

Sanitary Design and Construction of Food Equipment¹

Ronald H. Schmidt and Daniel J. Erickson²

To ensure safe food and adequate sanitation programs, the equipment used for processing and handling food products must be designed, fabricated, constructed, and installed according to sound sanitary design principles. This ensures the equipment can be adequately cleaned and sanitized, and that surfaces are resistant to daily exposure to corrosive food products and cleaning/sanitizing chemicals.

Equipment that does not meet basic sanitary design principles, or is installed or used improperly cannot be adequately cleaned and sanitized.

Equipment Standards and Design Criteria

Federal, state, and local regulatory agencies routinely inspect food equipment for general sanitary fabrication, construction, and design as well as proper installation. The US Department of Agriculture (USDA)/Food Safety & Inspection Service (FSIS) pre-approves equipment for use in meat, poultry, and egg product facilities (FSIS, 2004).

Similarly, the USDA/Agricultural Marketing Service (AMS)/Dairy Division (www.usda.ams.gov) has an approval process for equipment used in

manufactured dairy facilities under their inspection. Food and Drug Administration (FDA) inspectors follow Current Good Manufacturing Practices (cGMPs) which generally address the fabrication and cleanability of food equipment (FDA, 2004a). In addition, the FDA has developed a general equipment evaluation program for equipment used in Grade A Dairy Facilities (FDA, 2000).

Standards for sanitary fabrication, construction, and design of food equipment have been developed by a variety of standards organizations. While there are subtle differences between these standards, the primary intent of each organization is the application of sound sanitary principles in food equipment manufacture. In the US, the primary food equipment organizations are 3-A Sanitary Standards, Inc. (www.3-a.org), the National Sanitation Foundation (NSF) (www.nsf.org), and Underwriters Laboratories (www.ul.org), which has more recently become involved in food equipment standards development as well.

3A Sanitary Standards have been developed for a variety of equipment used in the dairy industry, as well as some equipment used in egg processing. The

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2. Ronald H. Schmidt, PhD, Food Science and Human Nutrition Department, University of Florida, Gainesville, FL 32611; and Daniel J. Erickson, Harold Wainness and Associates, St. Paul, MN 55113.

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founding organizations of 3A represent equipment manufacturers, dairy processors, and regulatory officials. 3A Standards are used as a reference under the *Grade A Pasteurized Milk Ordinance (PMO)*, the official regulatory document for the *National Conference on Interstate Milk Shipments (NCIMS)*. 3-A Sanitary Standards may also be required under many state and local regulations.

The National Sanitation Foundation (NSF) traditionally has developed standards for equipment used in food service and retail foods. In more recent years, the NSF has been involved in developing standards for food processing equipment. The NSF and 3A have recently collaborated in standards development for meats and poultry equipment (3-A/NSF 15159) which has been under review by an International Organization for Standardization (ISO) working group.

The European Hygienic Design Group (EHEDG) is the primary organization for food equipment approval in Europe. While EHEDG has published a series of guidelines for the construction and design of food processing equipment, they have chosen not to issue standards. Acceptance for food processing equipment used in some European countries is based upon "cleanability" testing performed in EHEDG laboratories. International trade associations [e.g. International Dairy Federation (IDF)], and international standards organizations [e.g. Codex Alimentarius and the ISO] are also generally involved in equipment hygiene standards. Some of these organizations have symbol or insignia use authorization programs that require third party verification of compliance with the appropriate standard or guideline.

General Aspects of Sanitary Construction and Design of Food Equipment

The surfaces of food equipment can be subdivided into two categories:

1. food product contact surfaces, and
2. non-product contact surfaces.

A *food product contact surface* is defined as a surface in "direct contact with food residue, or where food residue can drip, drain, diffuse, or be drawn" (FDA, 2004b). Because these surfaces, if contaminated, can directly result in food product contamination, rigid sanitary design criteria must be met. *Non-product contact surfaces* are those that are part of the equipment (e.g., legs, supports, housings) that do not directly contact food. As contamination of *non-product contact surfaces* can cause indirect contamination of the food product, these surfaces cannot be ignored with regard to sanitary design.

Food Product Contact Surfaces

In terms of sanitary design, all *food contact surfaces* should be:

- smooth;
- impervious;
- free of cracks and crevices;
- nonporous;
- nonabsorbent;
- non-contaminating;
- nonreactive;
- corrosion resistant;
- durable and maintenance free;
- nontoxic; and
- cleanable.

If the surface is coated with metal alloy or non-metal (e.g. ceramics, plastic, rubber) in any way, the final surface must meet the above requirements. 3A Standards require that such coatings maintain corrosion resistance, and be free of surface delamination, pitting, flaking, chipping, blistering, and distortion under conditions of intended use. Similarly, if any other modification or process is used in fabrication (e.g., welded, bonded, or soldered) it should be done using appropriate materials and in a manner that ensures the final surface meets the sanitary design criteria.

Materials

A variety of materials are used in the construction and fabrication for different applications in food equipment. These materials vary in their properties with regard to workability, compatibility, and sanitary design features. Depending upon the application, various metals as well as non metals (e.g., plastics, rubber) are used. Some materials are not recommended and should be avoided.

Metals

- **Stainless steel** is the preferred general use metal for food contact surfaces because of its corrosion resistance and durability in most food applications. However, not all stainless steel is equal. In general, the properties of the stainless steel alloy are related to its relative composition with regard to chromium and nickel level. Corrosion resistance varies with chromium level, and structural strength varies with nickel level. The relative levels of these components are often given as a ratio. For example, the American Iron and Steel Institute (AISI) 300 Series Stainless Steel, commonly recommended for food contact surfaces is also termed 18/8 indicating that it is 18% Cr and 8% Ni. 3A Sanitary Standards require 316 (or 18/10) stainless steel for most surfaces. They allow the use of 304 stainless steel only for utility usage (e.g. pipes), and restrict the use of 303 stainless steel. 3A Standards also provide specifications regarding alloys and other coatings used in fabrication. The properties of stainless steel can change with continued use, especially under conditions where the chromium oxide layer is altered (e.g. incompatible cleaners, abrasive cleaners, abrasive cleaning pads, or chlorine and related sanitizers). Therefore, it is recommended that surfaces be passivated (using nitric acid or other strong oxidizing agents) initially and on a regular frequency thereafter, to maintain a passive (non-reactive) oxide film on the surface. Passivation of stainless steel food contact surfaces is recommended after any surface repair, polishing, or working.

- **Titanium** has excellent durability and corrosion resistance (especially in an acidic environment) . However, its use is limited by high cost. Titanium is used in stainless steel alloys for food equipment used in the processing of food products with high acid and/or salt content (e.g., citrus juice, tomato products).
- **Platinum**, another excellent corrosion resistant material, would also be highly desirable, but, obviously, the cost of this rare material would prohibit its use.
- **Gold** has been approved as a food contact surface in certain 3-A Sanitary Standards. In some cases, gold is used for soldering optical sensors (e.g., fiber optics) into stainless steel fittings. Gold is desirable in these applications for its resistance to abrasion and compatibility with glass.

Other metals are limited by application as follows:

- **Copper** is primarily used for equipment used in the brewing industry, with some use for cheese vats in Swiss cheese manufacture, due to tradition. Care should be used with copper equipment when processing acid products, as copper residues can leach into the product.
- **Aluminum** is used in certain parts and components where lighter weight is desired. However, aluminum has poor corrosion resistance and can become pitted and cracked with continued use. Care should taken when cleaning and sanitizing aluminum components as oxidizing chemicals can accelerate the pitting of the metal. In most food contact applications, aluminum must be coated with an acceptable material. Plastic coatings such as polytetrafluorethylene (PTFE or Teflon®) are common.
- **Carbonized metal** and **cast iron** are only used for frying and cooking surfaces, and similar applications in food service.
- **Galvanized iron** should be avoided as a food contact surface because it is highly reactive with acids.

Non-metals

A variety of non-metal materials are used as food contact surfaces in specific applications of food equipment (e.g., probes, gaskets, membranes). These materials should meet the same sanitary design and cleanability requirements as metals when used in these applications as described in 3 A Sanitary Standards and other standards. Non-metal surfaces, in general, lack the corrosion resistance and durability of metal surfaces, therefore, maintenance programs should include frequent examination for wear and deterioration under continued use, and replacement as appropriate.

Non-metal materials used in food contact surfaces include:

- **Plastics, rubber, and rubber-like** materials that should be food grade and should meet the requirements designated under 3A Sanitary Standards (18-03 and 20-20). Multi-use plastics, rubber, and rubber-like materials may also be considered as *indirect food additives* under FDA regulations.
- **Ceramics** are used primarily in membrane filtration systems. They may also be used in other limited applications if wear resistance is necessary.
- **Glass** may be used as a food contact surface. These applications are limited due to the potential for breakage. Specially formulated glass materials such as Pyrex® have proven successful. When glass is used, it must be durable, break resistant or heat resistant glass. Some applications where glass is used are light and sight openings into vessels and in very limited glass piping applications.
- **Paper** has been used over the years as a gasket material in piping systems designed for daily disassembly. Paper is considered a single use material.
- **Wood**, which is highly porous and difficult to clean, should be avoided as a food contact surface. Wood is restricted in food service applications by most regulatory agencies, with

the exception of hardwood cutting boards and tight grain butcher blocks.

Surface Texture and/or Finish

If any surface is ground, polished, or textured in any way, it must be done so the final surface is smooth, durable, free of cracks and crevices, and meets the other sanitary design requirements described above. 3A Sanitary Standards require that ground or polished stainless steel surfaces meet a No. 4 ground surface, and unpolished surfaces meet a No. 2B or mill finish. The 3-A Sanitary Standards development group has recently adopted an industry recognized method for determining an acceptable food contact surface termed *roughness average* or *Ra value*. The Ra is determined using a sensitive instrument (termed a profilometer) which employs a diamond tipped stylus to measure peaks and valleys in a relatively smooth surface.

Construction and Fabrication

Food equipment should be designed and fabricated in such a way that all food contact surfaces are free of sharp corners and crevices. All mating surfaces must also be continuous (e.g., substantially flush). Construction of all food handling or processing equipment should allow for easy disassembly for cleaning and inspection. Where appropriate (e.g., vessels, chambers, tanks), equipment should be self-draining and pitched to a drainable port with no potential hold up of food materials or solutions (Fig. 1).

Piping systems not designed for routine disassembly must be sloped to drain (Fig. 2). Piping systems installed in modern food processing systems designed for cleaning-in-place (CIP), require special consideration and close monitoring with regard to drainage.

A. Internal Angles

Internal angles should be coved or rounded with defined radii as shown in Fig. 3. Equipment standards specify appropriate radii for specific equipment applications and components. For example, radii requirements stated in the 3A Sanitary Standards

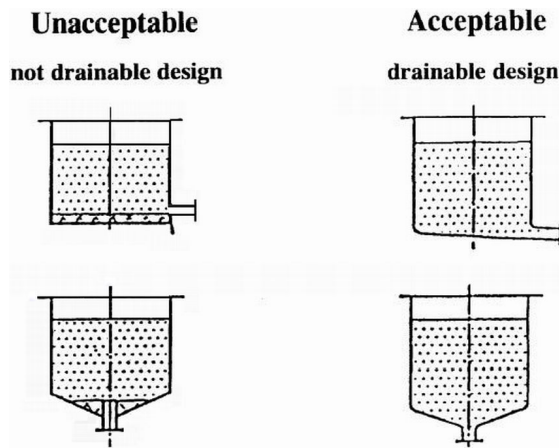


Figure 1. Examples of acceptable vs. unacceptable self-drainage design for tanks and vessels (Adapted from EHEDG, 1995).

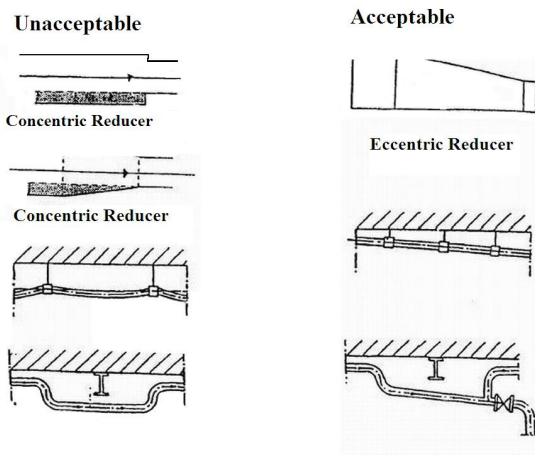


Figure 2. Drainage of pipes (From Graham, 1992)

indicate that “all internal angles 135 degrees or less should have a minimum radii of 1/4 inch (6.35 mm).” The standards allow for smaller radii where needed for function within certain specifications.

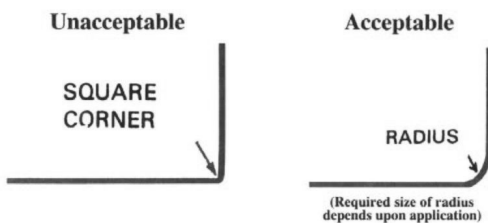


Figure 3. Acceptable vs. unacceptable internal angles of food equipment (From FDA, 2000)

B. Permanent Joints

All joints should be smooth, durable, and meet all sanitary design criteria. Equipment standards generally require that welded joints on stainless steel surfaces be continuous, butt-type joints (See Fig. 4) and ground to at least as smooth as a No. 4 finish. If the welded joint is at a corner, it must be covered to the appropriate radius and ground smooth (see Fig. 5). Use of soldered joints should be limited by application with use of only non-toxic materials. Press fits and shrink fits are generally discouraged and should be limited only to applications where welded joints are not possible (e.g. bushings).

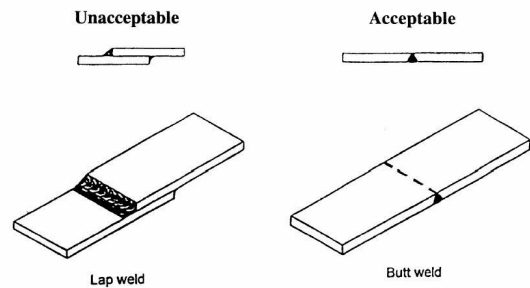


Figure 4. Permanent welded joints showing butt weld vs. lap weld (Adapted from EHEDG, 1995)

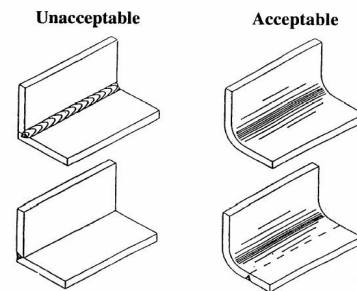


Figure 5. Corner welds in food equipment (from FDA, 2000).

C. Connections, Attachments, and Ancillary Equipment

Care should be taken when connecting pipes, gauges, thermometers, probes, or other equipment to food contact surfaces. It is necessary to ensure the connection does not create a dead end or an area where food product can accumulate and is not accessible to cleaning solutions. Such connections should be *close coupled* (e.g., pipe connection should

not be of length greater than one pipe diameter) as shown in Fig. 6. Examples of an acceptable and an unacceptable gauge connection are shown in Fig. 7.

Shafts, bearings, agitators, and other attachments or ancillary components should be attached to food equipment in such a way that the food contact zone is sealed from contamination caused by leakage of lubricants or other contaminants into the product zone. Such components should be accessible and removable for cleaning. Threads of food equipment are to be avoided in or over the food product zone.

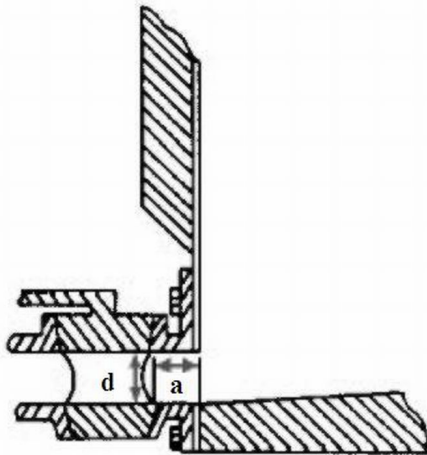


Figure 6. Closed connection length (a) no greater than the pipe diameter (d) (From FDA, 2002)

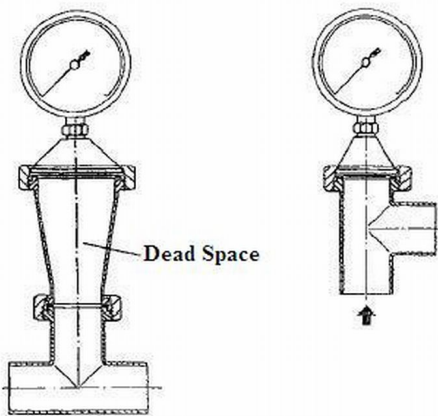


Figure 7. Acceptable vs. unacceptable gauge connection (From FDA, 2000)

D. Openings, Covers, and Top Rims

Any opening or cover should be designed, fabricated, and constructed in such a manner as to adequately protect food products from contamination and to divert potential contamination away from the food product zone. Openings should be lipped and

covered with a shoe box type design (See Fig. 8). And the top rims of equipment should be constructed and fabricated to avoid the collection of water droplets or dust (See Fig. 9).

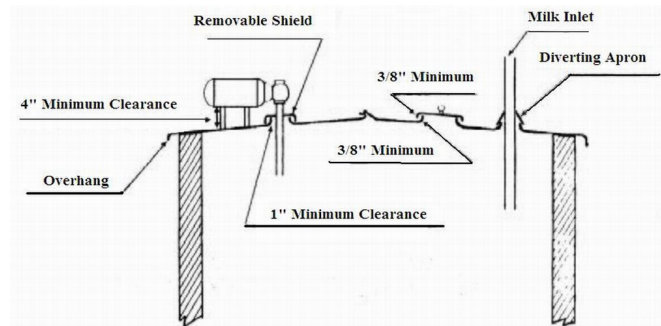


Figure 8. Acceptable shoe box design openings and covers (From FDA, 2000).

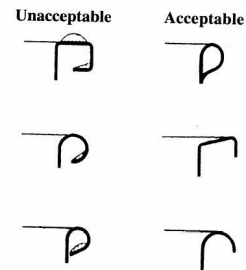


Figure 9. Top rim of food equipment (From FDA, 2000)

Non-Product Contact Surfaces

Non-product contact surfaces of food equipment are a well documented source for environmental contamination of a food facility with pathogens (especially *Listeria monocytogenes*). These areas can also be harborage areas for insects and rodents. Therefore, care should be used in evaluating these surfaces of equipment with regard to sanitary construction and design. In general, non-product surfaces of equipment should be constructed with appropriate materials and fabricated in such a manner as to be reasonably cleanable, corrosion resistant, and maintenance free. As much as is practicable, tubular steel equipment framework should be entirely sealed and not penetrated (e.g., bolts, studs), to avoid creating niches for microorganisms (see Fig. 10). Whenever practicable, attachments should be welded to the surface of the tubing and not attached via drilled and tapped holes.

Ledges or areas where dust can collect should be avoided. Tops of equipment, shields, covers, or boxes, should be sloped at a 45 degree angle or more. To avoid niche areas for microbiological growth, the legs of equipment should be sealed at the base and not be of hollow design. Threads used on leveling components should be of the enclosed type as shown in Fig. 11.



Figure 10. Tubular Framework with Bolted Attachments Potential Microbial Niche (From Marconnett, 2004)

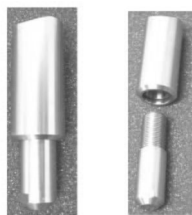


Figure 11. Enclosed threads on leveling components (from Marconnett, 2004)

Food Equipment Installation

Food equipment should be installed in a logical sequence to avoid cross contamination. Space around and between equipment and between equipment, and walls should be adequate enough to allow for sufficient cleaning. There should be no potential harborage for insects and rodents. Unless sealed to walls, food equipment should be at least 4 inches from walls. Floor mounted equipment should be sealed to the floor, platform, or pedestal or should be no less than 6 inches from the floor. Table mounted equipment should be sealed to the table, or be no less than 4 inches from the counter top (see Fig. 12).

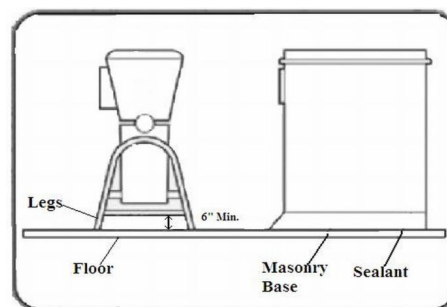


Figure 12. Floor mounting of stationary food equipment (from FDA 2004b).

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