

3-A[®] Sanitary Standards for Equipment for Packaging Viscous Products, Number 23-06

Standards Developing Organizations

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 (USDA)

European Hygienic Engineering & Design Group (EHEDG)

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Note: The highlighted text denotes changes to the previous document.

Disclaimers

3-A Sanitary Standards and 3-A Accepted Practices are developed through the efforts of experts, working on a volunteer basis, using science-based information and their professional experiences to reach consensus decisions on the sanitary (hygienic) criteria in these 3-A documents.

3-A SSI, its employees and its volunteer committees/working groups shall not incur any obligation or liability for damages, including consequential damages, arising from or in connection with the development, use, interpretation, or reliance upon this 3-A Sanitary Standard.

3-A Sanitary Standards and 3-A Accepted Practices do not include provisions for mechanical, electrical, or personnel safety. Such safety criteria are established by government regulations and other standards development organizations (SDOs). Other SDO standards may be referenced.

Drawings and illustrations contained herein are examples to assist in understanding the criteria in this 3-A Sanitary Standard. Appendix drawings and illustrations are not intended to show all variations of the equipment or system nor are they exclusive of alternate approved methods. Appendix drawings and illustrations are non-normative.

Foreword

This 3-A Sanitary Standard establishes minimum sanitary (hygienic) requirements for design, materials, fabrication, and/or installation of Equipment for Packaging Viscous Products.

This 3-A Sanitary Standard is for use on a voluntary basis by directly and materially affected organizations such as equipment and machinery fabricators, processors, regulatory agencies and by other SDOs to assure adequate public health protections exist for the equipment or systems and covered products. 3-A SSI uses these documents as its source of sanitary criteria for 3-A Symbol authorization.

This 3-A Sanitary Standard was developed jointly by 3-A SSI, the United States Public Health Service (USPHS), the United States Department of Agriculture – Dairy Programs (USDA), and the European Hygienic Engineering & Design Group (EHEDG).

It is our intent to encourage inventive genius and provide a forum to discuss new developments. Suggestions for improvement and new technology are welcome at any time for consideration by 3-A SSI. Please forward comments to 3-A SSI, 6888 Elm Street, Suite 2D; McLean, VA 22101-3829, USA or by fax: 703-761-6284, or by e-mail to: 3-ainfo@3-a.org.

A SCOPE

A1 These standards cover the sanitary aspects of unitized equipment for holding, opening, forming, dispensing, filling, closing, sealing, or capping containers for viscous products, or wrapping viscous products, and all parts essential to these functions. The equipment shall perform one or more of the following functions:

1. Holding the container preparatory to further processing
2. Opening the container
3. Forming the container
4. Dispensing a preformed container
5. Applying and sealing a supplementary fitment
6. Other processing equipment, as defined herein
7. Filling the container
8. Closing the container
9. Sealing the container
10. Capping the container
11. Wrapping the container
12. Applying a tamper-evident security seal.

The equipment shall start at the point(s) where the product, container, container blank, container material or wrapping material first enters the equipment. The equipment shall end where the packaged product exits the unitized equipment.

A2 These standards do not pertain to the container, to free-standing container forming equipment or to other equipment such as labelers, printers, daters, cappers, applicators of supplementary fitments or devices or wrappers not furnished as part of the unitized equipment, nor shall it apply to fillers of nonviscous products.

A3 In order to conform to these 3-A Sanitary Standards, equipment for packaging viscous products shall conform to the following design, material, and fabrication criteria and the applicable documents referenced herein.¹

B DEFINITIONS

B1 *Product:* Shall mean viscous comestibles such as frozen desserts, cottage cheese, sour cream, yogurt, butter, spreads, cream cheese, processed cheese and other similar viscous products, including added ingredients.

B2 *Viscous:* Shall mean semifluid product which is pumpable or flowable at packaging condition.

B3 *Container:* Shall mean a single service packaging enclosure or material being formed into the package, including its body, cap, cover, fitment or closure, and a wrapper or other structure, capable of holding the product.

B4 *Mechanical Holding, Opening, Forming, and Dispensing Equipment:* Shall mean the equipment for performing all or part of the following integral functions of feeding, holding, forming, seaming, opening and dispensing the containers.

B5 *Mechanical Filling Equipment:* Shall mean the equipment for filling the container with the product.

B6 *Mechanical Capping, Closing, Sealing, and Wrapping Equipment:* Shall mean the equipment for capping, closing, sealing the container and applying the security seal, or wrapping the product.

B7 *Other Processing Equipment:* Shall mean product handling equipment such as pumps, mixers, blenders, hoppers, ingredient feeders, and texturizers, integral to the filler equipment, which process, treat, flavor or add supplements to the product immediately prior to filling.

B8 *Unitized:* Shall mean the connection, assembly, or attachment of functional subunits, in a permanent manner (e.g., welding or with fasteners), to form the complete machine.

B9 *Inspectable:* Designed, fabricated, and installed to make product contact surfaces available for close visual observation.

B10 *Splash Contact Surfaces:* Nonproduct contact surfaces that during normal use are subject to accumulation of soil and which require routine cleaning and from which the accumulated soil cannot drain, drop, or be drawn into the product or product contact surfaces.

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

B11 Surfaces

B11.1 *Product Contact Surfaces:* Shall mean all surfaces which are exposed to the product, surfaces from which liquids may drain, drop, or be drawn into the product or into the container, and surfaces that touch the product contact surfaces of the container.

B11.2 *Nonproduct Contact Surfaces:* Shall mean all other exposed surfaces.

B11.2.1 *Splash Contact Surfaces:* Shall mean all other nonproduct contact surfaces that during normal use are subject to accumulation of soil and which require routine cleaning.

B12 Cleaning

B12.1 *Mechanical Cleaning or Mechanically Cleaned:* Shall denote cleaning solely by circulation and/or flowing chemical detergent solutions and water rinses onto and over the surfaces to be cleaned, by mechanical means.

B12.2 *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.

B13 Surface Modifications²

B13.1 *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.

B13.1.1 Surface treatments include:

1. Mechanical (shot peening³, polishing)
2. Thermal (surface hardening laser, electron beam)
3. Diffusion (carburizing, nitriding)

4. Chemical (etching, oxidation)
5. Ion Implantation
6. Electropolishing

B13.2 *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.

B13.2.1 Coating processes include:

1. Chemical (conversion coatings)
2. Engineering Plating (e.g., Electrodeposition⁴, gold)
3. Thermal spraying (e.g., flame, plasma, arc spray)
4. Physical Vapor Deposition
5. Chemical Vapor Deposition
6. Overlays and Encapsulation

B14 *Bond:* Shall mean the adhesive or cohesive forces holding materials together. This definition excludes press and shrink fits.

B15 *Arithmetical Mean (R_a):* Shall be the arithmetical mean of the absolute values of the profile departure within a sampling length.⁵

B16 *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 $\log_{10}$ reductions (99.999%) to 7 $\log_{10}$ 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.

B17 *Supplementary Fitment or Device:* Shall mean any component or assembly which is attached to the container. Examples include but are not limited to pour spouts, closures, handles and tamper evident seals.

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.

³ AMS-S-13165, *Shot Peening of Metal Parts*. Society of Automotive Engineers (AWS), 400 Commonwealth Dr., Warrendale, PA 15096-0001.

⁴ SAE-AMS-QQ-C-320, Chromium Plating (Electrodeposited). SAE-AMS QQ-N-290A, Nickel Plating (Electrodeposited). Society of Automotive Engineers (AWS), 400 Commonwealth Dr., Warrendale, PA 15096-0001.

⁵ Additional information on arithmetical mean (R_a) is contained in ANSI B.46.1-1978. Available from The American National Standards Institute, 1430 Broadway, New York, NY 10018 (212-354-3300).