

# **3-A Sanitary Standard for Formers, Fillers, and Sealers of Containers for Fluid and Viscous Products,**

## **Number 17-13**

### ***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)*

**3-A SSI Effective Date:** May 3, 2020

# TABLE OF CONTENTS

|                                                                |    |
|----------------------------------------------------------------|----|
| <b>TITLE</b>                                                   | 1  |
| <b>TABLE OF CONTENTS</b>                                       | 2  |
| <b>DISCLAIMERS</b>                                             | 5  |
| <b>FOREWORD</b>                                                | 5  |
| <b>A SCOPE</b>                                                 | 6  |
| <b>B NORMATIVE REFERENCES</b>                                  | 6  |
| <b>C DEFINITIONS</b>                                           | 8  |
| C1 Container                                                   | 8  |
| C2 Controlled Environment                                      | 8  |
| C3 Filling Head                                                | 8  |
| C4 Other Processing Equipment                                  | 8  |
| C5 Perforated Screens                                          | 8  |
| C6 Product                                                     | 9  |
| C7 Supplementary Fitment or Device                             | 9  |
| C8 <b>Surfaces</b>                                             | 9  |
| C8.1 Dry Product Contact Surfaces                              | 9  |
| C8.2 Dry Non-Product Contact Surfaces                          | 9  |
| C8.3 Sterilant and Sanitizer Contact Surfaces                  | 9  |
| C8.4 Splash Contact Surfaces                                   | 9  |
| C9 Unitized                                                    | 9  |
| C10 Woven Wire                                                 | 9  |
| C11 Slip-On Connectors                                         | 9  |
| C12 Product Tank                                               | 9  |
| <b>D MATERIALS</b>                                             | 9  |
| D1 <b>Product and Solution Contact Surfaces</b>                | 9  |
| D1.1 Metals                                                    | 9  |
| D1.2 Non-Metals                                                | 10 |
| D2 <b>Non-Product Contact Surfaces</b>                         | 11 |
| <b>E FABRICATION OF PRODUCT AND SOLUTION CONTACT SURFACES</b>  | 11 |
| E1 <b>Surface Texture</b>                                      | 11 |
| E2 <b>Joints</b>                                               | 11 |
| E2.1 Permanent Joints                                          | 11 |
| E2.2 Non-Permanent Joints                                      | 11 |
| E3 <b>Coatings</b>                                             | 12 |
| E4 <b>Cleaning and Inspectability</b>                          | 12 |
| E5 <b>Draining</b>                                             | 12 |
| E6 <b>Dead Ends</b>                                            | 12 |
| E7 <b>Gaskets, Gasket Retaining Grooves, O-rings and Seals</b> | 12 |

|                 |                                                                |    |
|-----------------|----------------------------------------------------------------|----|
| E8              | <b>Radii</b> .....                                             | 12 |
| E9              | <b>Threads</b> .....                                           | 13 |
| E10             | <b>Perforated Surfaces</b> .....                               | 13 |
| E11             | <b>Coil Springs</b> .....                                      | 13 |
| E12             | <b>Shafts</b> .....                                            | 13 |
| E13             | <b>Bearings</b> .....                                          | 13 |
| E14             | <b>Openings and Covers</b> .....                               | 13 |
| E15             | <b>Hose Assemblies</b> .....                                   | 14 |
| E16             | <b>Flexible Tubing</b> .....                                   | 14 |
| E17             | <b>Product Tanks</b> .....                                     | 14 |
| E18             | <b>Shields and Guards</b> .....                                | 14 |
| E19             | <b>Fill Valves Entering the Package (Bottom-Up Fill)</b> ..... | 15 |
| E20             | <b>Solution Pumps</b> .....                                    | 15 |
| <b>F</b>        | <b>FABRICATION OF NON-PRODUCT CONTACT SURFACES</b> .....       | 15 |
| F1              | <b>Surfaces</b> .....                                          | 15 |
| F2              | <b>Joints</b> .....                                            | 16 |
| F3              | <b>Coatings</b> .....                                          | 16 |
| F4              | <b>Cleaning and Inspectability</b> .....                       | 16 |
| F5              | <b>Draining</b> .....                                          | 16 |
| F6              | <b>Threads</b> .....                                           | 16 |
| F7              | <b>Service Piping and Lines</b> .....                          | 16 |
| F8              | <b>Panels, Doors, or Access Ports</b> .....                    | 16 |
| F9              | <b>Guards and Other Safety Devices</b> .....                   | 16 |
| F10             | <b>Supports</b> .....                                          | 16 |
| F11             | <b>Name and/or Information Plates (Nameplates)</b> .....       | 16 |
| F12             | <b>Sterilizing Chambers</b> .....                              | 16 |
| F13             | <b>Bearings</b> .....                                          | 16 |
| F14             | <b>Casters</b> .....                                           | 17 |
| F15             | <b>Recirculated Liquid Cooling and/or Heating Media</b> .....  | 17 |
| <b>G</b>        | <b>SPECIAL CONSIDERATIONS</b> .....                            | 17 |
| <b>APPENDIX</b> |                                                                |    |
| 1               | <b>STAINLESS STEEL AND EQUIVALENT MATERIALS</b> .....          | 20 |
| 2               | <b>PRODUCT CONTACT SURFACE FINISH</b> .....                    | 20 |
| 3               | <b>AIR VENTING</b> .....                                       | 20 |
| 4               | <b>CIP CLEANING</b> .....                                      | 20 |
| 5               | <b>ENGINEERING DESIGN AND TECHNICAL CONSTRUCTION FILE</b> ...  | 20 |

6     **INSTRUCTION HANDBOOK FOR INSTALLATION,  
MAINTENANCE, AND CLEANING**.....20

7     **ELECTROLESS NICKEL ALLOY** .....20

8     **HANDLING OF COLLECTED MILK**.....20

9     **RECOMMENDED REPLACEMENT OF SINGLE USE NOZZLE  
SCREENS** .....20

10    **RECOMMENDED CLEANING AND SANITIZING OF  
MULTIPLE USE NOZZLE SCREENS** .....21

11    **INFORMATION PLATE** .....21

12    **HARMONIZATION**.....21

## 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 Sanitary Standards Inc. (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. Illustrations are not intended to show all variations of the equipment or system nor are they exclusive of alternate approved methods. Illustrations are non-normative.

Metric conversions are provided for convenience and are not intended to be mandatory.

The Appendix is an advisory or informative section unless specifically cited in the Materials or Fabrication Section as requiring conformance.

## Foreword

This 3-A Sanitary Standard establishes minimum sanitary (hygienic) requirements for design, materials, fabrication, and/or installation of Formers, Fillers, and Sealers of Containers for Fluid and Viscous Products equipment and/or system(s).

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, and regulatory agencies, and by other SDOs to assure that adequate public health protections exist for the equipment or systems and covered products. 3-A SSI uses this document as its primary 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) / United States Food and Drug Administration (USFDA), the United States Department of Agriculture (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](mailto:3-ainfo@3-a.org).

**A SCOPE**

A1 This 3-A Sanitary Standard applies to the sanitary aspects of the unitized equipment for holding, opening, forming, dispensing, filling, closing, sealing, or capping containers for fluid or 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. Forming the container
3. Dispensing a preformed container
4. Opening the container
5. Rinsing the container
6. Sanitizing or disinfecting the container
7. Applying and sealing a supplementary fitment or device
8. Filling the container
9. Sealing the container
10. Closing the container
11. Capping the container
12. Wrapping the product
13. Applying a tamper-evident security seal
14. Other processing equipment (as defined herein)

A2 The equipment shall start at the points where the product, utilities (air, water, steam, cleaning chemicals, etc.), container, container blank, container material, or wrapping material first enters the unitized equipment. The equipment shall end where the packaged product and the utilities exit the unitized equipment.

A3 This standard does not pertain to the container, to free-standing container forming equipment or to other free-standing equipment including, but not limited to cappers, labelers, printers, daters, applicators of supplementary fitments or devices or wrappers not furnished as part of the unitized equipment.

A4 To conform to this 3-A Sanitary Standard, formers, fillers, and sealers, shall conform to the following criteria for design, materials of construction, fabrication techniques and installation, as applicable, and the current revisions or editions of all referenced documents cited herein.

**B NORMATIVE REFERENCES**

B1 The following listed 3-A Sanitary Standards, 3-A Accepted Practices and other documents shall be considered as Normative References and the provisions of the referenced documents shall apply to this Standard without further reference in this document unless necessary to describe special considerations

**B2 3-A Sanitary Standards****Doc. No. Title (3-A Sanitary Standard for):**

|      |                                                                         |
|------|-------------------------------------------------------------------------|
| 00-  | General Requirement                                                     |
| 01-  | Insulated Tanks                                                         |
| 02-  | Centrifugal and Positive Rotary Pumps                                   |
| 04-  | Homogenizers and Reciprocating Pumps                                    |
| 11-  | Plate Type Heat Exchangers                                              |
| 12-  | Tubular Heat Exchangers                                                 |
| 28-  | Flow Meters                                                             |
| 32-  | Uninsulated Tanks                                                       |
| 33-  | Metal Tubing                                                            |
| 35-  | Blending Equipment                                                      |
| 42-  | In-Line Strainers                                                       |
| 44-  | Diaphragm Pumps                                                         |
| 51-  | Plug-Type Valves                                                        |
| 52-  | Plastic Plug-Type Valves                                                |
| 53-  | Compression-Type Valves                                                 |
| 54-  | Diaphragm-Type Valves                                                   |
| 55-  | Boot Seal Type Valves                                                   |
| 57-  | Disc-Type Valves                                                        |
| 58-  | Vacuum Breakers and Check Valves                                        |
| 59-  | Automatic Positive Displacement Samplers for Fluid Products             |
| 60-  | Rupture Disc Assemblies                                                 |
| 61-  | Steam Injection Heaters                                                 |
| 62-  | Hose Assemblies                                                         |
| 63-  | Sanitary Fittings                                                       |
| 64-  | Pressure Reducing and Back Pressure Regulating Valves                   |
| 65-  | Sight and/or Light Windows and Sight Indicators in Contact with Product |
| 73-  | Shear Mixers, Mixers, and Agitators                                     |
| 74-  | Sensors and Sensor Fittings and Connections                             |
| 75-  | Belt-Type Feeders                                                       |
| 78-  | Spray Cleaning Devices Intended to Remain in Place                      |
| 84-  | Personnel Access Ports for Wet Applications                             |
| 85-  | Double-Seat Mixproof Valves                                             |
| 88-  | Machine Leveling Feet and Supports                                      |
| 103- | Robot-based Automation Systems                                          |

**B3 3-A Accepted Practices**

Note: New 3-A Accepted Practices shall be considered to be included in this section 45 days after they have been accepted by the Consensus Body without revision of this General Standard.

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