

3-A[®] Sanitary Standards for Pulsation Dampening Devices, Number 82-00

Formulated by
International Association of Food Industry Suppliers (IAFIS)
International Association for Food Protection (IAFP)
United States Public Health Service (USPHS)
The Dairy Industry Committee (DIC)
United States Department of Agriculture – Dairy Programs (USDA)

It is the purpose of the IAFIS, IAFP, USPHS, DIC, and USDA in connection with the development of the 3-A Sanitary Standards Program to allow and encourage full freedom for inventive genius or new developments. Pulsation Dampening Device specifications heretofore or hereafter developed which so differ in design, materials, and fabrication or otherwise as not to conform to the following standards but which, in the fabricator's opinion, are equivalent or better, may be submitted for the joint consideration of the IAFIS, IAFP USPHS, DIC, and USDA at any time. The 3-A Sanitary Standards and 3-Accepted Practices provide hygienic criteria applicable to equipment and systems used to produce, and package milk, milk products, and other perishable foods or comestibles. Standard English is the official language of 3-A Sanitary Standards and 3-A Accepted Practices.

A SCOPE

- A1 These standards cover the sanitary requirements for pulsation dampening devices used in hygienic and aseptic processing systems for fluid dairy products and other fluid comestibles.
- A2 In order to conform to these 3-A Sanitary Standards, pulsation dampening devices shall comply with the following design, material, and fabrication criteria and the applicable documents referenced herein.¹

B DEFINITIONS

- B1 *Product:* Shall mean fluid milk, fluid milk products, and other fluid comestibles.
- B2 *Pulsation Dampeners:* Shall mean equipment capable of reducing or eliminating fluid pulsations and/or fluid pressure peaks.
- B3 **Surfaces**
- B3.1 *Product Contact Surfaces:* Shall mean all surfaces which are exposed to the product and surfaces from which liquids may drain, drop, diffuse, or be drawn into the product.
- B3.2 *Nonproduct Contact Surfaces:* Shall mean all other exposed surfaces.

B4 Cleaning

- B4.1 *Mechanical Cleaning or Mechanically Cleaned:* Shall mean soil removal by impingement, circulation, or flowing chemical detergent solutions and water rinses onto and over the surfaces to be cleaned by mechanical means in equipment or systems specifically designed for this purpose.
- B4.2 *Manual (COP) Cleaning:* Shall mean soil removal when the equipment is partially or totally disassembled. Soil removal is effected with chemical solutions and water rinses with the assistance of one or a combination of brushes, nonmetallic scouring pads and scrapers, high or low pressure hoses and tank(s) which may be fitted with recirculating pump(s), and with all cleaning aids manipulated by hand.

B5 Surface Modification²

- B5.1 *Surface Treatments:* Shall mean a process whereby chemical compositions or mechanical properties of the existing surface are altered. There is no appreciable, typically less than 1 µm, build-up of new material or removal of existing material.

¹ Use current revisions or editions of all referenced documents cited herein.

² Additional information on surface modification is contained in *Advanced Materials and Processes*, Volume 137(1), "Coatings and Coating Practices" by H. Herman, "Surface Modification" by F. A. Smidt. ASM International, Materials Park, OH 44073 (216) 338-5151.

- B5.1.1 Surface treatments may include:
1. Mechanical (shot peening³, polishing)
 2. Electropolishing
- B5.2 *Coatings*: Shall mean the results of a process where a different material is deposited to create a new surface. There is appreciable, typically more than 1 µm, build-up of new material. The coating material does not alter the physical properties of the substrate.
- B5.2.1 Coating processes include:
1. Engineering Plating
(e.g., Electrodeposition⁴, gold deposition)
- B6 *Corrosion Resistant*: Shall mean the surface has the property to maintain its original surface characteristics for its predicted service period when exposed to the conditions encountered in the environment of intended use, including expected contact with product and cleaning, sanitizing, or sterilization compounds or solutions.
- B7 *Dead End*: Shall mean an area or space wherein a product, ingredient, cleaning, or sanitizing agent, or other extraneous matter may be trapped, retained, or not completely displaced during operational or cleaning procedures.
- B8 *Easily or Readily Accessible*: Shall mean a location which can be safely reached by personnel from the floor, platform, or other permanent work area.
- B9 *Easily or Readily Removable*: Shall mean quickly separated from the equipment with the use of simple hand tools if necessary.
- B10 *Inspectable*: Shall mean all product contact surfaces can be made available for close visual observation.
- B11 *Microbial Impermeability*: Shall mean the ability of the equipment to prevent the ingress of

microorganisms from the environment to product contact surfaces.

- B12 *Nontoxic Materials*: Shall mean those substances which under the conditions of their use are in compliance with applicable requirements of the Food, Drug, and Cosmetic Act of 1938, as amended.
- 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.
- B14 *Shadow Areas*: Shall mean zones in product contact surfaces where cleaning solutions will not flow directly across the surface.
- B15 *Soil*: Shall mean the presence of unwanted organic residue or inorganic matter, with or without microorganisms, including food residue, in or on the equipment.
- B16 *Simple Hand Tools*: Shall mean implements such as a screwdriver, wrench, or mallet normally used by operating and cleaning personnel.
- B17 *Sterilization*: Shall mean a process effected by heat, chemicals, or other mechanical means that destroys all vegetative bacteria and inactivates relevant bacterial spores.
- B18 *Flexible Liners*: Shall mean a membrane or bladder which separates compressible media from product.
- B19 *Liner Supports*: Shall mean fabrications or structures which maintain the desired function, shape, attachment or seal of the liner.
- B20 *Bond*: Shall mean the adhesive or cohesive forces holding materials together. This definition excludes press and shrink fits.

C MATERIALS

C1 Metals

- C1.1 Product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AISI)

³ MIL-S-13165C (1), *Military Specification: Shot Peening of Metal Parts*. Available from Standardization, Document Order Desk (Department of Navy), 700 Robbins Avenue, Building 4, Section D, Philadelphia, PA 19111-5094 (215) 697-2179.

⁴ Federal Specification #QQ-C-320B for Chromium Plating (Electrodeposited), with Amendment 4. Federal Specification #QQ-N-290A for Nickel Plating (Electrodeposited). Available from the General Services Administration, Federal Supply Services Bureau, Specification Section, 470 East L'Enfant Plaza, Suite 8100, Washington, DC 20407 (202) 755-0325.

300 Series⁵ (excluding 301 and 302) or corresponding Alloy Cast Institute (ACI) types⁶ 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 E.)

C1.2 Pulsation dampener housings, liner supports, and end caps made of the materials provided for in C1.1 may have their product contact surfaces modified by surface treatment or coating(s).

C1.3 Pulsation dampener housings, liner supports, and end caps may also be made of other nontoxic structurally suitable metal(s) that have their product contact surfaces modified by coating(s).

C2 Nonmetals

C2.1 Rubber and rubber-like materials may be used for flexible liners, liner supports, housing gaskets, housing seals, and parts having the same functional purposes.

C2.1.1 Rubber and rubber-like materials, when used for the above-specified application(s), shall conform to the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-.

C2.2 Plastic materials may be used for gaskets, liner supports, and parts having the same functional purposes.

C2.2.1 Plastic materials, when used for the above-specified application(s), shall conform to the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-.

C2.3 Rubber and rubber-like 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 bactericidal treatment or sterilization.

⁵ The data for this series are contained in the *AISI Steel Products Manual, Stainless & Heat Resisting Steels*, Table 2-1. Available from the American Iron and Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086 (412) 776-1535.

⁶ Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016 (708) 299-9160.

C2.4 The adhesive, if used, on bonded rubber and rubber-like materials and bonded plastic materials shall be nontoxic.⁷

C3 Additional Material Requirements

C3.1 In a processing system to be sterilized by heat and operated at a temperature of 250°F (121°C) or higher, all materials having product contact surface(s) used in the construction of the pulsation dampeners and nonmetallic component parts shall be such that they can be (1) sterilized by saturated steam or water under pressure (at least 15.3 psig or 106 kPa) at a temperature of at least 250°F (121°C) and (2) operated at the temperature required for processing.

C4 Nonproduct Contact Surfaces

C4.1 All nonproduct contact surfaces shall be of corrosion-resistant material or material that is rendered corrosion resistant. If coated, the coating used shall adhere. All nonproduct contact surfaces shall be relatively nonabsorbent, durable, and cleanable. Parts removable for cleaning having both product contact and nonproduct contact surfaces shall not be painted.

D FABRICATION

D1 Surface Texture

D1.1 All product contact surfaces shall have a finish at least as smooth as a No. 4 ground finish on stainless steel sheets and be free of imperfections such as pits, folds and crevices in the final fabricated form. (See Appendix, Section F.)

D2 Permanent Joints

D2.1 All permanent joints in metallic product contact surfaces shall be continuously welded.⁸

⁷ Adhesives shall comply with 21 CFR 175 - Indirect Food Additives: Adhesives and Components of Coatings. Document for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (202) 512-1800.

⁸ Criteria for hygienic welds may be found in AWS/ANSI D18.1 – *Specification for Welding of Austenitic Stainless Steel Tube and Pipe Systems in Sanitary (Hygienic) Applications*. Available from the American Welding Society, 550 N.W. LeJeune Rd., Miami, FL 33126, phone: (305) 443-9353, fax: (305) 443-7559, e-mail: info@amweld.org; and EHEDG Doc. 9 – *Welding Stainless Steel to Meet Hygienic Requirements*. Available from the European Hygienic Equipment Design Group, Ellen Moens, Avenue Grand Champ 148, 1150 Brussels, Belgium.