

3-A® Accepted Practices for Supplying Air Under Pressure in Contact With Milk, Milk Products and Product Contact Surfaces, Number 604-05

Standard Developer
3-A Sanitary Standards, Inc. (3-A SSI)
In Collaboration With
United States Public Health Service (USPHS)/
United States Food and Drug Administration (USFDA)
United States Department of Agriculture – Dairy Programs (USDA)
European Hygienic Engineering & Design Group (EHEDG)

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Foreword

This 3-A Accepted Practice is to establish minimum sanitary (hygienic) requirements for Supplying Air Under Pressure in Contact With Milk, Milk Products and Product Contact Surfaces. Standard English is the official language of 3-A Sanitary Standards and 3-A Accepted Practices.

This 3-A Accepted Practice is for voluntary use by directly and materially affected organizations such as equipment and machinery fabricators, processors, regulatory agencies and by 3-A SSI to assure adequate public health protection exist for the devices and covered products. 3-A Sanitary Standards, Inc. use these documents as the source for sanitary criteria as part of 3-A Symbol authorization.

This 3-A Accepted Practice was developed jointly by 3-A SSI, the United States Public Health Service (USPHS)/United States Food and Drug Administration (USFDA), the United States Department of Agriculture – Dairy Programs (USDA), and the European Hygienic Engineering & Design Group (EHEDG).

It is our purpose to encourage inventive genius and provide a forum to discuss new developments. Suggestions for improvement and new technology are welcome any time for consideration by the 3-A Sanitary Standards Committees. Please forward comments to the 3-A SSI, 1451 Dolley Madison Boulevard, Suite 210, McLean, VA 22101-3850, USA. By fax: 703-761-6284. By e-mail to: 3-ainfo@3-a.org.

A SCOPE

A1 These 3-A Accepted Practices shall pertain to the sanitary aspects of the equipment and filters used in the supplying of air under pressure for contact with food, food products, other comestibles, product contact surfaces, and solution contact surfaces. The system shall begin with the air intake filter and end at point(s) of application.

A2 In order to conform to these 3-A Accepted Practices, equipment for the supplying of air as defined herein shall conform to the following design, material, fabrication and installation criteria and the applicable special requirements,¹

A3 Normative References

Doc. No. Title (3-A Sanitary Standards for:)

- 18- Multiple-use Rubber and Rubber-Like Materials Used as Product Contact Surfaces
- 20- Multiple-use Plastic Materials
- 33- Polished Metal Tubing
- 58- Vacuum Breakers and Check Valves
- 63- Sanitary Fittings

Doc. No. Title (3-A Accepted Practices for:)

- 605- Permanently Installed Product and Solution Pipelines and Cleaning Systems

B DEFINITIONS

B1 *Air Under Pressure:* Shall mean air, the pressure of which has been increased by mechanical means to exceed atmospheric pressure, and which is in contact with products or other comestibles, and solution contact surfaces, the automatic opening of containers, the drying of product contact surfaces, and for other purposes where specifically directed at a product contact surface.

B1.1 *Low Pressure Air:* Shall mean air that has been pressurized to less than 15 psig (1 bar) by mechanical means utilizing a fan or blower.

B1.2 *Compressed Air:* Shall mean air that has been compressed by mechanical means to 15 psig (1 bar) or above.

B2 *Bond:* Shall mean the adhesive or cohesive forces holding materials together. This definition excludes press and shrink fits.

B3 Air Contact Surfaces

B3.1 *Processing Air Contact Surfaces:* Shall mean all surfaces in contact with filtered air prior to coming in contact with the product, commencing at the frame of the final air filter and ending at the first downstream product contact surface.

B3.2 *Exhaust Air Contact Surfaces:* Shall mean the surfaces of the air ducts, plenum chamber(s) (if provided), and appurtenances from the final product contact surface through the exhaust system.

B4 Air systems categories

B4.1 *Central System:* Shall mean those which furnish air to more than one piece of equipment. (See Figure 1.) Such systems usually require the use of an air storage tank.

B4.2 *Individual System:* Shall mean those which furnish air to one piece of equipment, and which may be an integral part of a given piece of equipment. (See Figures 2, 3, 4 and 5.)

B5 *Product:* Shall mean food, food products or other comestibles.

B6 *Solutions:* Shall mean water, homogenous mixtures of cleaning agents, sanitizers, and combinations of these.

B7 Surfaces

B7.1 *Product Contact Surfaces:* Shall mean all surfaces which are exposed to the product and surfaces from which liquids (materials) may drain, drop, diffuse or be drawn into the product or into the container, and surfaces that touch the product contact surfaces of the container.

B7.2 *Solution Contact Surfaces:* Shall mean the interior surfaces of the system which are used exclusively for supply and recirculation of cleaning and/or sanitizing solutions, except those used to supply concentrated cleaning and/or sanitizing chemicals to the point of use.

¹ Use current revisions or editions of normative documents cited.

- B7.3 *Nonproduct Contact Surfaces*: Shall mean all other exposed surfaces.
- B8 *Corrosion Resistant*: Shall mean the surface has the property to maintain its original surface characteristics for its intended service period when exposed to the conditions encountered in the environment of intended use, including expected contact with product and cleaning, sanitizing treatment, or sterilization compounds or solutions.
- B9 *Easily or Readily Accessible*: Shall mean a location which can be safely reached by personnel from a floor, platform (fixed or moveable), or other permanent work area.
- B10 *Easily or Readily Removable*: Shall mean quickly separated from the equipment with the use of simple hand tools.
- B11 *Nontoxic Materials*: Shall mean those substances which under the conditions of their use are in compliance with applicable requirements of the Food and Drug Administration.
- B12 *Simple Hand Tools*: Shall mean implements, normally used by operating and cleaning personnel, such as a screwdriver, wrench, or mallet.
- B13 *Sanitizing or Sanitization*: Shall mean a process applied to a cleaned surface which is capable of reducing the numbers of the most resistant human pathogens by at least 5 log₁₀ reductions (99.999%) to 7 log₁₀ reductions (99.99999%) by applying accumulated hot water, hot air, or steam, or by applying an EPA-registered sanitizer according to label directions. Sanitizing may be effected by mechanical or manual methods.

C MATERIALS

C1 Metals

- C1.1 Product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AISI) 300 Series² (excluding 301 and 302) or corresponding Alloy Cast Institute³ (ACI) types or metal which under conditions of intended use is at least as corrosion-resistant as stainless steel of the foregoing types, and is nontoxic and nonabsorbent, (See Appendix, Section G.)

C2 Nonmetals

- C2.1 Rubber and rubber-like materials may be used for gaskets, flexible tubing, connectors, and parts having the same functional purposes.
- C2.2 Rubber and rubber-like materials when used for the above-specified application(s) shall conform to the applicable provisions of the 3-A Sanitary Standard, Number 18-.
- C2.3 Plastic materials may be used for gaskets, and parts having the same functional purposes.
- C2.3.1 Plastic materials when used for the above-specified application(s) shall conform to the applicable provisions of the 3-A Sanitary Standard, Number 20-, except that:
- C2.3.1.1 Plastic materials may be used for flexible tubing or fittings. Tubing and fittings as referenced in D7.5.1 shall be constructed of materials meeting Title 21, Part 170-199 of the Code of Federal Regulations or otherwise accepted by the Food and Drug Administration for food contact.
- C2.4 Rubber and rubber-like materials and plastic materials having product contact surfaces shall be of such composition as to retain their surface and conformational characteristics when exposed to the conditions encountered in the environment of intended use and in cleaning and sanitization.

² AISI Steel Products Manual, Stainless & Heat Resisting Steels, Table 2-1. Available from the American Iron and Steel Society, 186 Thorn Hill Road, Warrendale, PA 15086

³ Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016.

C3 Pressurized Air Filters and Filter Media

- C3.1 All filters shall consist of materials which, under the conditions of intended use, are nontoxic, nonmedia releasing, and do not release toxic volatiles or other contaminants, including those which may impart any flavor or odor to the product or to the air.
- C3.2 Bonding materials⁴ in the media, if used, shall be nontoxic, nonvolatile and insoluble under all conditions of use.
- C3.3 The adhesive⁴, if used, for bonding rubber and rubber-like materials and bonding plastic materials shall be nontoxic.

D FABRICATION**D1 Surface Texture**

- D1.1 All product contact surfaces shall have a texture at least as smooth as 32 μ in. or 0.8 μ m R_a finish on stainless steel sheets and be free of imperfections such as pits, folds and crevices in the final fabricated form. (See Appendix, Section I.)

D2 Permanent Joints

- D2.1 All permanent joints in metallic product contact surfaces shall be continuously welded.
- D2.2 All metal tubing shall conform to the applicable provisions for welded sanitary product pipelines found in the 3-A Accepted Practices, Number 605-.

D3 Fittings

- D3.1 All sanitary fittings and connections shall conform to the applicable provisions of 3-A Standard, Number 63-.

D4 Air Supply Equipment

- D4.1 Air supply shall be taken from a clean space or from relatively clean outer air and shall pass through a filter upstream from the compressing equipment. This filter shall be located and constructed so that it is easily

accessible for examination, and the filter media are easily removable for cleaning or replacement. The filter shall be protected from weather, drainage, water, product spillage and physical damage.

- D4.2 Air under pressure shall be oil free. Oil free air may be produced by one of the following methods, or their equivalent:

D4.2.1 Use of carbon or teflon ring piston, or diaphragm type, or water lubricated compressors.

D4.2.2 Use of lubricated compressors with effective provisions for removal of all oil by condensation and coalescing or absorption.

D4.2.3 Water lubricated or nonlubricated blowers.

D5 Air Under Pressure

- D5.1 Air under pressure systems in excess of 15 psig (1 bar) shall be provided with methods of moisture removal. The removal of moisture may be achieved by condensation and coalescing filtration or absorption, or equivalent, to prevent free water in the system.

D6 Filters

D6.1 Filters shall be constructed and installed so as to assure effective passage of air through the filter media only.

D6.2 Intake air filter efficiency shall be at least 98% SAE J726, June 1987⁵ using AC coarse test dust.

D6.3 The coalescing filter and any traps as referenced in D4.2.2 and D5, when used, shall be located in the air pipeline downstream from the compressing equipment, and from the air tank, if one is used (See Figures 1, 3 and 5.). The filter shall be readily accessible for examination, cleaning, and for replacing the filter media. The moisture trap shall be equipped with a petcock or other means for draining accumulated water.

⁴ Adhesives shall comply with 21 CFR 175 – *Indirect Food Additives: Adhesives and Components of Coatings*. Document is available for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

⁵ Society of Automotive Engineers, 400 Commonwealth Drive, Warrendale, PA 15096-0001 (412) 776-4841