MGNewell
We Make It Work Better.




Food Equipment Hygienic Design: An Important Element of a Food Safety Program

By Ron Schmidt, Ph.D.

In recent years, there have been several serious, high-profile foodborne illness outbreaks in the U.S. and other parts of the world. The primary response to these outbreaks has been increased implementation of the Hazard Analysis and Critical Control Points (HACCP) system and other food safety programs, and increased reliance on third-party auditing programs. The foodborne outbreaks also triggered recent food safety legislative activity and the U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA).

Throughout my career as a food science professor, I have had concerns that much of the food equipment used in many food industry segments is not of appropriate hygienic design to ensure continuous cleanability and durability, primarily due to the lack of adequate food equipment standards for these industry segments. While the food safety systems required today are a definite improvement over what was common back in the day, I am concerned that they may not adequately stress equipment hygienic design standards. In this article, I will describe the importance and general principles of hygienic design, examine current regulatory and third-party auditing programs with regard to their emphasis on food equipment and stress the importance of effective and appropriate hygienic design standards.

We need to take a minute to thank an important microorganism, *Listeria monocytogenes*, the food pathogen that has had the most impact on the many improvements in facility hygienic design in the past 30 years. Increased use of corrosive chemicals in *L. monocytogenes* control programs has created new challenges for food equipment manufacturers as well.

Inadequate cleaning and sanitizing programs, and poor equipment design, construction and maintenance have been listed as causative factors in foodborne illness outbreaks. For example:

• In the 1960s, *Salmonella* contamination issues in dry milk products led to more stringent equipment surveillance in milk drying facilities by regulatory officials, and played a role in the development and improvement of 3A Sanitary Standards for dry milk processing and handling equipment.

• In 1994, a nationwide *Salmonella* Enteritidis outbreak[1] from ice cream was caused by a contaminated tanker truck that had not been effectively cleaned after hauling raw, unpasteurized eggs. It was not clear from the investigative report whether the truck also had crevices or surfaces that affected cleanability or created niches to harbor the pathogen.

• In 2008, an *L. monocytogenes outbreak* was linked to deli meat products in Canada[2] where the contamination may have been associated with a meat slicer that had uncleanable surfaces and possible stress cracks.

• In 2009, a far-reaching and well-publicized *Salmonella* Typhimurium outbreak was associated with peanuts and peanut products.[3] Investigations revealed that facility maintenance, equipment design and maintenance, cleaning and sanitizing

Greensboro Division / Corporate Headquarters
301 Citation Court
Greensboro, NC 27409
Phone: 336.393.0100 / 800.334.0231
Fax: 336.393.0140

Louisville Division
4400 Bishop Lane, Suite 112
Louisville, KY 40218
Phone: 502.459.7475 / 800.459.7475
Fax: 502.459.7633

Nashville Division
334 Free Hill Road, Suite B
Hendersonville, TN 37075
Phone: 615.822.3030 / 855.749.4820
Fax: 615.822.3031

www.mgnewell.com sales@mgnewell.com espanol@mgnewell.com

programs were major causative factors in the outbreak.

• In 2011, another deadly *L. monocytogenes* outbreak in cantaloupes was clearly caused by equipment that had been inadequately cleaned, was poorly maintained and was not of cleanable design and construction.[4]

Hygienic Design and Construction Standards

Worldwide, several organizations are involved in food equipment hygienic design. Despite variation between these organizations with regard to their standards and/or recommendations, they are in general harmony with food safety intent and the importance of the application of sound principles of hygienic design and construction. Some of these organizations are generally described below. More detailed discussion is provided for 3A Sanitary Standards Inc. (3A SSI), with which I am most familiar, to provide more insight into the use of equipment standards by regulatory and industry personnel.

European Hygienic Design Group (EHEDG).[5] A collaborative effort of equipment manufacturers, food industries, research institutes and public health authorities, EHEDG is a recognized authority in hygienic design and engineering throughout the world. EHEDG promotes hygienic design through its guidelines, documents, training materials, education programs and laboratory testing methods for cleanability and related topics. The Center for Integrated Food Manufacturing[6] at Purdue University is now partnering with EHEDG to offer training workshops and provide food equipment testing in the U.S.

National Sanitation Foundation (NSF) International.[7] NSF International has high visibility in the food industries worldwide, with a variety of certification and auditing programs, training programs and publications. The NSF mark is most commonly found on equipment used in the retail foods and foodservice industries and is recognized as an indication that such equipment meets NSF standards. Further, *NSF/3-A/ANSI 14159-1 Hygiene Requirements for the Design of Meat and Poultry Processing Equipment*[7] has been developed in collaboration with 3A SSI.

3A Sanitary Standards Inc.[8] 3A SSI is best known for equipment standards in the dairy industry. However, 3A is not just for dairy. In recent years, other industries have recognized these standards, with more food processors specifying 3A standards in equipment purchases. 3A SSI has been open to working with other industry groups and welcomes participation from other food industry sectors interested in the development of appropriate standards for their equipment. A general 3A standard, which embodies the general principles of hygienic design, is also being developed that equipment fabricators and food industry personnel may use as a guideline. 3A SSI has been very active in outreach training and knowledge transfer through its website and hygienic design workshops held at the company's annual meeting and at other venues.

3A SSI is organized into three interest groups: fabricators (equipment manufacturers), users (processors) and sanitarians (state and federal regulatory sanitarians and academicians). This working model is unique in that the standards development process requires representation and input from regulatory sanitarians in addition to industry representatives.

The 3A symbol provides assurance that equipment meets the applicable 3A Sanitary Standard. Obtaining this symbol requires an on-site evaluation (at the facility where the equipment is manufactured) of the equipment by a certified conformance evaluator. A system is also in place to file reports of alleged noncompliance if equipment bearing a 3A symbol is observed (usually during a regulatory inspection) and deemed out of compliance with the applicable 3A standard.

General Principles of Equipment Hygienic Design and Construction

Improved hygienic design enhances cleanability, decreasing the risk of biological (pathogens), physical and chemical (e.g., allergens) contamination. Furthermore, equipment that is designed and constructed to meet hygienic principles is easier to maintain and reduces the risks of physical hazards (e.g., metal fragments from food equipment) in food processing.

Surfaces of food equipment and related ancillary equipment are divided into food contact and nonfood product contact surfaces. While most of the discussion in this article relates to food contact surfaces, it should be recognized that nonfood product contact surfaces are very important and cannot be overlooked, as these surfaces have been implicated in environmental contamination.

Under 3A Sanitary Standards, the accepted definition of a food contact surface is *any surface that has direct contact with food residue, or where food residue can drip, drain, diffuse or be drawn.* All food contact surfaces must meet specific hygienic design and fabrication requirements to ensure cleanability. Corrosion resistance and durability of the materials used are also important to maintain cleanability. Where appropriate, equipment should also be constructed to allow accessibility for inspection to observe whether it is adequately cleaned.

Hygienic equipment design encompasses the following:
Materials: Food contact surfaces of food equipment must be fabricated from materials that are smooth, impervious, nontoxic, nonabsorbent and corrosion resistant under conditions of intended use.[9] Each of these terms may be open to interpretation. It is only through well-written equipment standards that each becomes defined.

Primarily because of its corrosion resistance and durability compared with most other materials available, stainless steel is by far the preferred material for fabricating food equipment. However, it should be noted that there are many types of stainless steel and that not all grades are recommended for food contact surfaces.[10, 11] 3A Sanitary Standards specify AISI 300 series (excluding 301), with 304 and 316 stainless steel being most common. These nonmagnetic stainless steel materials are composed of alloys in which chromium and iron predominate. Chromium oxide that forms on the surface (i.e., passive layer) protects the inner layer (i.e., active layer), containing iron, from corrosion. If the passive layer is compromised, the surface is vulnerable to corrosion when exposed to chlorides (e.g., chlorine), other corrosive materials or other environmental stresses. Thus, it is generally recommended that a passivation treatment be done, following a recommended procedure and frequency.[12]

3A Sanitary Standards allow for the use of other metals for specific applications, provided that they are demonstrated to be at least as corrosion resistant as 300 series stainless steel. In addition, there has been an increased use of nonmetal materials (e.g., plastics, rubber, ceramic) in food contact applications. At the minimum, such materials must be safe and nontoxic through regulatory approval as an indirect additive or food contact substance. However, such approval does not provide assurance that the material is durable and will maintain a cleanable surface under conditions of intended use. When purchasing equipment fabricated using these materials, it is recommended that such assurances be provided by the manufacturer.

Surface Finish and Modification: Even the most durable, corrosion-resistant material is not recommended as a food contact surface if the surface is rough or if it has cracks and crevices. For food contact, stainless steel surfaces are usually finished through polishing, grinding or other means to obtain a smooth finish.[13] Most hygiene standards require that food contact surfaces have a roughness average (Ra) of 0.8 µm or less, determined using a profilometer, which corresponds to a No. 4 finish on stainless steel.[8, 14, 15] Stainless steel with a 2B or milled finish is acceptable, with limitations. The 2B finish is used for its superior fat-release properties in equipment intended to process and handle higher-fat products (e.g., butter, meats).

Construction and Fabrication: Food equipment must be constructed and fabricated to ensure that interior surfaces are free of cracks, crevices or sharp angles. 3A and other standards specify that interior angles or corners (including gasket grooves) be rounded to a specific radius. Fabricated equipment must also be constructed such that it is pitched to a drainable port and is self-draining (no holdup).

To maintain appropriate fluid motion in cleaning and processing, all connections to equipment must be “closed coupled” such that no dead ends or dead spaces exist. Dead spaces can be inadvertently created when a connection pipe is used

on a tank or line to attach ancillary equipment (e.g., thermometers, gauges). To prevent a dead space, the length of the connecting pipe cannot exceed its diameter.

A common error in equipment construction and fabrication (and repair) is the use of inappropriate welds and welding materials, and/or the use of noncleanable bolts and threads within the food contact zone. Hygienic design standards generally specify the welding materials allowed and that welds be of butt type (not overlapping) and ground to a smooth finish (Ra of 0.8 µm or less).[8, 16] Bolts and threads, if necessary, in the food contact zone must be of the acceptable hygienic type.

Installation, Operation and Maintenance: In general, food equipment should be installed to allow 360-degree access for cleaning and housekeeping. If mounted to the wall or floor, it should be properly sealed. Depending upon its size and type, food equipment should be elevated either on a pedestal or on legs at a height that meets recommendations [17] to allow cleaning under the equipment. All legs, levelers and related supports should be designed and constructed to have no hollow areas, penetrated framework or exposed threads that are not of cleanable design. Food equipment should be operated in a way that ensures effective cleaning and does not allow cross-connections between product and other solutions (e.g., cleaning solutions, allergens, raw food materials). The majority of the food equipment is cleaned and sanitized using mechanical or clean-in-place (CIP) systems. However, it should be noted that not all food equipment is designed for total automated CIP cleaning and should be partially disassembled for manual cleaning as required.

Regulatory Surveillance Programs

There is considerable variation in regulatory inspection programs with regard to auditing and evaluating equipment. FDA inspections for most food industries follow current Good Manufacturing Practices.[18] The provisions for equipment design and construction use general terminology (e.g., *adequately cleanable, corrosion resistant, nontoxic*) and do not explicitly mention specific hygienic design and construction criteria to further clarify these terms. Thus, interpretation of the finer points of hygienic design is left to the individual inspector or auditor. Under FDA regulatory HACCP for seafood[19] and fruit and vegetable juices,[20] it is required that facilities and food contact surfaces be addressed through Sanitation Standard Operating Procedures (SSOPs). Interpretation of the adequacy of these SSOPs and their implementation varies by individual facility and by regulatory official.

FSMA requires that all food facilities implement a Hazard Analysis and risk-based preventive controls plan. The implementation and enabling regulations have not been finalized. However, it is likely that food contact surfaces will be covered under prerequisite programs similar to what's been done in the FDA-mandated HACCP programs.

Grade A milk and milk products are regulated under the National Conference on Interstate Milk Shipments (NCIMS),[21] a cooperative federal/state program in which facilities are inspected under the Grade A Pasteurized Milk Ordinance (PMO).[18] Under the PMO, utensils and equipment shall be constructed of materials that are smooth, nonabsorbent, corrosion resistant and nontoxic, and constructed as to be easily cleaned. While these general terms are open to interpretation, the PMO provides more definition by referencing 3A Sanitary Standards as meeting these PMO provisions. Under the NCIMS program, equipment is evaluated during routine inspections, state ratings and FDA check ratings. In addition, FDA conducts state training programs, has issued M-I-00-2: "Milk and Milk Product Equipment — A Guide for Evaluating Construction"[22] and participates in regional dairy equipment review committees with participating states.

The U.S. Department of Agriculture (USDA)/Agricultural Marketing Service (AMS) provides voluntary grading and inspection of dairy facilities. This agency routinely performs equipment review on equipment before it is installed in a plant and during plant inspections, and accepts 3A Sanitary Standards as meeting their requirements. For equipment for which standards do not exist, the equipment review follows *USDA Guidelines for the Sanitary Design and Fabrication of Dairy Processing Equipment*[23] which follows 3A standards.

Under traditional meat and poultry regulations, the USDA/Food Safety and Inspection Service maintained an approved list of equipment allowed in facilities. However, the agency has moved away from this system in recent years with the advent

of HACCP regulations. The AMS is currently providing an equipment review as a service to the meat and poultry industry.

Third-Party Auditing Programs

A variety of third-party organizations audit food facilities. In recent years, auditing to meet standards under the Global Food Safety Initiative (GFSI), [24] required by major retail foods outlets, has been dominant. The primary GFSI-benchmarked food safety schemes include: British Retail Consortium, Food Safety System Certification 22000 (FSSC 22000), Global GAP, International Food Safety and Safe Quality Food.

The primary focus of audits under these GFSI benchmarks is on the overall food safety management system, including HACCP and related programs. Food equipment design, construction and maintenance are addressed to a varying degree under the HACCP prerequisite program requirements, as well as in other provisions of the standards where general terminology is used. The FSSC (e.g., ISO 22000/PAS 220) scheme has, perhaps, the most specific verbiage with regard to equipment and provides that food contact equipment be designed and constructed *to facilitate appropriate cleaning; of durable materials; of materials designed for food use; be impermeable and rust- or corrosion-free; and meet established principles of hygienic design.*

Summary and Conclusions

Food equipment hygienic design is more important than ever before and is addressed in a general manner in most regulatory and industry food safety programs. However, the terms used are only broadly defined, and interpretation of acceptability is left to the individual auditor and her or his particular aptitude for equipment evaluation.

As we move forward with the implementation of food safety programs, we also need to give more scrutiny to hygienic design features of equipment through the development of more specific and meaningful equipment standards to ensure compliance and food safety. The American Meat Institute and Grocery Manufacturers Association have recently issued guidelines that include hygienic design principles. [25] While this is definitely a step in the right direction, more specific standards are needed. Many segments of the food industry could benefit from developing standards that are specific to equipment used in a particular commodity area. Accomplishing this goal will take a concerted effort and partnership between the food industry and regulatory communities.

***Ron Schmidt, Ph.D.**, professor emeritus, recently retired after 36 years in teaching, research and extension in the Food Science and Human Nutrition Department, University of Florida. The primary emphasis of his academic career has been in dairy foods, food safety, food regulations, food fermentation and biochemistry. He taught a variety of undergraduate and graduate food science classes throughout his career, most recently Food Regulations and HACCP Systems. Through his extension and outreach programs, he is recognized for his food industry training and consulting programs in dairy processing, food safety, HACCP and other areas. He has served in a leadership role in various food science professional organizations and is currently on the board of directors of the NCIMS Program and is the chairperson of 3A SSI.*

References

1. Hennessy, T. W., C. W. Hedberg, L. Slutsker, K. E. White, J. M. Besser-Wiek, M. E. Moen, J. Feldman, W. W. Coleman, L. M. Edmonson, K. L. MacDonald and M. T. Osterholm. 1996. A national outbreak of Salmonella Enteritidis infections from ice cream. *N Engl J Med* 16:1281–1286.
2. www.phac-aspc.gc.ca/alert-alerte/listeria_200808-eng.php.
3. www.cdc.gov/salmonella/typhimurium/update.html.
4. www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/120811/index.html.
5. www.ehedg.org/.
6. ag.purdue.edu/foodsci/cifm/Pages/default.aspx.
7. www.nsf.org.
8. www.3-a.org/.
9. edis.ifas.ufl.edu/FS119.
10. Tuthill, A. H. and R. A. Covert. 2000. Stainless steels: An introduction to their metallurgy and corrosion resistance. *Dairy Food Environ San* 20:506–517.
11. Schmidt, R. H., D. J. Erickson, S. Sims and P. Wolff. 2012. Characteristics of food contact surface materials: Stainless steel. *Food Prot*

Trends 32(10):574–584.
12. Anonymous. 2007. Passivation of stainless steel: Summary of guidelines recommended by 3-A Sanitary Standards and the European Hygienic Engineering Design Group (EHEDG). *Trends Food Sci Technol*18:S112–S115.
13. Tuthill, A. and R. Avery. 1992. Specifying stainless steel surface treatments. *Adv Mater Process*December:34–38.
14. ISO. 1984. Surface roughness — terminology — Part 1; Surface and its parameters. ISO 4287-1, International Organization for Standards, Geneva, Switzerland.
15. Bilgili, S. F. 2006. Sanitary/hygienic processing equipment design. *Worlds Poult Sci* J 62: 115–122.
16. Eastwood, C. A., D. L. Woodall, D. A. Timperley, G. J. Curiel, P. Peschel and G. Hauser. 1993. Welding stainless steel to meet hygienic requirements. Document 9. European Hygienic Engineering Design Group (EHEDG).
17. www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/default.htm.
18. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=110.
19. www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5048589.
20.www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/JuiceHACCP/ucm073594.htm.
21. www.ncims.org.
22. www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/CodedMemoranda/MemorandaofInformation/ucm080156.htm.
23. www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRD3641024.
24. www.mygfsi.com/
25. Higgins, K. T. 2012. Standardized sanitation. *Food Eng* August 6.