTRIBUTION PIPING

Contaminants

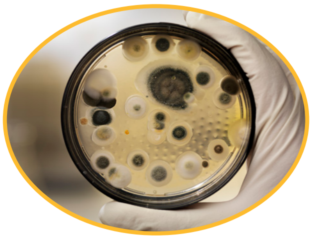
- Rust
- Pipescale



Hazards (Contaminants) In Compressed Air			
Biological	Micro-organisms (Viable & Non-Viable Particles)		
Chemical	Oil Vapour	Liquid Oil	Oil Aerosols
Physical	Water Vapour	Liquid Water	Water Aerosols
	Atmospheric Particles	Compressor Wear Particles	Rust & Pipescale

In order to supply the manufacturing facility with compressed air, the air compressor must constantly move and compress large volumes of ambient air.

Micro-organisms



Ambient air can contain up to 100 million micro-organisms per cubic metre. Due to their small size, bacteria, viruses, fungi, yeasts, moulds and spores will pass through the intake filter and into the compressed air system. Tests carried out by the Danish Technological Institute proved that microorganisms can survive in compressed air systems up to 400 bar, where the warm moist environment inside the air receiver and distribution piping provides an ideal environment for their rapid growth.

Water Vapour

Water enters the compressed air system as a vapour (gas). The ability of air to hold water vapour is dependent upon its pressure and its temperature. The higher the temperature, the more water vapour that can be held by the air, the higher the pressure, a greater amount of water vapour is squeezed out.

As ambient air is compressed, the temperature of the air increases significantly allowing the heated air to easily retain all of the water vapour entering the compressor.

Oil Vapour

Vehicle emissions and inefficient industrial processes lead to oil vapour contamination in the ambient air. Typical concentrations in ambient air can seem low (between 0.05 and 0.5mg per cubic metre), however values measured in compressed air increase significantly after compression when contaminants become concentrated. Once in a compressed air system, oil vapour can taint ingredients, finished products and packaging with an oily smell. Cooling also causes oil vapour to condense into liquid oil and form oil aerosols.

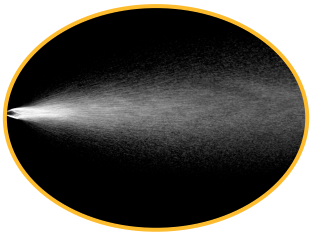
Atmospheric Particulate

Ambient air in industrial and urban environments will typically contain between 140 & 150 million dirt particles in every cubic metre.

As 80% of these particles are less than 2 microns in size, they are therefore too small to be captured by the compressor air intake filter and will travel unrestricted into the compressed air system.

Once in the compressed air system, many of the hazards found in ambient air change phase, leading to the creation of additional contaminants. The air compressor, air receiver and distribution also add to the problem.

Liquid Water and Water Aerosols



After compression, compressed air is cooled to a usable temperature by an after-cooler. This cooling reduces the air's ability to retain water vapour, resulting in condensation of water vapour into liquid water. The presence of liquid water also causes aerosols to be formed.

After-coolers typically incorporate a water separator to reduce the amount of liquid entering the compressed air system (these do not remove 100% of the condensed liquid and have no effect on aerosols).

The air leaving the after-cooler and entering the compressed air system is now 100% saturated with water vapour.

Any further cooling of the compressed air will result in more water vapour condensing into liquid water and the generation of more aerosols.

Condensation occurs at various stages throughout the system as the air is cooled further by the air receiver, the distribution piping and the expansion of air in valves, cylinders, production equipment.

Liquid Oil and Oil Aerosols

As with water, oil vapour drawn in with the ambient air is cooled and condensed within the after-cooler leading to the formation of liquid oil and oil aerosols (even with oil-free compressors) which carry downstream. The majority of air compressors in use today use oil in their compression stage for sealing, lubrication and cooling. Even though the oil is in direct contact with the air as it is compressed, due to the efficiency of modern air / oil separators built into the compressor, only a small proportion of this lubricating oil is carried over into the compressed air system as a liquid or aerosol (typically no more than 5mg/m^3 for a well maintained screw compressor) or as oil vapour.

Rust and Pipescale

Rust and pipescale can be directly attributed to the presence of water in the compressed air system and is usually found in air receivers and distribution piping. Over time, the rust and pipescale breaks away to cause damage or blockage in production equipment which can also contaminate final product and processes.

Rust and pipescale problems often increase for a period of time after the installation of dryers into older piping systems which were previously operated with inadequate or no purification equipment.

Compressed Air Contaminants of Concern

When it comes to producing food & beverage grade compressed air, all of the ten contaminants highlighted must be treated and reduced to acceptable levels. However, some contaminants pose a greater risk than others and require specific attention. Of particular concern are:

Water

Liquid Water / Water Aerosols / Water Vapour

For general industrial manufacturing, the treatment of water vapour to prevent corrosion is the primary concern. If no free water is visible, then the air is considered “dry”.

However for food and beverage grade compressed air, the major concern is around the combination of wet compressed air how this promotes the growth of micro-organisms.

Micro-organisms

Viable & Non-viable Particles

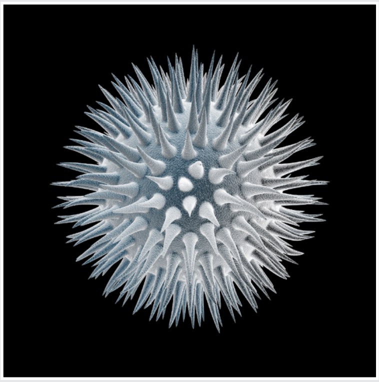
The definition of Micro-organism is: A living organism too small to be seen with the naked eye but visible under a microscope”. In simple terms, it is a particle of dirt that is alive.

Ambient air contains viable and non-viable particles. A non-viable particle is a particle that does not contain a living micro-organism but acts as transportation for viable particles, a viable particle is a particle that contains one or more living micro-organisms.

There can be up to 100 million micro-organisms per cubic metre of ambient air.

Examples of Micro-organisms found in ambient air and typical size in microns

Viruses
0.02µm - 0.2µm



Pathogenic Bacteria
0.3 µm - 5µm

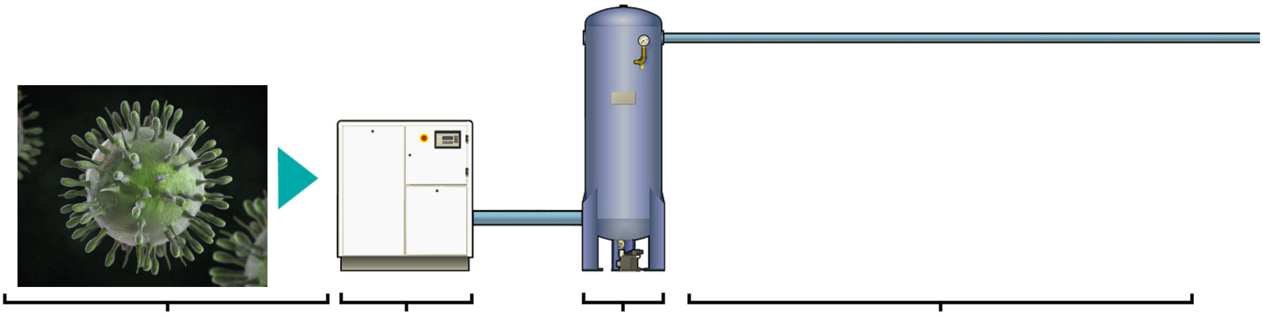
Fungi
(Moulds / Yeasts)
3µm - 10µm

Micro-biological contamination from compressed air can:

- Potentially harm the consumer
- Diminish product quality, rendering a product unfit for use
- Lead to a product recall
- Cause legal action against a company
- Damage a brand (reputation)

Compression = Concentration

As the air compressor is running, large volumes of ambient air are drawn into the compressor intake. Particles the size of micro-organisms are too small to be captured by the panel and intake filters used on modern air compressors, therefore, they travel unrestricted into the compressed air system.



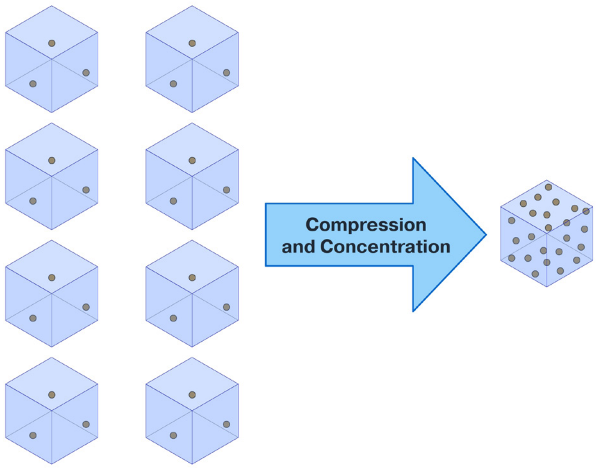
Ambient air can contain up to 100,000,000 micro-organisms per cubic metre

Micro-organisms are concentrated as ambient air is compressed

Fact: The heat of compression does not kill micro-organisms or sterilise compressed air

Micro-organisms continue to grow inside the wet compressed air system. They are present in both the compressed air and the liquid condensate.

Compressed air used in manufacturing processes with direct contact & in-direct contact applications result in product contamination. Manufacturing area, production equipment, surrounding ambient air can also be contaminated with micro-organisms.



When the ambient air is compressed, it is "squeezed" down into a smaller volume. Unfortunately, this does not apply to the contaminants in the ambient air which instead are concentrated. The higher the pressure the air is compressed to, the higher the concentration of contamination.

Myth

During compression, the temperature of the air increases rapidly (typically in the range of 80˚C to 120˚C for oil lubricated compressors and 180˚C to 200˚C for oil free compressors). It was often thought that this temperature increase was enough to kill off micro-organisms and sterilise the compressed air.

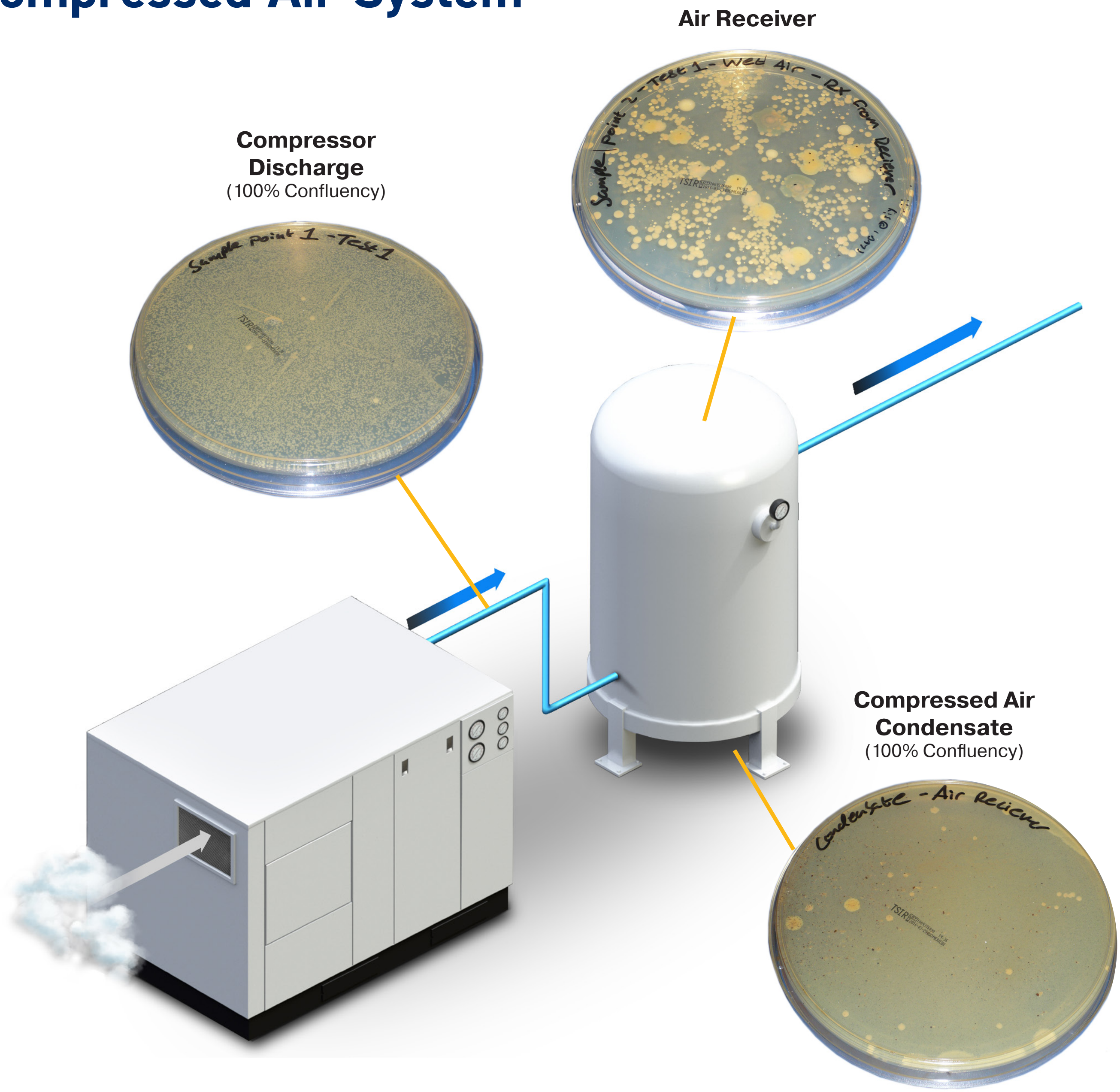
Fact

Whilst heat may kill some micro-organisms (typically viruses), time spent at temperature is also a factor for others. As soon as the ambient air is compressed, it is passed through an after-cooler to reduce its temperature to around 10˚C above ambient. Micro-organisms are adaptive and the rapid heating and cooling can cause bacteria and fungi to change state to protect itself (forming a spore). Spores can lie dormant for long periods of time until the right conditions for growth present themselves. Cooling the compressed air has the effect of condensing water vapour into liquid water, generating aerosols of water and fully saturating the compressed air with water vapour. As the wet compressed air enters the storage and distribution system, it provides the ideal environment for further growth of micro-organisms.

Examples of Microbial Growth in a Compressed Air System

The following samples taken directly at the outlet of a typical industrial air compressor and at the air receiver pressure gauge port clearly show the presence of micro-organisms in untreated compressed air, entering the compressed air distribution system. Additionally, samples taken from the compressed air condensate also show the presence of micro-organisms in the liquid discharges from the compressed air system.

Microbial Sampling of an Untreated Compressed Air System



Hazard Analysis Including the Compressed Air System

A Hazard Analysis team reviewing the compressed air system with a compressed air expert has the potential to highlight a high number of new critical control points.

Each compressed air usage point around the manufacturing facility initially becomes a CCP.

Critical Control Points require management, constant monitoring and if they fail, could lead to a quality incident.

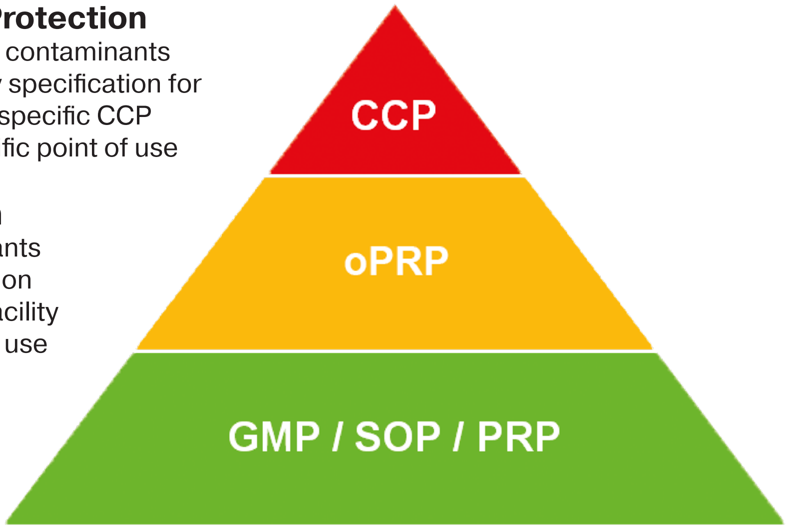
Reducing the Reliance on CCPs

However, as previously mentioned, the FSMS does not rely on Critical Control Points alone and should be underpinned by GMPs, PRPs, and oPRPs. If a CCP is required, then the first two defence layers are missing or inadequate.

Final Level of Protection
- Identifies specific contaminants
- Detailed air purity specification for hazards found at specific CCP
- Covers only specific point of use

2nd Level of Protection
- Identifies specific contaminants
- Detailed air purity specification
- Covers treatment of entire facility based upon compressed air use

1st Level of Protection
- Low on detail for example "treat compressed air to prevent contamination"



Therefore, following the identification of a CCP, ask "Can this CCP be eliminated by implementing a GMP, PRP or oPRP?".

CCPs are the last line of defence and if a CCP is required then the first two defence layers are missing or inadequate.

A correctly implemented PRP and oPRP can:

- Remove the need to apply full CCP control measures at multiple points in the plant
- Remove the need for constant monitoring of every identified contaminant at each individual CCP (Something very difficult and expensive to for all compressed air contaminants)
- Reduce capital costs
- Reduce management burden
- Allows focus on true CCPs

The Cost of Non-compliance

To operate any compressed air system, safely and cost effectively, contamination must be reduced to acceptable limits. The importance of reducing contamination is increased significantly when compressed air is used as part of the food and beverage manufacturing process.

Poor compressed air quality and failure to control contamination can cause numerous problems for a food or beverage manufacturer, many of which are not immediately associated with contaminated compressed air.

Product

- Contaminated ingredients
- Contaminated food and beverage
- Contaminated packaging
- Spoiled products

Consumer

- Potentially unwell / seriously ill consumers

Manufacturer

- Brand damage
- Legal actions
- Financial loss
- Potential imprisonment

Manufacturing Process

- Inefficient production processes
- Reduced production efficiency
- Increased manufacturing costs
- Failed quality audits

Compressed Air System

- Growth, storage & distribution of micro-biological contamination
- Corrosion within storage vessels and the distribution system
- Contaminated / damaged production equipment
- Blocked or frozen valves & cylinders
- Premature unplanned desiccant changes for adsorption dryers
- High operational and maintenance costs

Food & Beverage Grade Compressed Air Finding a Usable Specification

Whether a manufacturer implements CCPs at each compressed air usage point or use PRPs & oPRPs to protect the entire compressed air system, there is still a major issue to overcome, the lack of a detailed compressed air purity (quality) specification.

Again, this is where the "Competent Person" plays a vital role. The competent person should have a detailed knowledge of compressed air purity (quality) standards as well as the recommendations on air purity made by the FSMS food safety schemes, etc.

As we have seen in the previous extracts from the FSMS schemes, the PRPs & GMPs relating to compressed air lack detail, are not written by compressed air subject matter experts and offer little or no meaningful specification to work to.

There is however, one document that has been developed by experts in compressed air systems and compressed air treatment. This is the British Compressed Air Society (BCAS) Food and Beverage Grade Compressed Air Best Practice Guideline 102-1 (abbreviated to BPG 102-1).

GMPs / Best Practice Guidelines	Food / Beverage Sector	Direct Reference to Compressed Air	Includes a Usable Compressed Air Specification
British Compressed Air Society Best Practice Guideline 102 Food & Beverage Grade Compressed Air	All Food & Beverage Manufacturing	✓	✓

British Compressed Air Society (BCAS) Food & Beverage Grade Compressed Air Best Practice Guideline 102-1

This best practice guideline is aimed at food and beverage manufacturers and was developed to provide enough detail to compliment the existing FSMS scheme PRPs and be implemented as an oPRP, thus eliminating the need for multiple CCPs around the manufacturing facility.

The British Compressed Air Society (BCAS) Food and Beverage Grade Compressed Air Best Practice Guideline 102-1 covers:

- PRPs - compressed air
- Development of a compressed air strategy
- Compressed Air Contamination (Hazards)
- Sources of the compressed air contamination
- Relevant international standards relating to compressed air
- Overview of the compressed air treatment technologies required to achieve food & beverage grade compressed air
- A detailed specification for compressed air based upon usage (application)
  - Direct Contact
  - In-direct contact
  - Non-Food Contact
  - All linked to ISO 8573-1:2010, the international standard for compressed air purity
- An explanation as to why each specification was chosen
- Use of HACCP & PRPs
- Recommendations towards compressed air system testing, service, maintenance & documentation
- Auditors notes

- The Best Practice Guideline can be applied to the use of compressed air in all food and beverage manufacturing facilities, however it does not cover the quality of other gases used e.g. CO_2 or nitrogen as these are covered by other standards.
- Following the best practice guideline is not mandatory and not required by law
- However following the Best Practice Guideline allows a manufacturer to show due diligence, should a 'quality incident' reach a court of law.
- The Best Practice Guideline can also be applied to ingredient suppliers should they use compressed air in their manufacturing, transportation or packaging processes.
- Although produced by the British Compressed Air Society, it should not be viewed solely as a document for use in the United Kingdom.
- In the absence of any European or Global recommendations or standards relating to compressed air use in the food and beverage industry, the Best Practice Guideline can be implemented in any country to protect both the consumer and the manufacturer.

Compressed Air Usage Designation

As the hazard analysis team review the compressed air system, BPG 102-1 states each usage point should be classified as either:

- Direct Contact
- In-direct Contact
- Non-food Contact

Definition: Direct Contact

Compressed air that directly contacts manufacturing equipment, production surfaces, ingredients, finished product or packaging materials.

Examples of Direct Contact

- Sparging
- Air knives (cutting / peeling / cooling)
- Spraying / coating
- Conveying (movement)
- Direct cooling
- Packaging
- Drying

Definition: In-direct Contact

Compressed air that is not supposed to come into contact with manufacturing equipment, production surfaces, ingredients, finished product or packaging materials, but may inadvertently do so.

Examples of In-direct Contact

- Valves, cylinders & pneumatics operating in the manufacturing environment where the contaminated exhaust air can then inadvertently contact manufacturing equipment, production surfaces, ingredients, finished product or packaging materials.

Definition: Non-food Contact

Non-food contact is a recommended specification for compressed air used on a food / beverage manufacturing site and does not have the potential to come into direct contact or in-direct contact with manufacturing equipment, ingredients, finished products or packaging, for example workshop air.

Air Quality (Purity) Requirements of BCAS Best Practice Guideline 102-1

Chapter 1, section 10 of BPG102-1 provides a minimum purity specification for each usage classification, based upon the ISO 8573-1:2010 classification standard.

Compressed Air Usage	ISO 8573-1:2010 Classification	Solid Particulate			Water	Oil
		Maximum no of Particles per m³			Pressure Dewpoint	Total Oil (Aerosol, liquid & vapour)
		0.1μ ~ 0.5μ	0.5μ ~ 1.0μ	1.0μ ~ 5.0μ	°C PDP	mg/m³
Direct Contact	Class 1:2:1	⩽20,000	⩽400	⩽10	⩽ -40°C PDP	⩽0.01 mg/m³
In-direct Contact	Class 1:2:1	⩽20,000	⩽400	⩽10	⩽ -40°C PDP	⩽0.01 mg/m³
Non-Food Contact	Class 2:4:2	⩽400,000	⩽6,000	⩽100	⩽ +3°C PDP	⩽0.1 mg/m³

The contaminant values for solid particulate and oil are those at the 'Reference Conditions' in ISO 8573-1 at a temperature of 20°C, absolute atmospheric pressure of 1 bar and relative water vapour pressure of zero. Humidity is to be measured at line pressure.

Selecting the Correct Purification Equipment to Meet the BCAS BPG 102-1 Air Purity (Quality) Requirements

ISO 8573-1:2010 classifies compressed air contamination as solid particulate, water and total oil. However, those contaminants can be found in 3 different phases (solid, liquid & gas) so in total there are 10 contaminants of concern.

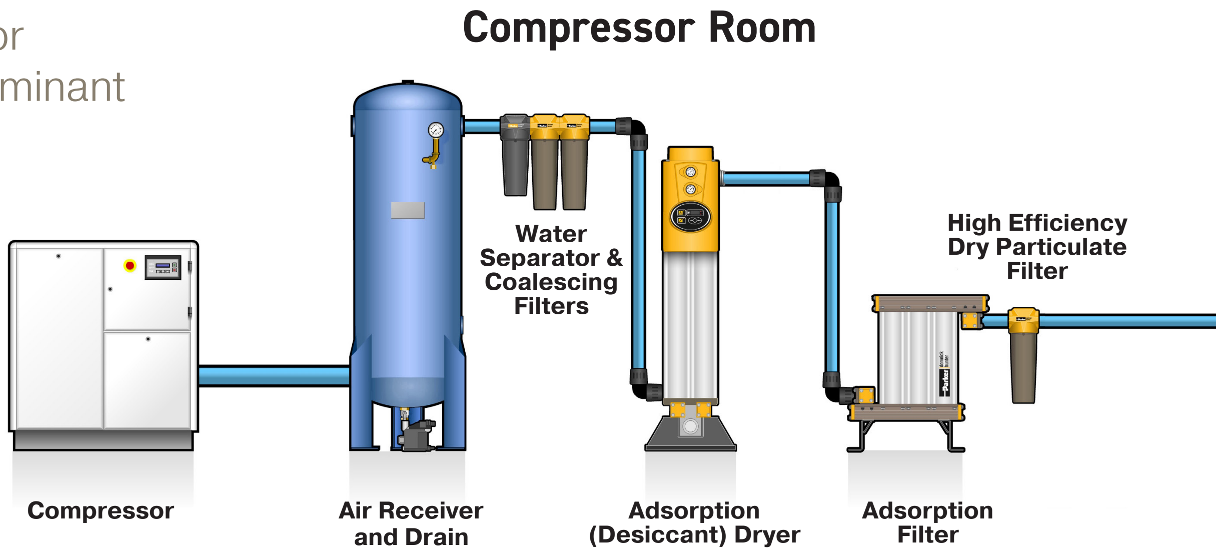
Purification technologies targeting contaminants in a specific phase are therefore required to reduce the 10 contaminants found in compressed air system to acceptable levels as defined in BCAS BPG 102-1.

The table below highlights filtration & drying technologies that comprise the purification system and the contaminants they reduce.

Purification Technologies	Contaminants									
	Atmospheric Particles	Rust	Pipescale	Micro-organisms	Liquid Water	Water Aerosol	Water Vapour	Liquid Oil	Oil Aerosol	Oil Vapour
Water Separator					●			●		
Coalescing Filters	●	●	●	●		●			●	
Adsorption Filter										●
Dryer							●			
Dry Particulate Filter	●	●	●	●						
Sterile Filters*				●						

* To ensure the highest level of food and beverage safety, Parker recommends that for critical direct contact applications, compressed air is further treated with a sterilising grade filter to remove all microbial contamination.

A solution for every contaminant



Water Separators

Although called water separators, they reduce the content of all liquids at the point of installation. Liquid in a compressed air system is usually a mixture of oil and water (even when using an oil free compressor).

Water separators are usually the first piece of purification equipment installed downstream of an after-cooler or wet air receiver and should be used to protect coalescing filters from liquid contamination. They will only reduce liquids and will have no effect on water or oil in an aerosol or vapour phase.

Coalescing Filters

When considering purification equipment, coalescing filters are vital for the cost effective operation of any compressed air system, regardless of the type of compressor installed.

A purification system will normally consist of two coalescing filters installed in series to remove water aerosols, oil aerosols, atmospheric particulate, micro-organisms, rust and pipescale.

Compressed Air Dryers

Water vapour is water in a gaseous form and will pass through water separators and coalescing filters just as easy as the compressed air. Water vapour in compressed air reduced using a dryer.

The water vapour reduction efficiency of a dryer (its performance) is expressed as a Pressure Dewpoint or PDP.

- Dewpoint refers to the temperature at which condensation will occur.
- Pressure Dewpoint or PDP refers to the dewpoint of air above atmospheric pressure.
- Dewpoint is expressed as a temperature (however this is not the temperature of the air).
- Compressed air with a PDP of -20˚C, would need the temperature to drop below -20˚C for any water vapour to condense into a liquid.
- A PDP of -40˚C is recommended for all food and beverage applications where air is in direct or in-direct contact with production equipment, ingredients, packaging or finished products because a PDP better than -26˚C will not only stop corrosion, it will also inhibit the growth of micro-organisms.

Adsorption Dryer

Adsorption dryers reduce water vapour in compressed air by passing air over a regenerative desiccant material which strips the moisture from the air. This method of drying is extremely efficient. A typical pressure dewpoint specified for an adsorption dryer is -40˚C as it not only prevents corrosion, more importantly it also inhibits the growth of micro-organisms.

There are many types of adsorption dryer available and whilst they all use the same principle to remove moisture from compressed air, there are a number of different methods used for the regeneration of the wet adsorbent material. For food and beverage applications, care should be taken when selecting an adsorption dryer as some regeneration methods used may have an impact on the contamination levels of the compressed air.

Refrigeration Dryer (not shown)

Refrigeration dryers work by cooling the compressed air further and condensing the water vapour into a liquid for removal by a water separator.

Refrigeration dryers are limited to positive pressure dewpoint to prevent freezing of the condensed liquid and are typically used for general purpose industrial applications with indoor piping.

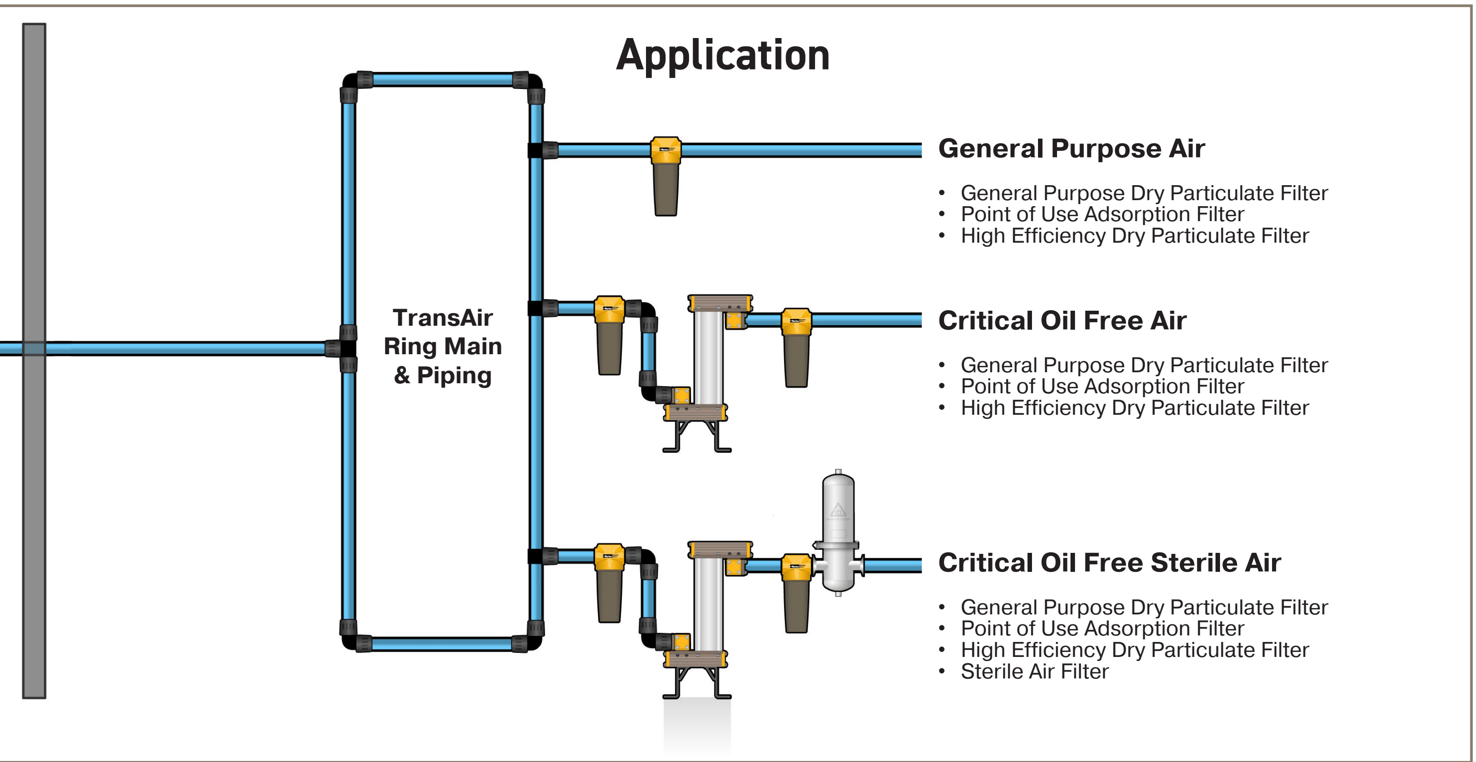
They should also not be used in any facility where piping is installed in ambient temperatures below the dryer dewpoint i.e. systems with external air receivers or piping.

They are also not recommended for direct contact or in-direct contact applications.

Adsorption Filters

To ensure 'technically oil free' compressed air, adsorption filters are employed. These utilise a large bed of activated carbon adsorbent for the effective reduction of oil vapour.

The combination of coalescing filters and adsorption filter will provide 'Technically Oil-Free' compressed air to the highest air quality classifications of ISO 8573-1, the international standard for compressed air quality.



Dry Particulate Filters

Dry particulate filters provide identical particulate reduction performance to the equivalent grade coalescing filter.

Relying on mechanical filtration techniques, high efficiency dry particulate filters can provide particle reduction down to 0.01 micron with a removal efficiency of 99.9999%.

When coupled with a -40°C Pressure Dewpoint, to inhibit and control the growth of micro-organisms, they can provide significant reduction of microbiological contaminants.

Sterile Filters

Absolute (100%) removal of solid particulates and micro-organisms is performed by a sieve retention or membrane filter.

They are often referred to as sterile air filters as they also provide sterilised compressed air.

Filter housings are manufactured from stainless steel to allow for in-situ steam sterilisation of both the filter housing and element.

It is important to note that the piping between the sterile filter and the application must also be cleaned and sterilised on a regular basis.

Important Notes:

- As adsorption or refrigeration dryers are only designed to reduce water vapour and not water in a liquid or aerosol form, they require the use of water separators and coalescing filters to work efficiently.
- Suppliers of oil-free compressors will often state that one of the coalescing filters is a particulate filter and the other is an oil removal filter, therefore, in oil-free compressor installations, there is no need for the oil removal filter. This is not correct.
- In reality, both filters remove exactly the same contaminants. The first filter is a general purpose filter which protects the second, high efficiency filter from heavy contamination.
- Omitting one of the filters in the belief that it is an oil removal filter will result in poor air quality due to contaminant bypass (carryover), high operational costs due to the pressure loss across the filter and more frequent filter element changes. Most importantly, omitting one of the filters will also invalidate performance guarantees.
- The dual coalescing filter installation ensures a continuous supply of high quality compressed air with the additional benefits of lower operational costs and minimal maintenance compared to a single high efficiency filter.
- Refrigeration dryers are not recommended for food and beverage applications where compressed air comes into direct contact (or in-direct contact) with ingredients, production equipment, finished products or packaging as the dewpoints provided are unable to inhibit microbiological growth.
- Refrigeration dryers are commonly available with quoted dewpoints of +3°C, +7°C or +10°C, however care must be taken when selecting this type of dryer as unlike adsorption dryers, the dewpoint quoted is not always provided constantly. Integrated dewpoint meters are typically just temperature gauges and do not indicate a true pressure dewpoint, which is often in the range of 8°C to 15°C.

Treatment of Solid Particulate

Compressed Air Usage	ISO 8573-1:2010 Classification Solid Particulate	Solid Particulate		
		Maximum no of Particles per m³		
		0.1µ ~ 0.5µ	0.5µ ~ 1.0µ	1.0µ ~ 5.0µ
Direct Contact	Class 1	⩽20,000	⩽400	⩽10
In-direct Contact	Class 1	⩽20,000	⩽400	⩽10
Non-Food Contact	Class 2	⩽400,000	⩽6,000	⩽100

The purity requirements for solid particulate are identical for both Direct Contact and In-direct Contact. The same level of purification equipment will be required for each.

This ISO 8573-1 Classification is achieved using a 0.01 micron dry particulate filter with an efficiency of 99.9999%. This grade of filtration will significantly reduce solid particulate, including micro-organisms (log reduction of CFU count).

The ISO 8573-1:2010 Class 1 particulate classification works in tandem with the specification for water (pressure dewpoint ⩽-40˚C).

If the specified dewpoint is not maintained or used, control of microbiological growth will be lost.

For applications requiring completely sterile compressed air, an absolute rated sterile air filter should be used at the point of use.

Treatment of Water Vapour

The ISO 8573-1 classifications 1 to 6 refer to water vapour, with no liquid water or water aerosols allowed. Water vapour is reduction in compressed air is performed using a dryer.

It has been found that a constant pressure dewpoint below -26˚C will inhibit (stop) the growth of micro-organisms. The lower the pressure dewpoint, the more effective the control.

A pressure dewpoint of ⩽-40˚C was selected for direct contact and in-direct contact applications as most global compressed air treatment manufactures supply dryers to match the ISO 8573-1 classifications.

Compressed Air Usage	ISO 8573-1:2010 Classification Water	Water
		Pressure Dewpoint
		˚C PDP
Direct Contact	Class 2	⩽ -40˚C PDP
In-direct Contact	Class 2	⩽ -40˚C PDP
Non-Food Contact	Class 4	⩽ +3˚C PDP

A dryer designed for ISO 8573-1:2010 Class 2 performance will deliver an outlet pressure dewpoint between -69˚C PDP & -40˚C PDP, thus always ensuring control over microbial growth

Important Note: ISO 8573-1 Class 3 was not selected as this classification, of dryer operates between -39˚C PDP & -20˚C PDP, and control over microbial growth cannot be guaranteed.

For non-food contact,a dryer delivering a dewpoint classification of class 4 can be used as long as this compressed air is not used in the manufacture of food & beverage products.

Focus on hygiene in dental compressors

Scientist warns of risk of bacterial growth in compressed air receivers

Having the familiar blast of air from your dentist during treatment, hardly anybody realises that it may be contaminated air that is blown directly into your mouth. Finn Djurhuus, head of section at DTI Industri, Danish Technological Institute in Aarhus, points at a source of contamination only few dentists have been aware of until now: their compressors.

Recently, we tested the compressors in four Danish dental clinics and the results we came up with were quite frightening. Problems caused by bacteria in the oxygen in water have been identified and dealt with for many years but only a few people have thought about the connection to compressed air.

More than 80% of all compressors in Denmark do not comply with current quality requirements under all working conditions

Condensate from the compressor should be lead out of the clinic. In the industry, we have diagnosed cases of illness among workers who have been exposed to exhaust air from compressed air components where the humidity in the receiver has been very high. We cannot eliminate the possibility that some cases of illness in dental clinics are caused by compressed air. Condensate that ought to be drained every day must be treated with the utmost care as tests show that it may contain a large concentration of bacteria. In cases where air leaks out of hoses and couplings it is a fact that a germfilled environment may be created. It is not unusual to find as many as 6 to 10 million germs per millilitre of compressor condensate. If we, theoretically, imagine that leaks in a hose system permit these particles to enter into the compressor again and again to be sent into the compressed air system, a concentration of 70 million germs might be reached.

No specific dental requirements

Only recently, attention has been drawn to hygiene in dental compressors. Dentists in Denmark are not obliged to observe the regulations in Aer Medicinalis. However, views in Pharmaca Europeae suggest that this will be standardized soon. The American standard NFPA 99 from 1990 has a chapter about dental clinics but it does not mention compressed air. As yet, no directives from the Danish National

Finn Djurhuus, chief adviser and head of section for DTI Industry in Aarhus, has worked with standardization, designing of systems, service and maintenance, and quality measurement of compressed air for more than 25 years. He is the author of several articles for national and international magazines on the subject "quality control of compressed air" and is member of a number of standardization committees.

Board of Health have been published. But in view of the general Danish spirit and environmental attitude, this is likely to be looked into very carefully by the Environmental Department. Bacteria blown directly into an open wound are of course hazardous to your health - ordinary bacteria might be acceptable but when dealing with enterobacteria, salmonella, listeria, coli etc. the effects are much more serious. The entertoxins, poisonous substances originating from the bacteria, pass filters above 2 nanometer but a filter with filtration degree of less than 2 nanometer does not exist. Therefore, we have to create conditions making the existence of these bacteria impossible including a relative humidity percentage of below 50.

The Monday test

Finn Djurhuus continues: We have focused on the food chain of bacteria nourished, cultivated and maintained in some dentists' air receivers. It is, therefore, important that steps should be taken to avoid accumulation of condensate in the compressed air tank of the compressor. This is to be inspected and emptied of possible condensate daily. The proof of an unclean receiver may be an unpleasant odour from the triple syringe the first time this is used after for instance a weekend. When clean blowing the syringe, the air receiver should be emptied of water and cleaned of impurities - the latter often ignored due to either lack of knowledge as to the necessity of this or the rather extensive job that this entails - cleaning a receiver internally is a complicated affair.

Air intake is extremely important

Many compressors are placed in a basement - perhaps even in the boiler room where the temperature nourishes bacterial growth. Several compressor intakes are placed close to the exhaust of other machinery or close to a busy street where the car exhaust is mixed with the air and compressed. We have also seen examples where the accumulation tank from the suction unit from several chairs has been placed very close to the air intake of the receiver. Small leaks in the suction system might then effect the air quality seriously.

Danger of corrosion

Increased germ flora and high air humidity will cause increased corrosion of the receiver resulting in rust. At 50% relative air humidity corrosion is hardly to be measured whereas at 60-100% relative air humidity we talk about a vertically progressive increase also resulting in contamination of the receiver, i.e. sludge at the bottom of the receiver. The corrosion rate in a receiver corresponds to 120 g per m2 per 100 hours.

Compressed air sample from oil lubricated compressor without drying of the air. After cultivation a large concentration of various germs was discovered.

Danish scientist, Finn Djurhus, was head of section at DTI Industri, Danish Technological Institute in Aarhus when he first used microbial testing to highlight the presence of micro-organisms in compressed air and compressed air condensate. Additionally he found that compressed air with a pressure dewpoint around -21˚C to -26˚C starts to inhibit microbial growth. Finn was also a technical advisor for the first edition of the BCAS food & beverage grade compressed air code of practice (now the BCAS Best Practice Guideline 102-1).


BIOHAZARD

Microbial Growth - It's All About Control

Using the recommended ISO 8573-1:2010 classifications for water and solid particulate, the number of micro-organisms (Colony Forming Units or CFU's) in the compressed air can be controlled, to the point where microbial levels are significantly lower than in the surrounding ambient air and suitable for food and beverage applications.

SEPARATE AND REMOVE ALL LIQUID WATER FROM COMPRESSED AIR

↓

FILTER AIR TO REDUCE WATER AEROSOLS ($<0.01\ mg/m^3$)

↓

REDUCE DEWPOINT TO A LEVEL THAT WILL INHIBIT THE GROWTH OF MICRO-ORGANISMS (≤-40°C PDP)

↓

FILTER AIR TO REDUCE MICRO-ORGANISMS (<0.01 MICRON @ 99.9999% Efficiency)

↓

FOR STERILE AIR FILTER AIR FURTHER TO CAPTURE ALL MICRO-ORGANISMS (<0.2 MICRON @ 100% Efficiency)

Microbial growth is controlled with a combination of very dry compressed air and the use of high efficiency filtration.

First all traces of liquid water and water aerosols must be eliminated from the compressed air.

Next, the dewpoint (dryness) of the compressed air must be reduced to a level known to inhibit (stop) the growth of micro-organisms.

Definition:

- Dewpoint refers to the temperature at which condensation will occur and is expressed as a temperature. Although expressed as a temperature, this figure is not the actual air temperature.

Dewpoint Hygrometer

- Atmospheric dewpoint refers to a dewpoint measurement taken at atmospheric pressure, Pressure dewpoint refers to a dewpoint measurement taken at system operating pressure.

Having the right compressed air dewpoint will inhibit (stop) the growth of micro-organisms, however dewpoint alone is not enough. If the micro-organisms present are merely inhibited from further growth, they can still survive in a state whereby once reintroduced to the right environment (moisture), they can again begin to grow.

By combining the correct dewpoint with point of use high efficiency dry particulate filters (particle reduction down to 0.01 micron @ 99.9999% efficiency), microbial concentrations (CFU count) can be reduced significantly and brought down to acceptable levels which will be below the concentrations found in the ambient air.

Should 100% sterile compressed air be required, additional absolute rated, air sterilisation filters providing 100% removal of micro-organisms and particles can also be employed.

Which Drying Technologies Deliver the Required Outlet Dewpoint to Inhibit Microbial Growth?

There are many different drying technologies available today, however, not all are able to deliver the outlet dewpoint required to inhibit the growth of micro-organisms.

The British Compressed Air Society Best Practice Guideline 104 - "The Filtration & Drying of Compressed Air" provides an excellent overview of the many drying technologies available.

- **Refrigeration Dryers** **(with 4 different cooling methods commonly used)**
- **Adsorption Dryers** **(with 6 different regeneration methods commonly used)**
- **Membrane Dryers** **(Dewpoint Suppression)**
- **HOC Adsorption Dryers** **(Dewpoint Suppression with 3 designs commonly used)**

Most global compressed air treatment manufacturers who produce these drying technologies, develop them to deliver an outlet dewpoint that corresponds to one of the six dewpoint classifications shown in ISO 8573-1:2010, the international standard for compressed air purity.

The dewpoint classifications can be seen in the table below, along with typical dryer technology used to achieve the required dewpoint.

ISO 8573-1:2010 Classification	°C PDP	Dewpoint Band	Dryer Technology
Class 1	⩽-70°C PDP	-80°C to -70°C	Adsorption / Hybrid*
Class 2	⩽-40°C PDP	-69°C to -40°C	Adsorption / Hybrid*
Class 3	⩽-20°C PDP	-39°C to -20°C	Adsorption / Hybrid*
Class 4	⩽+3°C PDP	-19°C to +3°C	Adsorption / Hybrid* / Refrigeration**
Class 5	⩽+7°C PDP	+4°C to +7°C	Refrigeration
Class 6	⩽+10°C PDP	+8°C to +10°C	Refrigeration

Important Notes:

* For classes 1 to 4, a hybrid dryer could be specified, however this technology incorporates an energy saving feature where by in summer, the adsorption dryer can be bypassed and shut off.

This will result in a pressure dewpoint that will not inhibit the growth of micro-organisms.

** Some but not all refrigeration dryers are classified as Class 4 for dewpoint (however the limiting factor is freezing of condensed water below 0°C, therefore adsorption or hybrid dryers are typically used achieve dewpoints from 2°C down to -19°C.)

Refrigeration dryers are typically classified as ISO 8573-1 Class 5 or Class 6 for water.

When control over the growth of micro-organisms is required, an adsorption dryer that can deliver a constant outlet dewpoint of ISO 8573-1 Class 2 (or Class 1) is recommended. Refrigeration dryers are typically classified as ISO 8573-1 Class 5 or Class 6 for water.

When control over the growth of micro-organisms is required, an adsorption dryer that can deliver a constant outlet dewpoint of ISO 8573-1 Class 2 (or Class 1) is recommended.

Choosing a Dryer Technology

When compressed air is used for direct contact and in-direct contact food & beverage applications, where water vapour reduction and control over the growth of micro-organisms are of extreme importance, a dryer capable of delivering a dewpoint capable of inhibiting the growth of micro-organisms (⩽-40°C PDP) and a constant outlet dewpoint is always required.

Drying Technology	Dryer Type	Able to Deliver Dewpoint to Inhibit Microbial Growth	Constant Outlet Dewpoint	Dewpoint Suppression
Refrigeration	Direct Expansion	✗	✓	✗
	Thermal Mass (cycling)	✗	✗	✓
	Variable Speed	✗	✓	✗
	Regenerative	✗	✓	✗
Adsorption	Heatless	✓	✓	✗
	Vacuum Assisted Heatless	✓	✓	✗
	Internally Heated Purge	✓	✓	✗
	Externally Heated Purge	✓	✓	✗
	Externally Heated Blower	✓*	✓*	✗*
	Externally Heated Vacuum	✓	✓	✗
Hybrid	Tandem Technology	✓**	✓	✗
Heat of Compression (HOC)	HOC Twin Tower Full Flow	✗	✗	✓
	HOC Twin Tower Split Flow	✗	✗	✓
	HOC Drum	✗	✗	✓
Separation	Membrane	✗	✗	✓

* Not all variants deliver constant outlet dewpoint, some are dewpoint suppression dryers.
** Not suitable if the adsorption dryer can be shut down during summer months.

From the table, it is clear to see that not all dryers available today are suitable for critical applications that require control over the quantity and growth of micro-organisms.

The dewpoint delivered by a refrigeration dryer dewpoint is not low enough to inhibit (stop) the growth of micro-organisms.

Dewpoint suppression dryers (further detail later in this document) such as membrane and HOC dryers are either not capable of delivering a dewpoint low enough to inhibit the growth of micro-organisms or their dewpoint varies too much and a minimum dewpoint cannot be guaranteed (i.e. it is not constantly below the minimum dewpoint required to control growth).

Adsorption dryers are therefore recommended for applications that require control over the quantity and growth of micro-organisms.

Refrigeration Dryers - No Control of Microbial Growth

It is not uncommon to find refrigeration dryers treating compressed air used for food and beverage applications, where the control of micro-organisms is important. The choice to install this type of dryer is typically down to replacing an existing dryer with an equivalent type, price, or both. Often, the relationship between dewpoint and microbial growth has been overlooked.

Unfortunately, if the compressed air is being used directly or in-directly during the manufacture of food or beverage products and the presence of high concentrations of micro-organisms is undesirable, then the use of a refrigeration dryer is not recommended.

Refrigeration dryers are typically promoted as delivering ISO 8573-1 classifications of Class 4, 5 or 6 for water vapour.

The most commonly used classification of the three is Class 4.

Important Note

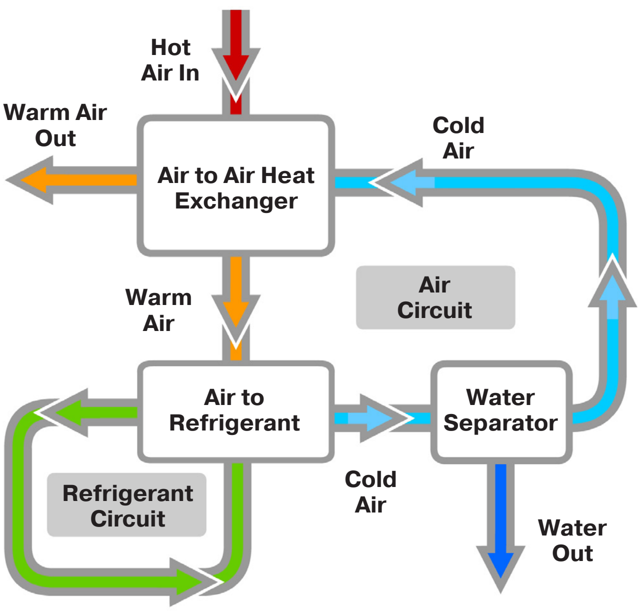
Care must be taken when selecting a dryer to achieve a Pressure Dewpoint of ISO 8573-1:2010 Class 4 for water vapour. Refrigeration dryers are typically unable to guarantee a constant outlet dewpoint of ⩽+3°C PDP.

ISO 8573-1:2010 Classification	°C PDP	Dewpoint Band
Class 4	⩽+3°C PDP	-19°C to +3°C
Class 5	⩽+7°C PDP	+4°C to +7°C
Class 6	⩽+10°C PDP	+8°C to +10°C

Operation

During operation, refrigeration dryers cool the compressed air down to a temperature of 3°C to induce condensation. They then employ a water separator for liquid reduction.

Example of a Refrigeration Dryer Circuit



Unfortunately, water separators are unable to remove 100% of the condensed liquid (with some separator designs, liquid reduction efficiency can drop off significantly below 100% of rated flow).

They are also unable to remove any aerosols generated in the dryer (common in cross flow & plate heat exchanger designs).

Therefore, the remaining liquid and aerosols are vaporised as they leave the dryer, raising the outlet dewpoint.

Refrigeration dryer performance can also be affected by:

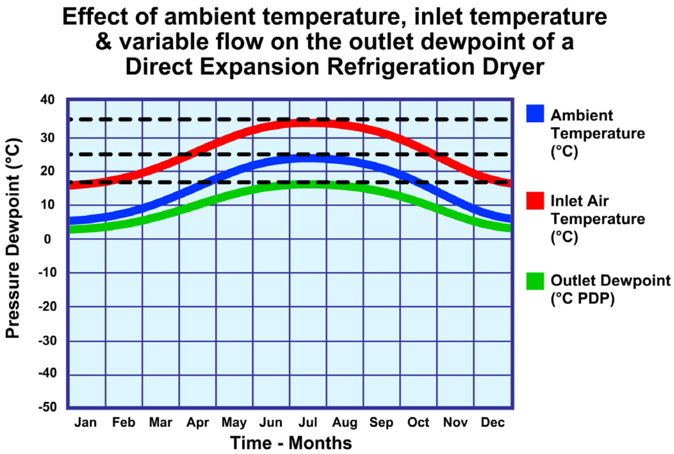
- High ambient temperatures & Relative Humidity
- High compressor room temperatures
- Poor ventilation
- Cleanliness of the condenser (air cooled, and water cooled)

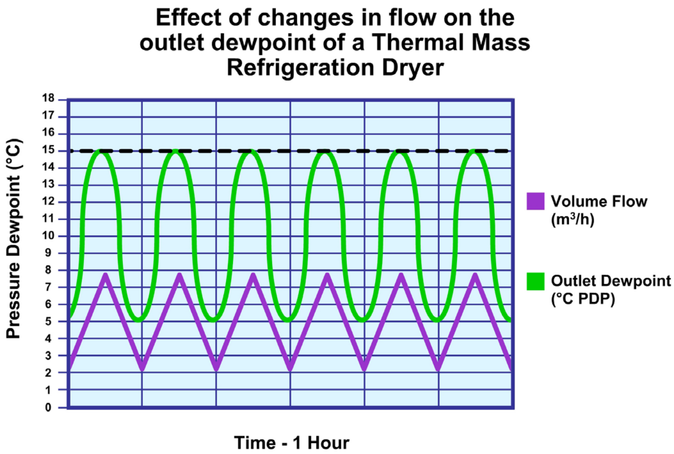
Refrigeration Dryer Type Also Affects the Delivered Outlet Dewpoint

Refrigeration dryers are also available as 3 differing dryer technologies:

- Direct Expansion
- Thermal Mass
- Variable Speed

The operation of each of these technologies can also have an impact on the delivered dewpoint. For example, thermal mass dryers cool a mass then turn the refrigeration compressor on and off to save energy. This has a direct impact on the outlet dewpoint they deliver.





Refrigeration Dryer Dewpoint Indication

On a refrigeration dryer, the dewpoint indicator or digital display does not actually show the outlet dewpoint in the same was as a desiccant dryer.

Dewpoint Measurement

Adsorption (desiccant) dryers use a hygrometer to measure outlet dewpoint. Refrigeration dryers however do not actually display a true dewpoint as they do not incorporate a hygrometer sensor.

Instead, refrigeration dryers are fitted with a temperature probe which typically indicates the temperature of the compressed air or sometimes the temperature of the refrigerant.

For a true reading of Pressure Dewpoint, a hygrometer must be used. This is in accordance with ISO 8573-3 the international standard for compressed air dryer testing.

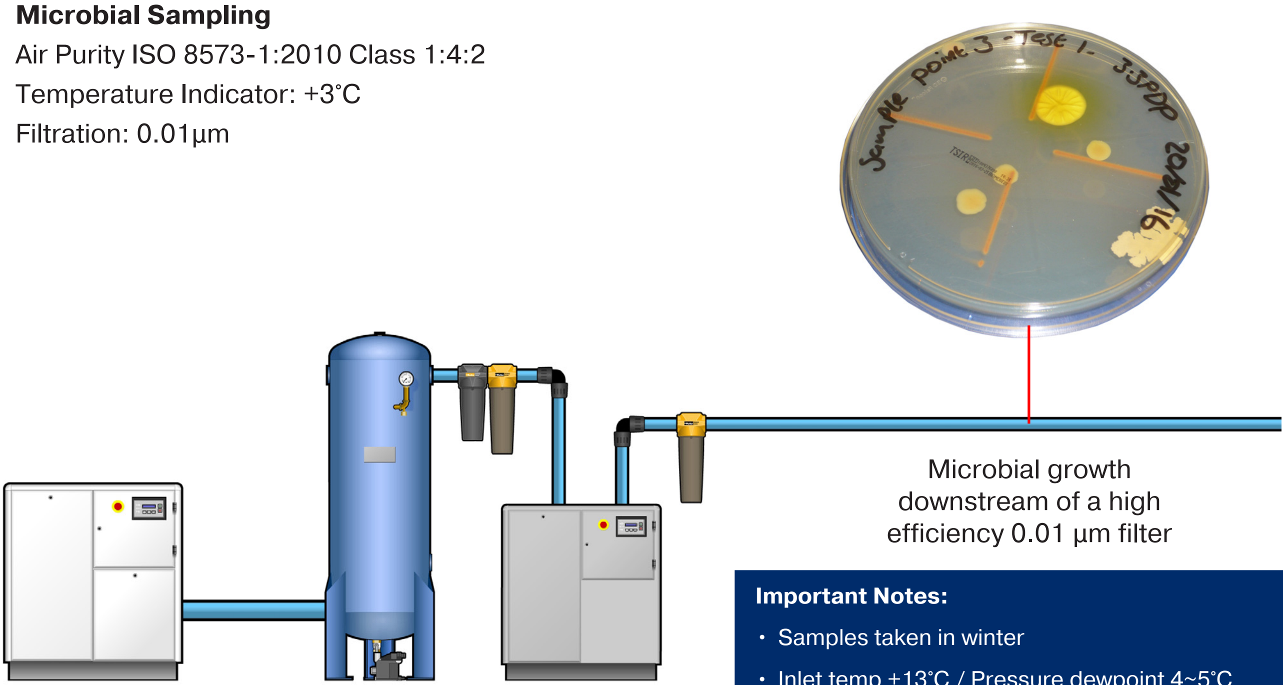
Important Notes:

- As previously mentioned, a pressure dewpoint lower than -26°C has been found to inhibit microbiological growth.
- As a refrigeration dryer dewpoint of does NOT inhibit the growth of micro-organisms, they can still grow freely in the compressed air system and left untreated, the high concentration of micro-organisms will not be effectively reduced by filtration.
- Microbial sampling of a compressed air system highlights why refrigeration dryers are not recommended.

Microbial Sampling Downstream of a Direct Expansion Refrigeration Dryer

The agar plate below is a sample taken downstream of a direct expansion refrigeration air dryer, selected to deliver an outlet dewpoint around +3˚C.

Microbial Sampling
Air Purity ISO 8573-1:2010 Class 1:4:2
Temperature Indicator: +3˚C
Filtration: 0.01µm



Microbial growth downstream of a high efficiency 0.01 µm filter

Important Notes:

- Samples taken in winter
- Inlet temp +13˚C / Pressure dewpoint 4~5˚C
- Downstream of high efficiency coalescing filter
- Refrigeration dryer operating at ⅓rd capacity.
- Summer temperatures and 100% duty will increase microbial count significantly

A typical refrigeration dryer installation comprises of a water separator for the treatment of liquids.

Next, a general purpose coalescing filter is used to protect the dryer from aerosols and particles.

The refrigeration dryer reduces the water vapour (however, not as low as an adsorption dryer).

At the outlet of the dryer a high efficiency coalescing filter is installed to capture liquids and aerosols carried over from the dryer.

Important Notes:

- As previously discussed, a pressure dewpoint lower than -26˚C is required to control microbiological growth
- A refrigeration dryer is unable to reach a dewpoint that will inhibit the growth of micro-organisms
- Refrigeration dryers are typically unable to deliver a constant outlet dewpoint.
- Micro-organisms can therefore grow freely in the downstream piping system
- The high concentration of micro-organisms will not be effectively reduced by point of use filtration (if installed)
- Refrigeration dryers should not be used to control the growth of micro-organisms

Adsorption Dryer Dewpoint

Constant Outlet Dewpoint or Dewpoint Suppression?

Whilst many manufacturers may claim that their adsorption (desiccant) air dryer will be able to deliver a dewpoint that will inhibit the growth of micro-organisms, adsorption dryers actually differ in the consistency of the outlet dewpoint they deliver. They will be designed to either deliver a constant outlet dewpoint (which has little variation) or provide dewpoint suppression (with large dewpoint variations).

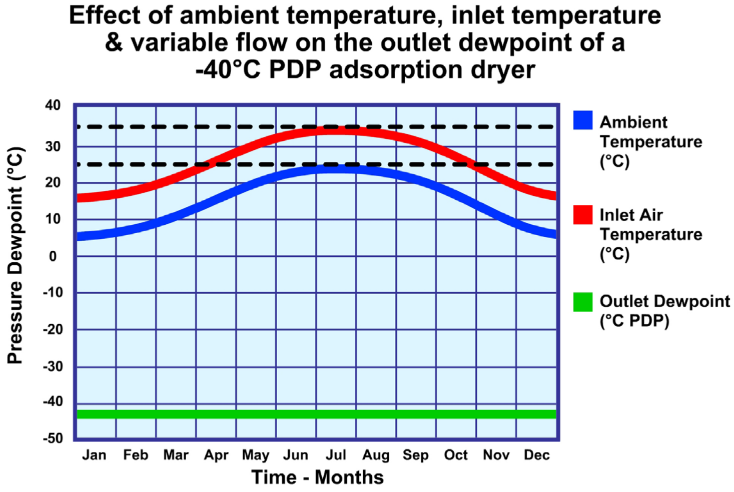
Constant Outlet Dewpoint

A constant outlet dewpoint dryer is first ‘sized’ to match worst case inlet and ambient conditions of the user’s site. This ensures the dryer has enough drying capacity (usually adsorbent material) to handle the maximum water vapour loading of the system, whilst being able to deliver a consistent outlet dewpoint.

A dryer delivering a constant outlet dewpoint will see small fluctuations, but always deliver the minimum pressure dewpoint it was sized for.

For example, if an adsorption dryer is sized to deliver a ⩽-40°C PDP, then -40°C PDP will be the worst dewpoint delivered. Typically, the outlet dewpoint will fluctuate between say -50°C & -40°C due to the way the adsorption dryer operates.

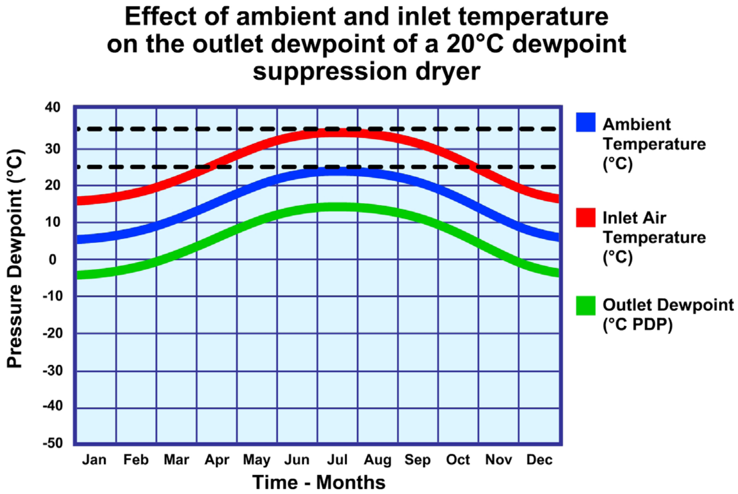
A constant outlet dewpoint is required for food and beverage applications to ensure control over microbial growth.



Dewpoint Suppression

Dryers designed to provide dewpoint suppression are not sized to match ambient conditions resulting in a smaller amount of adsorption material available for drying. The disadvantage is that the outlet dewpoint delivered by a suppression dryer can vary significantly.

Dewpoint suppression dryers are affected by changes in ambient air temperature and inlet temperature. If a dryer is designed to provide a dewpoint suppression of -20°C, then it will reduce the dewpoint to 20 degrees below the compressed air temperature (this figure of -20°C should not be confused as a constant outlet dewpoint as it often is).



Dewpoint Suppression - Heat of Compression (HOC) Adsorption Dryers

One variant of dewpoint suppression dryer, the Heat of Compression (HOC) dryer is an adsorption dryer designed to utilise the high compression temperatures generated by an oil free screw compressor (the heat is used to regenerate the adsorbent material).

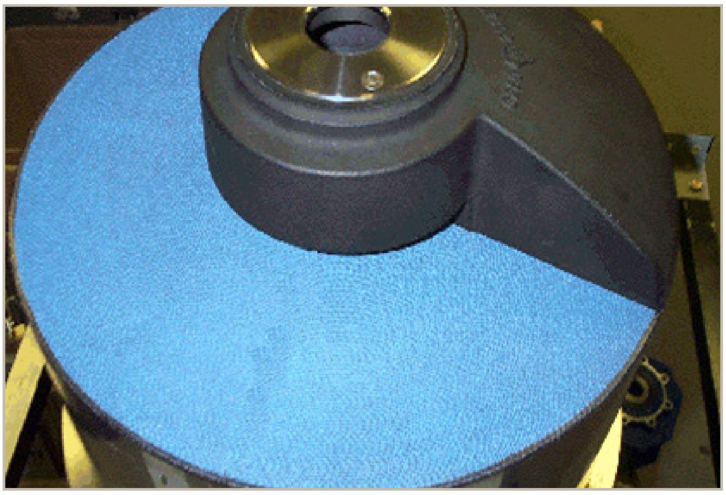
HOC dryers are not sized to match ambient conditions, therefore their adsorbent beds are significantly smaller than a constant dewpoint dryer (typically only 5% - 10% of a constant outlet dewpoint dryer).

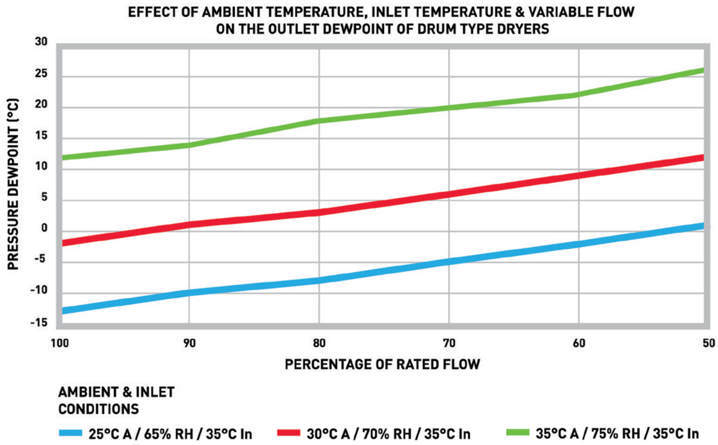
A small adsorption bed has a direct impact on outlet dewpoint (and adsorbent lifetime), especially as water vapour loading increases in summer.

HOC dryers are sold as low energy air dyers and have great appeal; however, they also require the compressor to be operating at maximum for optimal regeneration.

Compressor loading varies constantly (especially with variable speed compressors), therefore without full heat for regeneration, the adsorption material is not fully dried during regeneration. If the adsorbent material is not completely regenerated, the outlet dewpoint will naturally suffer.

Changes in ambient temperature also affect the ability to cool the adsorbent material. Hot adsorbent will not dry the compressed air efficiently, again varying the outlet dewpoint.





Important Notes:

- The combination of small adsorbent bed, constantly changing compressor duty and inefficient cooling means the outlet dewpoint from an HOC dryer is constantly changing, delivering only dewpoint suppression, not a constant outlet dewpoint.
- A dewpoint suppression dryer should not be used for food and beverage applications as the variable outlet dewpoint is unable to ensure control over microbial growth.

How to identify if an Adsorption Dryer Provides Constant Dewpoint or Dewpoint Suppression

Equipment manufacturers do not always state if their compressed air dryer delivers a constant outlet dewpoint or a suppression dewpoint. It is often assumed that if a manufacturer states a dewpoint, it is delivered all the time the dryer is operating, but unfortunately this is not always the case. One way to determine if the dryer delivers a constant dewpoint is to see if the manufacturer states a dewpoint classification in accordance with ISO 8573-1 for water.

ISO 8573-1:2010 is the International Standard relating to compressed air purity and includes 6 dewpoint classifications in bands from -70°C to +10°C.

To comply with an ISO 8573-1:2010 classification, a dryer must always deliver the outlet dewpoint within the band of one classification.

ISO 8573-1:2010 Classification	°C PDP	Dewpoint Band
Class 1	⩽-70°C PDP	-80°C to -70°C
Class 2	⩽-40°C PDP	-69°C to -40°C
Class 3	⩽-20°C PDP	-39°C to -20°C
Class 4	⩽+3°C PDP	-19°C to +3°C
Class 5	⩽+7°C PDP	+4°C to +7°C
Class 6	⩽+10°C PDP	+8°C to +10°C

A constant outlet dewpoint dryer will typically state an ISO 8573-1:2010 classification as the dewpoint can clearly fall within a defined band. A dewpoint suppression dryer such as an HOC adsorption dryer or membrane dryer does not typically state an ISO 8573-1:2010 classification as the outlet dewpoint varies too greatly and falls into 2 or more bands.

Additionally, installing a dryer fitted with a dewpoint hygrometer or using a separate dewpoint hygrometer downstream of the dryer will allow the user to easily verify that the dryer is delivering the agreed outlet dewpoint.

Recommended Dryer Technologies

Whilst constant dewpoint adsorption dryers are able to deliver a dewpoint that inhibits the growth of micro-organisms, some technologies may not be the preferred solution for an application. Two of the externally heated dryers listed in the table below use untreated ambient air for regeneration of the desiccant material.

It is therefore recommended that a user who is considering the use of these drying technologies to control the growth of micro-organisms performs a Hazard Analysis on the dryer technology to determine any potential risk to their manufacturing process before selecting this type of dryer technology.

Drying Technology	Dryer Type	Able to Deliver Dewpoint to Inhibit Microbial Growth	Constant Outlet Dewpoint	Uses Untreated Ambient Air for Regeneration
Adsorption	Heatless	✓	✓	×
	Vacuum Assisted Heatless	✓	✓	×
	Internally Heated Purge	✓	✓	×
	Externally Heated Purge	✓	✓	×
	Externally Heated Blower	✓*	✓*	✓
	Externally Heated Vacuum	✓	✓	✓
Hybrid	Tandem Technology	✓**	✓	×

* Not all variants deliver constant outlet dewpoint, some are dewpoint suppression dryers.
** Not suitable if the adsorption dryer can be shut down during summer months.

Microbial Sampling Downstream of a Constant Outlet Dewpoint Adsorption Dryer

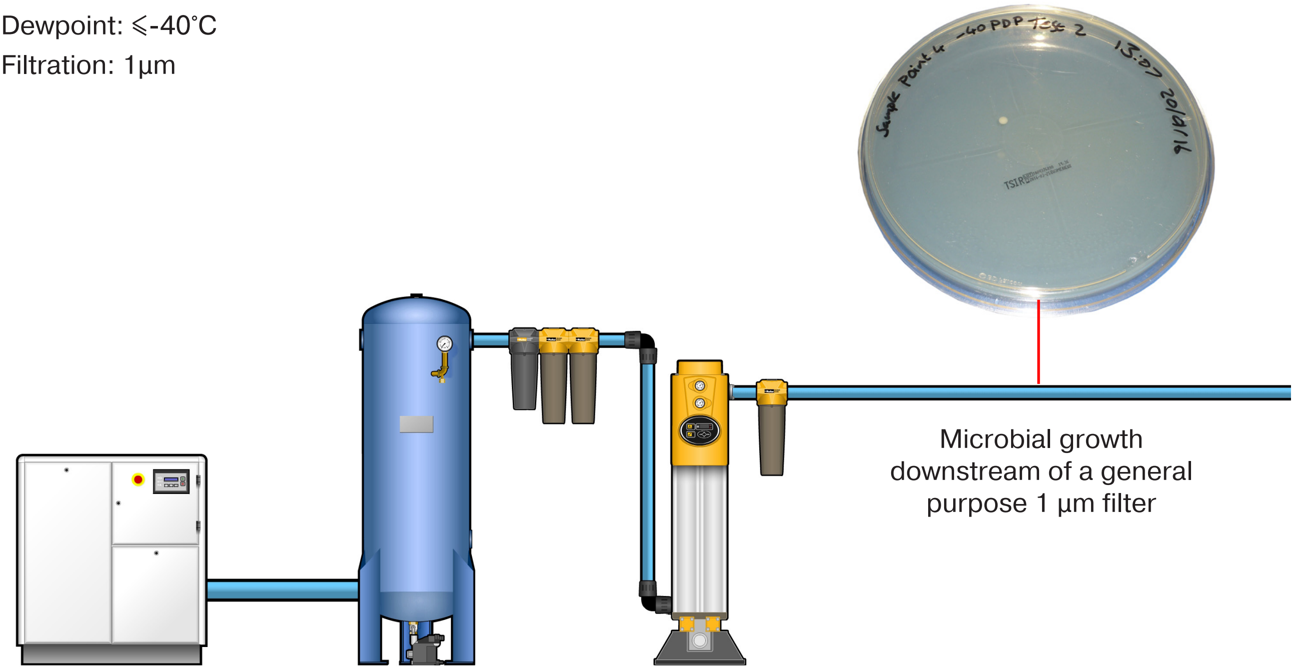
The agar plate below is a sample taken downstream of an adsorption (desiccant) air dryer, delivering a constant outlet dewpoint ⩽-40˚C.

Microbial Sampling

Air Purity ISO 8573-1:2010 Class 2:2:2

Dewpoint: ⩽-40˚C

Filtration: 1µm



A typical adsorption (desiccant) air dryer installation comprises of a water separator for the treatment of liquids. Next, a pair of coalescing filters are installed for the reduction of water aerosols (plus atmospheric particulate, rust, pipescale, micro-organisms and oil aerosols). Coalescing filters are installed in pairs, the first a general purpose grade which is designed to protect the finer, high efficiency filter. The adsorption (desiccant) air dryer reduces the water vapour, its performance is measured as outlet dewpoint. As the adsorbent desiccant material used in this type of air dryer can produce particulate, a general purpose dry particulate filter is typically installed in the compressor room.

Important Notes:

- The coalescing filters before the dryer will start to reduce the quantity of micro-organisms, however as the air is still saturated with water vapour at this point, growth downstream of the filter will still occur.
- The 1 micron filter on the outlet of the dryer is typical for a compressor room installation, however this filtration grade is not fine enough to trap particles the size of micro-organisms.
- High efficiency grade (0.01 micron @ 99.9999% efficiency) filters should be installed at each point of use.
- This is the recommended setup to control the growth and quantity of micro-organisms in a compressed air system and deliver food & beverage grade compressed air.

Oil Free Compressor or Oil Free Air?

For food and beverage applications, it is common for manufacturers and auditors to insist on an oil free compressor to be installed. This is often in the mistaken belief that the oil free compressor will provide oil free or food and beverage grade compressed air.

Treatment of Total Oil

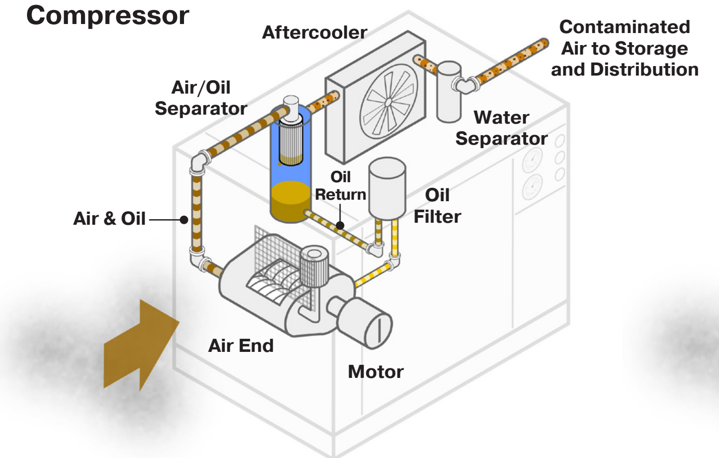
Compressed Air Usage	ISO 8573-1:2010 Classification TOTAL OIL	Oil
		Total Oil (Aerosol, liquid & vapour)
		mg/m³
Direct Contact	Class 1	⩽0.01 mg/m³
In-direct Contact	Class 1	⩽0.01 mg/m³
Non-Food Contact	Class 2	⩽0.1 mg/m³

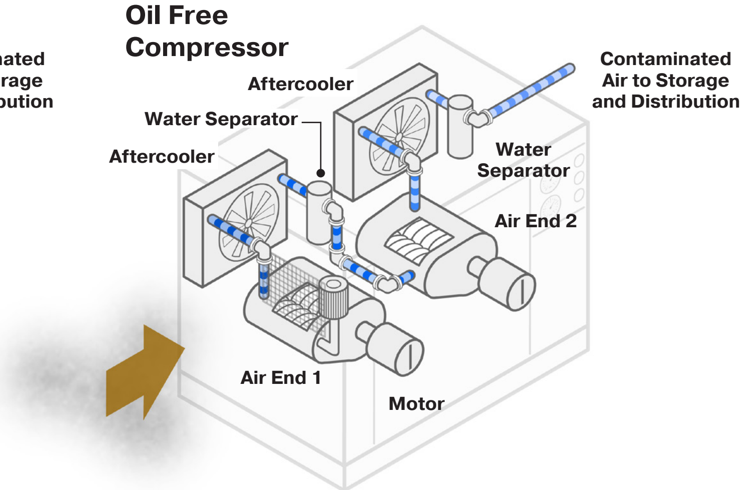
Total oil refers to liquid oil, oil aerosols and oil vapour.

The purity requirements selected for food grade compressed air is Class 1 for total oil.

The BCAS BPG 102-1 does not specify the type of air compressor that should be used to deliver this purity classification, instead section 10.5 of the document specifies the use of 'Technically Oil Free' compressed air for direct and in-direct contact applications and includes the statement:

"Oil free air can be delivered by both an 'oil free' or oil-injected/lubricated compressor, with the correct purification equipment installed downstream."





Compressor Lubricants

The BCAS Food & Beverage Grade Compressed Air Best Practice Guideline 102-1 contains information relating to lubricants in Annex B, section 3.2.

Oil Lubricated Compressors
'Where lubricated or oil injected compressors are in use and non-food and beverage grade oil is used and the HACCP process identifies a risk, then the oil shall be replaced with food and beverage grade oil in line with the procedures identified in the EHEDG (European Hygienic Engineering & Design Group) Document 23.'

Oil Free Compressors (Totally Oil Less)
'Where oil free compressors are used no lubricant is involved in the compression process therefore the procedures identified in the EHEDG Document 23 will not be required'.

Oil Free Compressors (Containing Lubricant)
'Compressors that employ lubricants in those parts not involved in the actual compression of the air will be subject to the HACCP process to determine the risks if any to the food and beverage production process.'

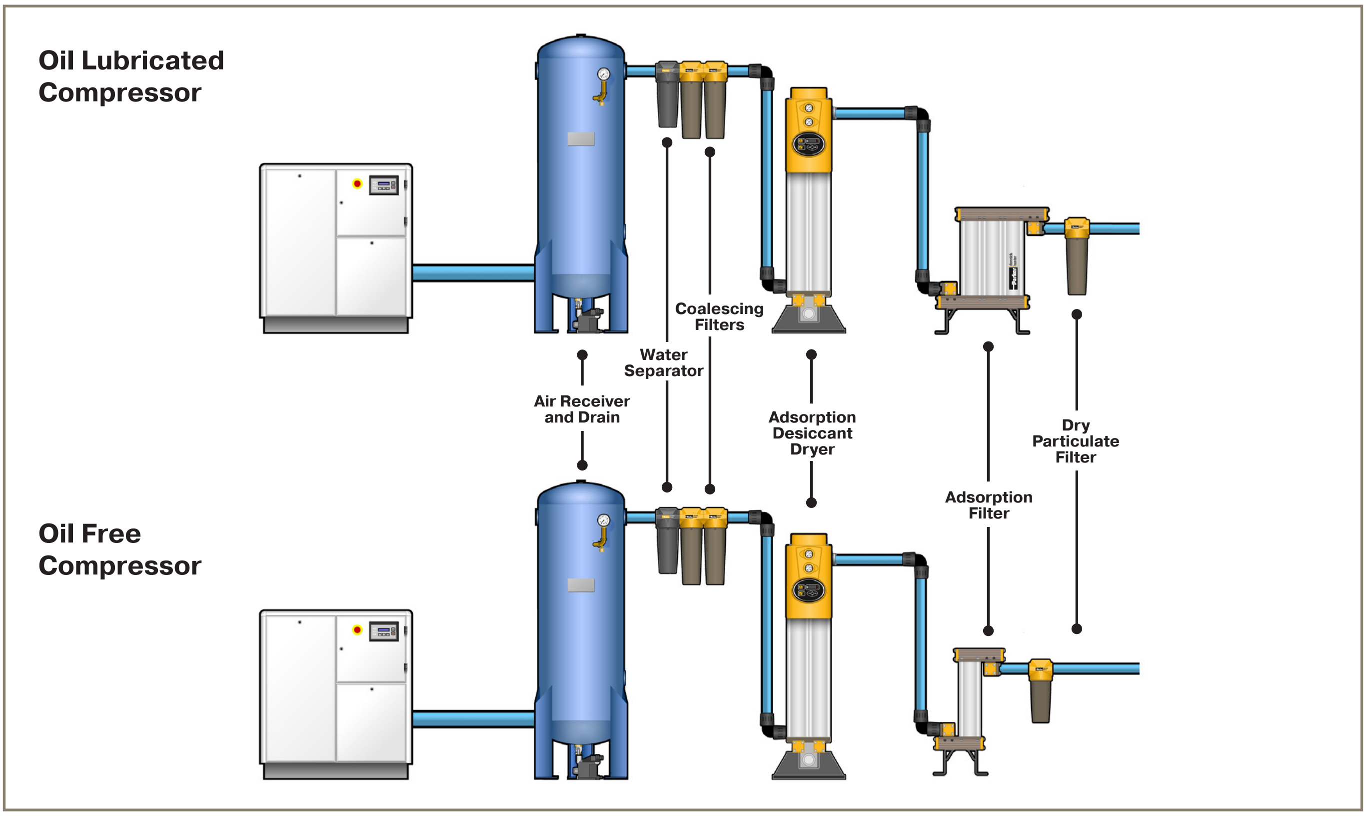
Therefore if the oil free compressor uses oil for lubrication of bearings, gearboxes, etc. then it is still subject to a HACCP risk analysis. If the risk analysis shows a potential for contamination by vapours, aerosols or liquid oil, then the procedures identified in the EHEDG Document 23 will still apply (i.e. use of food and beverage grade lubricant).

‘Technically Oil Free’ Compressed Air

To ensure food and beverage safety, the compressed air used for direct contact and in-direct contact applications should be ‘Technically Oil Free’ air. Most importantly, this quality of compressed air can be achieved from both oil free and oil lubricated compressors. Unfortunately, oil lubricated compressors are often overlooked.

Important Notes:

- Oil free compressors alone do not provide oil free compressed air / contaminant free compressed air / Food & Beverage Grade Compressed Air.
- In order to have ‘Technically Oil Free Air’ for direct contact and in-direct contact applications, purification equipment is required.



Regardless of whether oil lubricated or oil free compressors are installed, the purification technologies required to deliver ‘Technically Oil Free’ air is identical.

Oil will be found in a compressed air system in 3 different phases (liquid, aerosol & gaseous)

Liquid Separators (also know as water separators or moisture separators) are used for the treatment of liquid oil.

Coalescing filters are used for the treatment of oil aerosols (mists/droplets) and solid particles.

Adsorption Filters, also known as oil vapour reduction filters or carbon towers used for the treatment of oil vapour (oil in a gaseous phase).

The size of the adsorption filters used for oil vapour reduction may become smaller with an oil free compressor installation as they only need to treat ambient oil vapour & vapour in piping systems, not the additional vapour introduced by a lubricated compressor.

However, the additional cost of an oil free compressor is much higher than the additional cost for a larger oil vapour reduction filter.

Combining the Purification Technologies

As previously mentioned, to achieve food grade compressed air requires multiple purification technologies. These must be installed in a specific order.

Food & Beverage Grade Compressed Air Direct Contact: ISO 8573-1:2010 Class 1:2:1 In-direct Contact: ISO 8573-1:2010 Class 1:2:1					
Order	**Purification Technology**		**Contaminant(s) Treated**	**Purification Levels**	**Protection Provided**
1	**Liquid Separator**		Reduction of Liquid Water Liquid Oil	No Free Liquid Water or Oil	Protects coalescing filters from liquid contamination
2	**General Purpose Coalescing Filter**	 	Reduction of Water Aerosols Oil Aerosols Atmospheric Particulate Compressor Wear Particles Rust & Pipescale	Particle Reduction down to 0.01 micron	Protects adsorption dryer from liquids, aerosols and particulate
3	**High Efficiency Coalescing Filter**			Maximum Remaining Aerosol Content Down to 0.01 mg/m^3	
4	**Adsorption Dryer**		Reduction of Water Vapour (plus control over growth of Micro-organisms)	Pressure Dewpoint $\leqslant$-40°C	Prevents growth of micro-organisms and protects adsorption filter
5	**Adsorption Filter**		Reduction of Oil Vapour	Total Oil Reduction $\leqslant$0.003 mg/m^3 (when used in conjunction with coalescing filters)	Provides technically oil-free compressed air
6	**General Purpose Dry Particulate Filter**		Reduction of Adsorbent Material Rust & Pipescale	Particulate Reduction Down to 1 micron	Protects high efficiency dry particulate filter from premature blockage
7	**High Efficiency Dry Particulate Filter**		Reduction of Adsorbent Material Micro-organisms	Particulate & Micro-organism Recuction Down to 0.01 micron (@ 99.9999% efficiency)	Protects the Consumer

Important Note:

Whilst the purification equipment above must be installed in a specific order to provide food & beverage grade compressed air, the purification equipment can be installed both in the compressor room and at point of use.

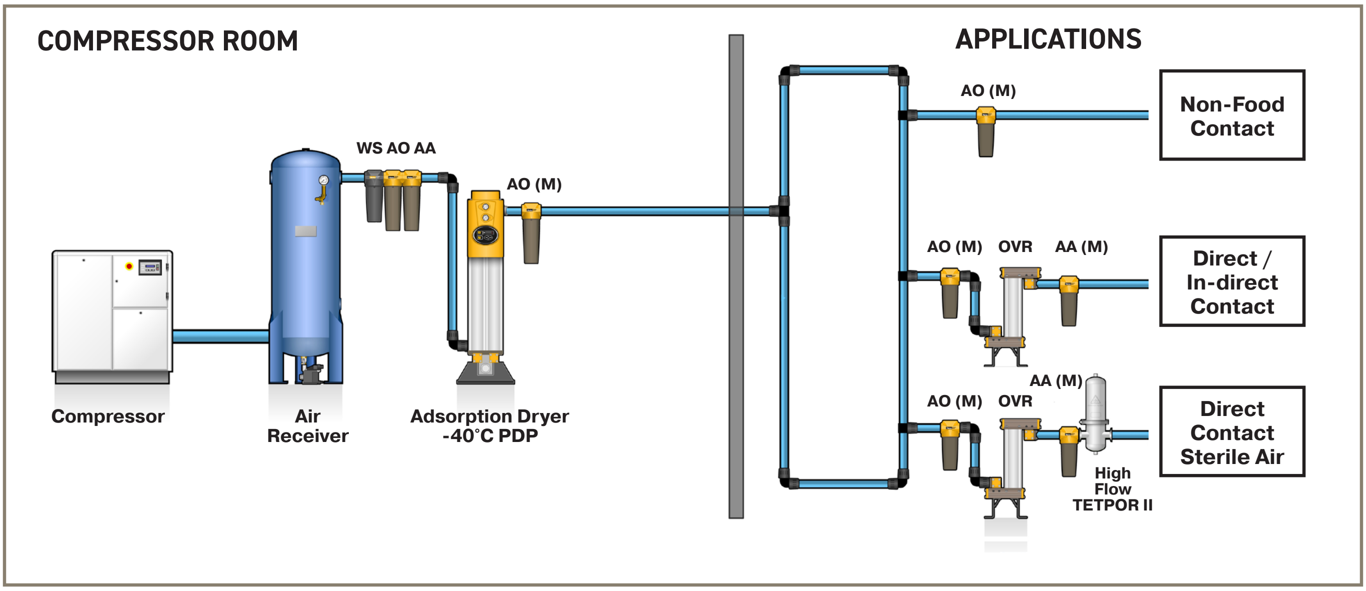
Cost Effective System Design

To provide food and beverage grade compressed air that will ensure consumer safety and protect against 'quality incidents', a careful approach to system design, commissioning, installation and operation must be employed.

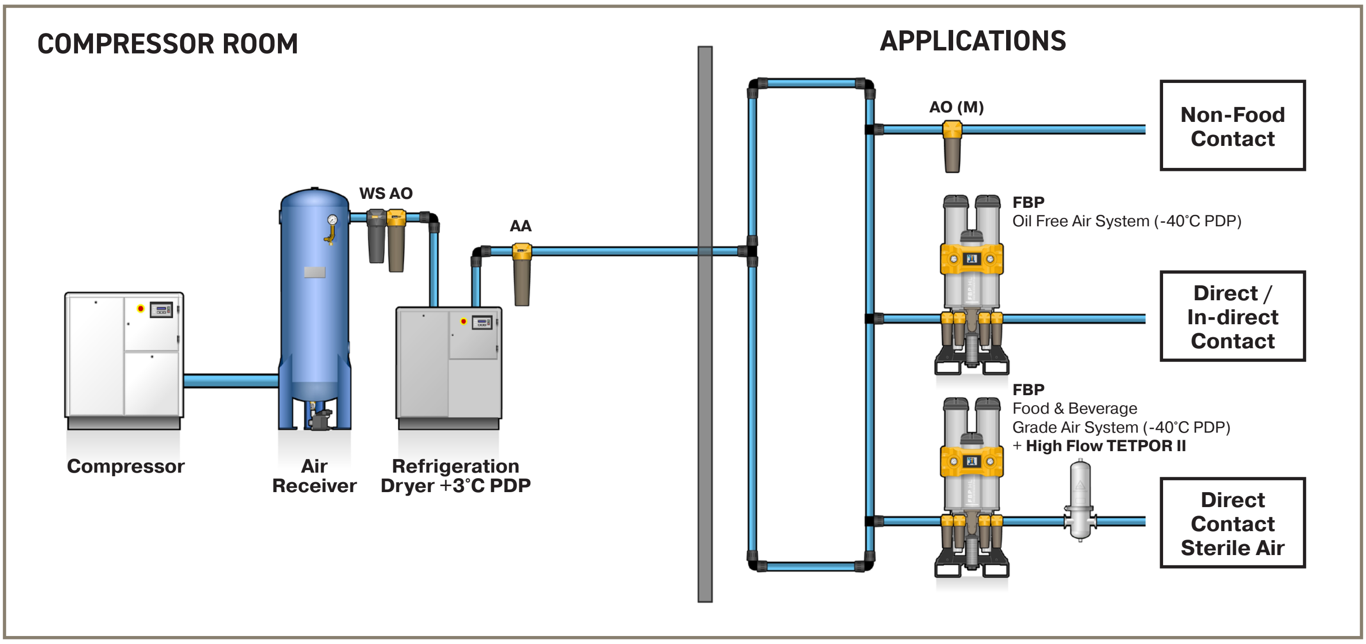
Treatment at one point alone is not enough and it is highly recommended to treat compressed air prior to entry into the distribution system (usually in the compressor room or at point of generation) to a specification that will provide contaminant free air for general purpose applications and protect air receivers and distribution piping from corrosion and damage.

Point of use purification should also be employed, with specific attention being focussed on the quality of air required by each application. This approach to system design ensures that air is not 'over treated' and provides the most cost effective solution to food and beverage grade compressed air.

System Example 1



System Example 2



Parker Food and Beverage Compressed Air Treatment Products

Parker GSFE filtration and dryer ranges have been designed to provide compressed air quality that meets or exceeds the classification levels shown in BCAS Best Practice Guideline 102-1 for Food and Beverage Grade Compressed Air.

Recommended Parker GSFE purification equipment for Food and Beverage Grade Compressed Air (In accordance with BCAS Best Practice Guideline 102-1)

BCAS BPG 102-1 Compressed Air Usage Designation	Solid Particulate	Water	Total Oil (Liquid + Aerosol + Vapour)
Direct Contact	Parker OIL-X Coalescing Filters Grades AO + AA	Parker FBP / MX / MXLE Adsorption Dryer ≤-40˚C PDP	Parker OIL-X Coalescing & Adsorption Filters Grades AO + AA + OVR or Parker FBP Food Grade Air System
In-direct Contact	Parker OIL-X Dry Particulate Filters Grades AO (M) + AA (M)		
Non-Food Contact	Parker OIL-X Coalescing Filters Grades AO + AA	Parker SPE / PSE Refrigeration Dryer	Parker OIL-X Coalescing Filters Grades AO + AA

Independently Verified Performance

Filtration performance of the Parker OIL-X range has been independently verified by LRQA

Parker OIL-X Liquid Separators - Grade WS
Liquid separator performance has been tested in accordance with ISO 12500-4 and ISO 8573-9.

Parker OIL-X Coalescing Filters - Grades AO & AA
Oil aerosol and particulate reduction performance has been tested in accordance with ISO 12500-1, ISO 8573-2 and ISO 8573-4.

Parker OIL-X Dry Particulate Filters - Grades AO (M) & AA (M)
Dry particulate reduction performance has been tested in accordance with ISO 8573-4.

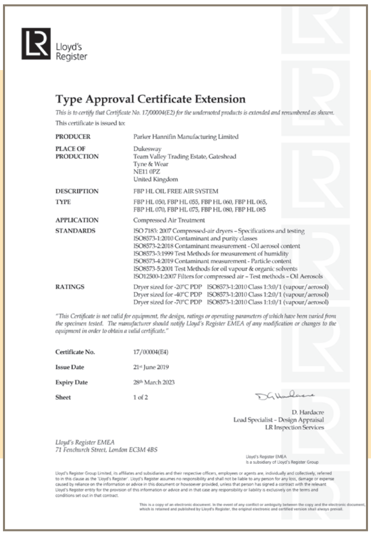
Parker OIL-X Adsorption Filters - Grade OVR
Oil vapour reduction performance has been tested in accordance with ISO 8573-5.

Parker OIL-X WS
Liquid Separators

Parker OIL-X AO & AA
Coalescing & Dry Particulate Filters

Parker OIL-X OVR
Adsorption Filters

Drying performance of the Parker heatless modular dryer ranges has been independently verified by Lloyds Register (now known as LRQA)


Lloyd's Register

Type Approval Certificate Extension

This is to certify that Certificate No. 17/00004(E2) for the undernoted products is extended and renumbered as shown.

This certificate is issued to:

PRODUCER	Parker Hannifin Manufacturing Limited
PLACE OF PRODUCTION	Dukesway Team Valley Trading Estate, Gateshead Tyne & Wear NE11 0PZ United Kingdom
DESCRIPTION	FBP HL OIL FREE AIR SYSTEM
TYPE	FBP HL 050, FBP HL 055, FBP HL 060, FBP HL 065, FBP HL 070, FBP HL 075, FBP HL 080, FBP HL 085
APPLICATION	Compressed Air Treatment
STANDARDS	ISO 7183: 2007 Compressed-air dryers – Specifications and testing ISO8573-1:2010 Contaminant and purity classes ISO8573-2:2018 Contaminant measurement - Oil aerosol content ISO8573-3:1999 Test Methods for measurement of humidity ISO8573-4:2019 Contaminant measurement - Particle content ISO8573-5:2001 Test Methods for oil vapour & organic solvents ISO12500-1:2007 Filters for compressed air – Test methods – Oil Aerosols
RATINGS	Dryer sized for -20°C PDP ISO8573-1:2010 Class 1:3:0/1 (vapour/aerosol) Dryer sized for -40°C PDP ISO8573-1:2010 Class 1:2:0/1 (vapour/aerosol) Dryer sized for -70°C PDP ISO8573-1:2010 Class 1:1:0/1 (vapour/aerosol)

"This Certificate is not valid for equipment, the design, ratings or operating parameters of which have been varied from the specimen tested. The manufacturer should notify Lloyd's Register EMEA of any modification or changes to the equipment in order to obtain a valid certificate."

Certificate No.	17/00004(E4)
Issue Date	21st June 2019
Expiry Date	28th March 2023
Sheet	1 of 2

D. Hardacre
Lead Specialist – Design Appraisal
LR Inspection Services

Lloyd's Register EMEA
71 Fenchurch Street, London EC3M 4BS

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Modular Heatless Adsorption Dryers

Parker FBP, MX & MXLE heatless adsorption dryer performance has been tested in accordance with ISO 7183, the international standard for testing of compressed air dryers.

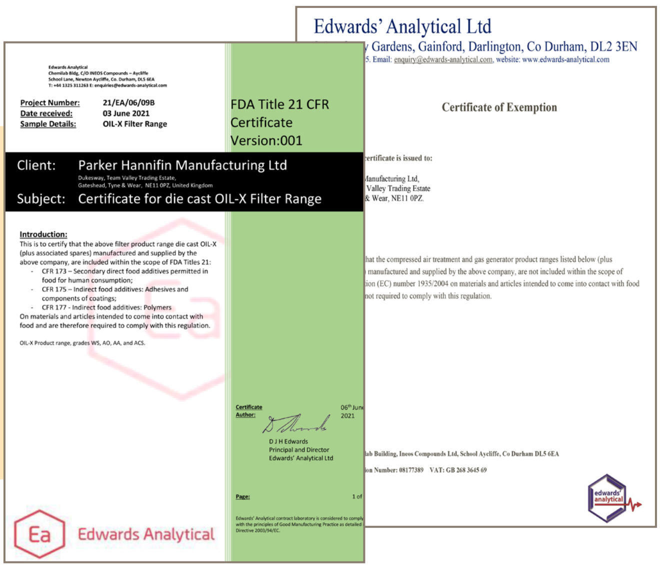
Parker FBP
Food Grade Air System

Parker MXS
Heatless Adsorption Dryer

Parker MXLE
Low Energy Heatless Adsorption Dryer

Food Safety - Materials of Construction

In addition to the independently verified performance validation of the Parker filtration and dryer ranges mentioned, the materials used in the construction of those ranges are suitable for use in food and beverage manufacturing and have been independently certified as FDA Title 21 CFR Compliant and EC1935-2004 exempt.


Edwards Analytical
Chemilab Bldg, C/O INEOS Compounds – Aycliffe
School Lane, Newton Aycliffe, Co. Durham, DL5 6EA
T: +44 1325 311263 E: enquiries@edwards-analytical.com

Project Number: 21/EA/06/09B
Date received: 03 June 2021
Sample Details: OIL-X Filter Range

FDA Title 21 CFR
Certificate
Version:001

Client: Parker Hannifin Manufacturing Ltd
Dukesway, Team Valley Trading Estate,
Gateshead, Tyne & Wear, NE11 0PZ, United Kingdom
Subject: Certificate for die cast OIL-X Filter Range

Introduction:
This is to certify that the above filter product range die cast OIL-X (plus associated spares) manufactured and supplied by the above company, are included within the scope of FDA Titles 21:
- CFR 173 – Secondary direct food additives permitted in food for human consumption;
- CFR 175 – Indirect food additives: Adhesives and components of coatings;
- CFR 177 - Indirect food additives: Polymers

On materials and articles intended to come into contact with food and are therefore required to comply with this regulation.

OIL-X Product range, grades WS, AO, AA, and ACS.

Certificate Author: D J H Edwards, Principal and Director, Edwards' Analytical Ltd — 06th June 2021

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Edwards' Analytical contract laboratory is considered to comply with the principles of Good Manufacturing Practice as detailed Directive 2003/94/EC.

Edwards Analytical

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Certificate of Exemption

ertificate is issued to:

lanufacturing Ltd,
Valley Trading Estate
& Wear, NE11 0PZ.

hat the compressed air treatment and gas generator product ranges listed below (plus
manufactured and supplied by the above company, are not included within the scope of
ion (EC) number 1935/2004 on materials and articles intended to come into contact with food
not required to comply with this regulation.

lab Building, Ineos Compounds Ltd, School Aycliffe, Co Durham DL5 6EA
ion Number: 08177389 VAT: GB 268 3645 69

edwards' analytical

Summary

- Food & Beverage manufacturers have a duty of care to protect the consumer
- Food & Beverage manufacturers have a legal responsibility to comply with food hygiene legislation
- Food hygiene legislation recommends the implementation of a FSMS based upon the principles of HACCP
- The FSMS can be developed in house or can be a 3rd party, auditable scheme
- Some FSMS schemes mention the compressed air system, others do not
- References to compressed air are vague and offer no practical advice
- The FSMS scheme references to compressed air do not highlight the potential hazards to look for when conducting the Hazard Analysis
- The FSMS scheme references to compressed air do not contain a usable compressed air specification to put in place once the hazards are identified
- Compressed air contains 10 biological, chemical and physical hazards (contaminants) originating from 4 different sources
- Compressed air contamination is not always visible to the human eye
- During the Hazard Analysis, it must be accepted by the Hazard Analysis team that compressed air contamination is present
- Compressed air contaminants must be treated and brought down to acceptable levels to ensure consumer safety
- The British Compressed Air Society have produced a usable compressed air purity standard for Food & Beverage Grade Compressed air (BPG 102-1)
- Using compressed air compliant with the BPG102-1 food & beverage grade compressed air standard will ensure consumer safety
- Compliance with the standard will require multiple purification technologies as the 10 contaminants are in 3 different phases
- A pressure dewpoint of ⩽-40°C is specified to control the growth of micro-organisms
- A refrigeration dryer will not prevent the continious growth of micro-organisms in the compressed air system
- A high efficiency 0.01 micron dry particulate filter at the point of use is used to capture up to 99.9999% of particulate, including micro-organisms (working in conjunction with the ⩽-40°C pressure dewpoint which first inhibits growth)
- Not all adsorption dryers are suitable to provide the constant outlet dewpoint required for food and beverage grade compressed air
- BCAS BPG102-1 specifices ‘Technically Oil-Free’ compressed air
- ‘Technically Oil-Free’ is obtainable from both an oil lubricated compressors and oil-free compressors
- The coalescing and adsorption filters required for ‘Technically Oil-Free’ compressed air this identical for both oil lubricated compressors and oil-free compressors

References & Bibliography

- British Compressed Air Society Best Practice Guideline 102-1 (Food & Beverage Grade Compressed Air)
- British Compressed Air Society Best Practice Guideline 102-4 (Filtration & Drying of Compressed Air)
- ISO 22000:2005 - Food safety management systems - Requirements for any organization in the food chain
- ISO/TS 22002:2009 - Prerequisite programmes on food safety - Part 1: Food manufacturing
- ISO 22004:2014 - Food safety management systems - Guidance on the application of ISO 22000
- ISO 8573-1:2010 - Compressed air - Part 1: Contaminants and purity classes
- ISO 8573-2:2018 - Compressed air - Contaminant measurement - Part 2: Oil aerosol content
- ISO 8573-3:1999 - Test methods for the measurement of humidity
- ISO 8573-4:2019 - Compressed air - Contaminant measurement Part 4: Particle content
- ISO 8573-5:2001 - Test method for oil vapour and organic solvent content
- ISO 8573-7:2003 - Test method for viable microbiological contaminant content
- ISO 8573-9:2004 - Test Methods for liquid water content
- ISO 12500-1:2007 - Filters for compressed air - Test methods - Part 1: Oil aerosols
- ISO 12500-4:2009 - Filters for compressed air - Methods of test - Part 4: Water
- ISO 7183:2007 - Compressed air dryers - Specifications and Testing
- DTI Industri, Danish Technological Institute technical paper by Finn Djurhus, highlighting the presence of micro-organisms in compressed air and compressed air condensate.
- Primus GFS
- Global Seafood Alliance
- GlobalGAP
- FSSC 22000
- Global Red Meat Standard
- CanadaGAP
- SQF Food Safety Code: Food Manufacturing, Edition 9
- BRCGS Global Standard Issue 8
- IFS International Featured Standards 7
- Japan Food Safety Management Association JFS-B Standard
- FDA Code of Federal Regulations Title 21CFR
- FDA Guidance RTE Foods
- 3-A Sanitary Standards 604-05

Recommended Reading

Parker White Paper by Mark White: Compressed Air Contamination

- Parker White Paper by Mark White: Oil Vapour in Ambient Air
- Parker White Paper by Mark White: How to Get Clean Dry Oil Free Compressed Air from Any Compressor
- Parker White Paper by Mark White: Controlling Micro-organism Growth in Compressed Air
- Parker White Paper by Mark White: Introduction to ISO ISO8573-1
- Parker White Paper by Mark White: Compressed Air Quality Testing

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