



REGULATORY AND BEST PRACTICES OVERVIEW

Process Filtration



Compliance

COMPRESSED AIR

GOOD MANUFACTURING PRACTICES - COMPRESSED AIR IN FOOD PLANTS	FILTRATION REQUIREMENT	CITATION
Food and Drug Administration (FDA) Code of Federal Regulations (CFR) Title 21, Part 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 indirect food additives.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=110.40
FDA Food Safety Modernization Act (FSMA)	Companies under FDA jurisdiction must employ risk-based (Hazard Analysis Critical Control Point [HACCP]-like) food safety management schemes. Compressed air points of use are critical control points when the air contacts food or packaging surfaces and therefore needs to be filtered.	https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm
FDA Guidance Ready-to-Eat (RTE) Foods - Section 5.A.2	We recommend that the final filter have an efficiency of at least 90-95% at 1 micron as rated in American Society of Heating Refrigerating and Air-Conditioning Engineers (ASHRAE) standard 52.2-2012.6. Depending on your product, your process and the design and construction of your plant, it may be appropriate to use High Efficiency Particulate Air (HEPA) filters that have an efficiency of 99.97-99.99% at 0.3 micron for removing bacteria, yeasts and molds.	https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm535981.pdf
FDA Guidance and Regulation - Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables, Section 3	Air inside a processing plant can be a vehicle for contamination of food by mold, yeast, dust, or pathogens if not properly controlled. Filtering compressed air when such air contacts fresh produce using a 0.3 micron filter (with an efficiency of approximately 75%).	https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm064458.htm
FDA Pasteurized Milk Ordinance (PMO) 2015 Revision, Appendix H, Section II	Filters shall be constructed so as to assure effective passage of air through the filter media only. The coalescing filter and associated traps shall be located in the air pipeline downstream from the compressing equipment, and from the air tank.	http://www.idfa.org/docs/default-source/d-news/2015-pmo-final.pdf
Food Safety System Certification (FSSC) ISO 22000:2005 - Food safety management systems - Section 3.8, 3.9 ISO/TS 22002-1:2009 - Prerequisite programs on food safety - Section 6.5	ISO22000:2005 states that prerequisite programs should be in place to address possible contamination sources including those affecting compressed air. ISO/TS 22002-1:2009 states that compressed air and gases intended for direct or incidental product contact (including those used for transporting, blowing or drying materials, rodents or equipment) shall be from a source approved for food contact use, filtered to remove dust, oil and water.	https://www.iso.org/standard/35466.html https://www.iso.org/standard/44001.html
Canadian Food Inspection Agency (CFIA) Food Safety Enhancement Program Manual - Section 3	Where required, ambient air, compressed air or gases utilized in processing equipment that contact product or packaging are appropriately sourced and treated to minimize contamination of product and packaging.	http://www.inspection.gc.ca/food/safe-food-production-systems/food-safety-enhancement-program/program-manual/eng/1345821469459/1345821716482?chap=4
Canadian Good Agricultural Practices (GAP) - Section 8.2	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.	http://www.canadagap.ca/manuals/manual-downloads/
International Featured Standards (IFS) Version 6, Section 4.9.10.2	Compressed air shall not pose a risk of contamination.	https://www.ifs-certification.com/index.php/en/standards/251-ifs-food-en
Global Red Meat Standard (GRMS) - Section 12.1.2	Hazards relevant to food safety shall be controlled in critical control points (CCP) and/or by Good Manufacturing Practices (GMP) measures.	http://www.grms.org/grms-standard
British Retail Consortium (BRC) - Issue 7, Section 4.5.4	Air, other gases and steam used directly in contact with, or as an ingredient in, products shall be monitored to ensure this does not represent a contamination risk. Compressed air used directly in contact with the product shall be filtered.	http://www.brcbookshop.com/p/1651/brc-global-standard-for-food-safety-issue-7-uk-free-pdf
British Compressed Air Society (BCAS) - Food and Beverage Grade Compressed Air Best Practice Guideline 102 Section 7.3.3	Maintain -40°F/C dew point in dry air. Remove particles greater than 0.1 micron at 99.9999%. Oil-in-Air Concentration must be less than 0.01 mg/m³.	http://www.bcas.org.uk/media/download.aspx?MediaId=496
Safe Quality Foods (SQF) 8 edition - Section(s): 3.5.6, 4.5.5, 9.5.6, 10.5.5, 11.5.5, 12.5.6 Section13.5.3	Compressed air or other gases used in the manufacturing process shall be clean and present no risk to food safety. Air or gases that come into contact with food packaging are filtered using an appropriate filter capable of removing dust, oil, moisture and microorganisms to avoid cross-contamination to packaged material.	http://www.sqfi.com/documents/
SQF Guidance Document for 7.2 Module 11 - Section 11.5.7	The recommended final stage of filtration in these food contact areas should have a rating of 0.01 micron with an efficiency of 99.999% (or as determined by appropriate risk analysis). Sufficient filtration is to be in place directly upstream of the final stage to protect the final stage from oil and water aerosols.	http://www.sqfi.com/wp-content/uploads/Module-11-Guidance-7.2.pdf
3-A Standard 604-05(2004) Section: D6.6.1	At Point of Use for Sterile Air: Remove particle greater than 0.3 micron at 99.9999%. At Point of Use for non-Sterile Air: Remove for point-of-use then 0.3 micron at 99%.	http://www.techstreet.com/3a/standards/3a-604-05-accepted-practice?product_id=1185988

RECOMMENDED DONALDSON SOLUTION

Donaldson filtration products protect against oil, particulates, bacteria, and other harmful contaminants that can affect the quality of your product or process.

Use the following setup to ensure that your process meets the demands of today's global compressed air regulations and best practices for food and beverage industries.

- DF-C Cyclone Separator
- UltraPac Heatless Dryer
- DF Housing with V-Grade Coalescing Element
- P-EG Housing with 5 µm P-GS Element
- PG-EG Sanitary Housing with P-SRF V Sterile Element
- Condensate Drain
- DS Oil / Water Separator

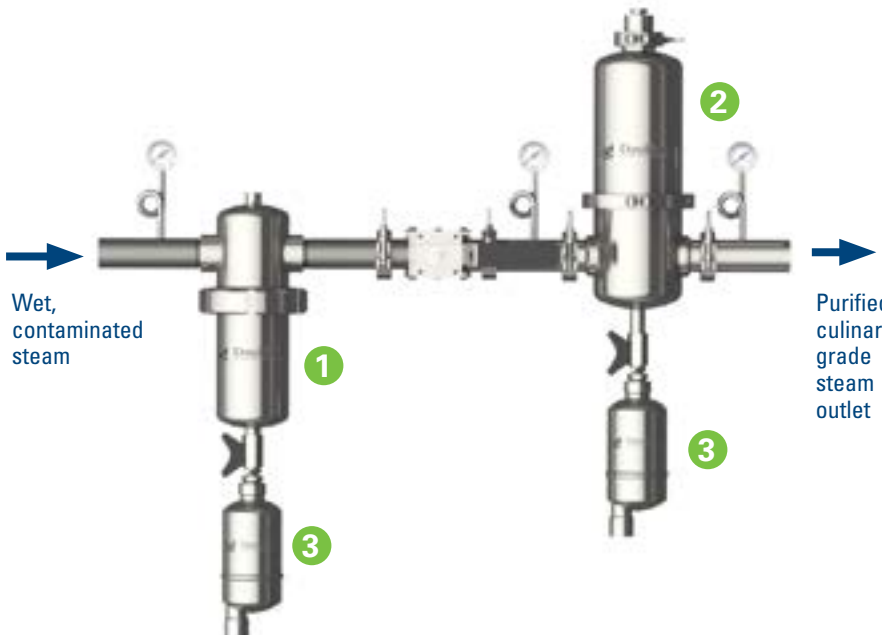
©2017-2018 Donaldson Company, Inc. All Rights Reserved. Donaldson and the color blue are marks of Donaldson Company, Inc. All other marks belong to their respective owners. {Contains Donaldson proprietary technology.}

LIQUID			
GOOD MANUFACTURING PRACTICES - WATER OR LIQUID IN FOOD PLANTS	FILTRATION REQUIREMENT	CITATION	RECOMMENDED DONALDSON SOLUTION
Food and Drug Administration (FDA) Inspection Technical Guides: Reverse Osmosis	One of the basic requirements of a Reverse Osmosis system is the prefiltration of water before RO modules.	https://www.fda.gov/ICECI/Inspections/InspectionGuides/InspectionTechnicalGuides/ucm072913.htm	<p>Donaldson filtration products protect against particulates, bacteria, and other harmful contaminants that can affect the quality of your product or processes.</p> <p>Use the following setup to ensure that your process meets the demands of today's global liquid regulations and best practices for food and beverage industries.</p>
FDA Pasteurized Milk Ordinance (PMO) 2007 Revision, Appendix H, Secion III & Appendix G	Boiler Feed Water Filtration: Feed water may be treated, if necessary, for proper boiler care and operation. Boiler feed water treatment and control shall be under the supervision of trained personnel or a firm specializing in industrial water conditioning. Such personnel shall be informed that the steam is to be used for culinary purposes.	http://www.idfa.org/docs/default-source/d-news/2015-pmo-final.pdf	
FDA Food Code - (2013) Chapter 5: Water, Plumbing and Waste Section 5-202.15	A water filter, screen, and other water conditioning device installed on water lines shall be designed to facilitate disassembly for periodic servicing and cleaning. A water filter element shall be of the replaceable type.	https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf	
FDA Guide to Inspections of Aseptic Processing and Packaging for the Food Industry	Filters should be changed at intervals recommended by the manufacture. Filters that are steam sterilized must be designed for steam sterilization, and changed out after the manufactures recommend number of steam cycles has been reached.	https://www.fda.gov/downloads/ICECI/Inspections/InspectionGuides/ucm091740.pdf	
Canadian Food Inspection Agency (CFIA) Food Safety Enhancement Program Manual - Section 3 A.4.1.1	The establishment has and implements documented water safety procedures to ensure that water and ice meet the potability requirements of the appropriate regulatory authority. Where filters are used they are kept effective and maintained in a sanitary manner.	http://www.inspection.gc.ca/food/safe-food-production-systems/food-safety-enhancement-program/program-manual/eng/1345821469459/1345821716482?chap=4	
Canadian Good Agricultural Practices (GAP) - Version 7.0, Section 7.1	Agricultural water, water that comes in direct contact with product, or water that may impact food safety through cross contamination must come from water sources that are annually assessed for potential hazards. Water filtration systems are recommended to ensure water sources pass yearly testing.	http://www.canadagap.ca/manuals/manual-downloads/	
International Featured Standards (IFS) Version 6, Section 4.9.9.3	The quality of water, steam or ice shall be monitored following a risk based sampling plan.	https://www.ifs-certification.com/index.php/en/standards/251-ifs-food-en	
British Retail Consortium (BRC) - Issue 7, Section 4.5.1	All water used as a raw material in the manufacture of processed food, the preparation of product, hand-washing or for equipment or plant cleaning shall be supplied in sufficient quantity, be potable at point of use or pose no risk of contamination according to applicable legislation.	http://www.brcbookshop.com/p/1651/brc-global-standard-for-food-safety-issue-7-uk-free-pdf	
Safe Quality Foods (SQF) 8 edition - Section 13.5.2.1 Section 3.5.1, 4.5.1, 9.5.1, 10.5.1, 11.5.1, 12.5.1, 13.5.1	Water used for product contact or food packaging materials shall be suitable to the operation and comply with local, national or internationally recognized potable water. Where water is stored on site, storage facilities should be adequately designed, constructed and maintained to prevent contamination.	http://www.sqfi.com/documents/	
SQF Guidance Document for 7.2 Module 11 - Section 11.5.2	Any water that is used in the process that could come in contact with the product must be verified to be in compliance with local and national standards. In the US and Australia for example, the potability standard for drinking water is <1 coliform / 100 mL water and membrane filtration is the preferred method. However, standards also apply for Salmonella spp, Shigella spp, enterovirulent E.coli, Vibrio cholera, Yersinia enterocolitica, Campylobacter jejuni, and protozoa.	http://www.sqfi.com/wp-content/uploads/Module-11-Guidance-7.2.pdf	
3-A Standard 609-03(2004) Section F1: Boiler Feeder Water Section B3: Safe Water	Safe water or water supplies acceptable to the regulatory jurisdiction should be used for boiler feeder water. Shall be safe water which means water from a supply located, protected and operated and shall be of a safe, sanitary quality. The water shall meet the standards perscribed in the National Primary Drinking Water Regulations of the Environmental Protection Agency (EPA) as referenced in the CFR, Title 40, Parts 141, 142 and 143...or from the requirements for water reclaimed from the condensing of milk and milk products in the Pasturized Milk Ordinance, Appendix D. V. Category I.	http://www.techstreet.com/standards/3a-609-03-accepted-practice?product_id=1185990	

- 1 P-PT Housing with PP-N Element
- 2 PF-EG Sanitary Housing with PP100 Element
- 3 PF-EG Sanitary Housing with PES-WN Element
- 4 P-EG Housing with 5 µm P-GS Element
- 5 Condensate Drain

©2017-2018 Donaldson Company, Inc. All Rights Reserved. Donaldson and the color blue are marks of Donaldson Company, Inc. All other marks belong to their respective owners. {Contains Donaldson proprietary technology.}

STEAM

GOOD MANUFACTURING PRACTICES - STEAM IN FOOD PLANT	FILTRATION REQUIREMENT	CITATION	RECOMMENDED DONALDSON SOLUTION
<p>Food Safety System Certification (FSSC) ISO 22000:2005 - Food safety management systems</p> <p>ISO/TS 22002-1:2009 - Prerequisite programs on food safety - Section 6.5</p>	<p>ISO22000:2005 states that prerequisite programs should be in place to address supplies of culinary grade steam.</p> <p>ISO/TS 22002-1:2009 states that steam intended for direct or incidental product contact (including water used for the manufacture of steam that will come in contact with food or used to heat water that will come in contact with food) shall comply with local, national or internationally recognized potable water microbiological and quality standards as required.</p>	<p>https://www.iso.org/standard/35466.html</p> <p>https://www.iso.org/standard/44001.html</p>	<p>Donaldson filtration products protect against particulates and other harmful contaminants that can affect the quality of your product or process.</p>
<p>Canadian Food Inspection Agency (CFIA) Food Safety Enhancement Program Manual - Section 3.A.4</p>	<p>Water, ice and steam can be a source of biological or chemical contaminants. Since water, ice and steam can be used for a variety of purposes (e.g., sanitation, hand washing, as an ingredient or processing aid), it is important to perform water sampling and testing to confirm potability.</p> <p>Where filters are used they are kept effective and maintained in a sanitary manner.</p>	<p>http://www.inspection.gc.ca/food/safe-food-production-systems/food-safety-enhancement-program/program-manual/eng/1345821469459/1345821716482?chap=4</p>	<p>Use the following setup to ensure that your process meets the demands of today's global steam regulations and best practices for food and beverage industries.</p>
<p>International Featured Standards (IFS) Version 6. Section 4.9.9.3</p>	<p>The quality of water, steam or ice shall be monitored following a risk based sampling plan.</p>	<p>https://www.ifs-certification.com/index.php/en/standards/251-ifs-food-en</p>	
<p>British Retail Consortium (BRC) - Issue 7, Section 4.5.4</p>	<p>Air, other gases and steam used directly in contact with, or as an ingredient in, products shall be monitored to ensure this does not represent a contamination risk.</p>	<p>http://www.brcbookshop.com/p/1651/brc-global-standard-for-food-safety-issue-7-uk-free-pdf</p>	
<p>Food and Drug Administration Act (FDA) Food Safety Modernization Act (FSMA)</p>	<p>Companies under FDA jurisdiction must employ risk-based (HACCP-like) food safety management schemes. Steam intended for direct or incidental product contact (including water used for the manufacture of steam that will come in contact with food or used to heat water that will come in contact with food) will therefore need to be filtered.</p>	<p>https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm</p>	
<p>FDA Guidance Ready-to-Eat (RTE) Foods - Section 13.E.(13)</p>	<p>Intensified cleaning and sanitizing includes sanitation measures that are performed in addition to normal sanitation procedures and are escalated in response to continuing findings of positives. Intensified cleaning and sanitizing can include increasing the frequency of cleaning and sanitizing for certain pieces of equipment, breaking down the equipment into its parts for further cleaning, and steam treating equipment.</p>	<p>https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM535981.pdf#page=15</p>	
<p>FDA Pasteurized Milk Ordinance (PMO) 2015 Revision, Appendix H, Section II</p> <p>PMO 2007 Revision, Appendix H, Section III & Appendix G</p>	<p>Steam Filtration: Figure 42 and 43 depict a culinary steam system, both diagrams require a pre-filter (entrainment separator) as well as a culinary steam filter.</p> <p>Boiler Feed Water Filtration: Feed water may be treated, if necessary, for proper boiler care and operation. Boiler feed water treatment and control shall be under the supervision of trained personnel or a firm specializing in industrial water conditioning. Such personnel shall be informed that the steam is to be used for culinary purposes.</p>	<p>http://www.idfa.org/docs/default-source/d-news/2015-pmo-final.pdf</p>	
<p>Safe Quality Foods (SQF) 8 edition - Section 13.5.2.1</p> <p>SQF Guidance Document for 7.2 Module 11 - Section 11.5.2.v</p>	<p>The manufacture of steam that will come in contact with packaging; shall comply with local, national or internationally recognized potable water microbiological and quality standards as required.</p> <p>Water used for the manufacture of steam that will come in contact with food or used to heat water that will come in contact with food shall comply with local, national or internationally recognized potable water microbiological and quality standards as required.</p>	<p>http://www.sqfi.com/documents/</p> <p>http://www.sqfi.com/wp-content/uploads/Module-11-Guidance-7.2.pdf</p>	
<p>3-A Standard 609-03(2004) Section D 2.1 - 2.2</p>	<p>Entrainment Separator: An entrainment separator capable of removing particles 10 microns in size and larger, and with an associated condensate trap.</p> <p>Final Filter: A filter capable of removing 95% of the particles 2 microns in size or larger, and with an associated trap.</p>	<p>http://www.techstreet.com/standards/3a-609-03-accepted-practice?product_id=1185990</p>	 <p>1 P-EG with 25 µm P-GSLN Element</p> <p>2 PG-EG Sanitary Housing with 5 µm P-GS Element</p> <p>3 Condensate Drain</p> <p>©2017-2018 Donaldson Company, Inc. All Rights Reserved. Donaldson and the color blue are marks of Donaldson Company, Inc. All other marks belong to their respective owners. (Contains Donaldson proprietary technology.)</p>

SUPERIOR FILTRATION. **MAXIMUM PROTECTION.**

Extensive Product Portfolio

- Process air, steam and liquid filtration products
- Performance engineered to sanitary guidelines
- Wide range of filtration media for any application
- Housings, elements, and parts in-stock, ready to ship

Advanced Technology

- Optimized filtration performance and efficiency
- Extensive research and development capabilities
- Advanced design and testing capabilities
- Over 1,000 engineers and scientists worldwide

Unrivalled Support and Expertise

- Expert technical specialists available as resource
- Comprehensive pre- and post-sale support
- Extensive filter analysis and trouble-shooting
- 100 years of successful global manufacturing



Registered



Standard No. 10-04*



Member of



Member of



Member of



Member of



Important Notice

Many factors beyond the control of Donaldson can affect the use and performance of Donaldson products in a particular application, including the conditions under which the product is used. Since these factors are uniquely within the user's knowledge and control, it is essential the user evaluate the products to determine whether the product is fit for the particular purpose and suitable for the user's application. All products, product specifications, availability and data are subject to change without notice, and may vary by region or country.



Donaldson Company, Inc.
Process Filtration
PO Box 1299
Minneapolis, MN
55440-1299 U.S.A.

Tel 800-543-3634 (USA)
Tel 800-343-3639 (within Mexico)
Fax 952-885-4791

processfilters@donaldson.com
donaldsonprocessfilters.com

F117065 (03/18) ENG Regulatory and Best Practices Overview
©2017-2018 Donaldson Company, Inc. All Rights Reserved.
Donaldson and the color blue are marks of Donaldson Company, Inc.
All other marks belong to their respective owners.
{Contains Donaldson proprietary technology}