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Principles of Sanitary Design

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By Joe Stout, RS

10 Principles of Equipment Design for Ready-to-Eat Processing Operations

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In January 2001, the American Meat Institute (AMI) Executive Board members, comprised of meat and poultry company CEOs, set forth their vision to share the best practices of member companies related to enhancing food safety in a noncompetitive and cooperative effort. Sanitary equipment design fit within this category. This decision set the stage for the creation of the AMI Equipment Design Task Force (EDTF), charged with developing equipment sanitary design principles that meet the expectations of the meat and poultry industries.

The EDTF is comprised of several AMI member companies, including BAR-S, ConAgra, Excel, Kraft, Hatfield Packing, Hormel, Smithfield Meats, Minot, Sara Lee and Tyson. These companies, represented on the task force by engineers, quality managers and sanitarians, established priorities and considered how improved equipment designs could favorably impact food safety goals. The EDTF's objectives not only centered on improving sanitary design to reduce and eliminate potential harborage areas where undesirable microorganisms might gather, but also on maintaining and extending product shelf life and other product quality attributes.

The result of the task force's initial work is a set of working principles that provides guidance to both equipment manufacturers and ready-to-eat (RTE) meat and poultry processors on elements of improved sanitary design under a general standard. The AMI 10 Principles of Sanitary Design also offer basic tenets that food processors in other categories can use. A flow chart for equipment design review and accompanying checklists created by the EDTF members provide a systematic look at the interation of equipment manufacturers and food processors in evaluating sanitary design attributes under the umbrella of the 10 Principles of Sanitary Design.

The Principles Defined And Detailed

During the development of the AMI 10 Principles of Sanitary Design, one of the most significant areas of the EDTF's discussion centered on the lack of understanding and/or the lack of use of standards pertaining to sanitary design of equipment. While there are many good sanitary design standards available for food processing equipment, they sometimes are not well understood, or perhaps unread, due to their complexity. Equipment manufacturers noted that equipment designs vary widely from processor to processor, even with the same piece of equipment in the same type of processing plant or industry, such that they are in effect designed to each company's individual preferences and specifications.

With these challenges in mind, the task force's first goal was to develop a framework in which all RTE meat and poultry processors and equipment manufacturers could understand the intentions and expectations of these many existing standards. The team began by using the NSF 14159-1 equipment design standard used by the U.S. Department of Agriculture's Agricultural Marketing Service (USDA AMS) as the foundation for the AMI 10 Principles of Sanitary Design. By developing an industry model rather than a company-specific model for sanitary equipment design, processors benefit from improved design that is accepted by other member companies, and equipment makers benefit from improved manufacturing efficiencies. As implementation of these principles has taken hold among AMI member companies, many equipment suppliers are now making an EDTF model, rather than a model for Hormel, a model for ConAgra, etc. Each of the 10 Principles of Sanitary Design address an important aspect of sanitary design associated with the successful implementation of this industry model as detailed in this article.

Principle 1. Cleanable to a Microbiological Level. *Food equipment must be constructed and be maintainable to ensure that the equipment can be effectively and efficiently cleaned and sanitized over the lifetime of the equipment. The removal of all food materials is critical. This means preventing bacterial ingress, survival, growth and reproduction.*

This includes product and non-product contact surfaces of the equipment. While a piece of equipment may be visually clean,

Aluminum

Use aluminum only when necessary. When aluminum is used anodite or applicable process to inhibit corrosion and wear. Inspect regularly.

Avoid coated aluminum in Zone 1

Salt Brine Corrosion Test

Bearings 1, 2, and 3: Thin, dense, chrome-plated
Bearings 3, 5, and 7: 400 series stainless steel
Bearing 4: Coated
Bearing 6: Black oxide coated

Choose Wisely!

Figure 1. Principle 2: Made of Compatible Materials.

absent of soil or organic matter, it does not necessarily mean that it is microbiologically clean. What food processors would like to see is a piece of equipment that can be cleaned to a microbiological level, as well as clean to the eye. This principle refers to any kind of unwanted microorganisms, including pathogens and spoilage organisms.

Principle 2. Made of Compatible Materials. *Construction materials used for equipment must be completely compatible with the product, environment, cleaning and sanitizing chemicals, and the methods of cleaning and sanitation. Equipment materials of construction must be inert, corrosion resistant, nonporous and nonabsorbent (Figure 1).*

This principle emphasizes the importance of making sure that a product surface is impervious to the materials to which it is exposed. This is very important because the use of incompatible construction materials may cause corrosion or pitting on a material such as aluminum, for example, that would create a harborage area where microorganisms, water, soil or food can collect. Essentially, the processor wants to minimize areas where microorganisms can hide, live and survive. By eliminating incompatible materials in the construction of the processing equipment, the processor reduces the likelihood of creating a hospitable environment where bugs can grow.

Principle 3. Accessible for Inspection, Maintenance, Cleaning and Sanitation. *All parts of the equipment shall be readily accessible for inspection, maintenance, cleaning and/or sanitation. Accessibility should be easily accomplished by an individual without tools. Disassembly and assembly should be facilitated by the equipment design to optimize sanitary conditions.*

Dave Kramer's quote applies here: "If you can't see it and you can't touch it, then you can't clean it." In other words, in a non-CIP environment you need to be able to get everything clean. There are four elements of cleaning that processors use: mechanical action, temperature, a chemical that will break up fats and proteins, and time. With these, the processor should be able to remove any food soil from equipment, as long as he gets the mechanical action and chemicals in the right amount of time and in the right concentration into those places where there are soils. Designing equipment to increase accessibility for cleaning ensures the success of this four-pronged protocol, since the soil will be more visible.

In addition, the more accessible the equipment is for cleaning by sanitation employees, the easier it is for them to do the job safely, properly and procedurally. If you are a sanitation employee and you need to call a maintenance employee to come and remove a guard or to mechanically get access to a certain area on a piece of equipment, cleaning will take that much more time and be that much more difficult to do. Principle 3 underscores the benefit of making systems easy for people to do the right things.

Principle 4. No Product or Liquid Collection. *Equipment shall be self-draining to assure that food product, water, or product liquid does not accumulate, pool or condense on the equipment or product zone areas.*

The processor does not want to have any areas in the system where water can collect, or where product can collect and later develop into a foreign material as it dries out, crusts and hardens. Standing water can serve as a harborage or growth point for microorganisms, and any time moisture is introduced into an environment there is an increased chance for microbial growth.

Principle 5. Hollow Areas Hermetically Sealed. Hollow areas of equipment (e.g., frames, rollers) must be eliminated where possible or permanently sealed (caulking not acceptable). Bolts, studs, mounting plates, brackets, junction boxes, name plates, end caps, sleeves and other such items must be continuously welded to the surface of the equipment and not attached via drilled and tapped holes (Figure 2).

In most food processing plants, there is a lot of framework used on pieces of equipment, and we want to make sure that there are no penetrations that would allow moisture and/or food materials or organic matter to get inside or under the surface of equipment. If this occurs, microorganisms will grow, leak out and recontaminate the environment. Eliminating or sealing hollow areas is easily addressed by equipment designers. One example is when equipment manufacturers would put a name tag on the piece of equipment, using a pop rivet to attach it. But a pop rivet is a penetration of the equipment surface that is not sealed, allowing water to get in. Because of the EDTF's work, many designers are eliminating the pop-riveted name tags today.

Figure 2. Principle 5: Hollow Areas Hermetically Sealed.

Principle 6. No Niches. *All parts of the equipment shall be free of niches such as pits, cracks, corrosion, recesses, open seams, gaps, lap seams, protruding ledges, inside threads, bolt rivets and dead ends. All welds must be continuous and fully penetrating.*

This principle means just what it says: Food processing equipment should not have harborage points. Not only should equipment be evaluated to ensure that the original welding by the manufacturer is continuous and niche-free, but processors also should take care when modifying equipment in the plant environment. Often equipment is modified by the processor to make it fit into a room or to make it consistent with other designs or product lines existing in the plant, and during such modification activities a hollow framework might be penetrated and create a microbial growth niche.

Principle 7. Sanitary Operational Performance. *During normal operations, the equipment must perform so it does not contribute to unsanitary conditions or the harborage and growth of bacteria.*

This principle is linked to Principle 4: A processor doesn't want anything on the production line that is going to cause microbial counts to increase throughout the course of the day. During operation, you want to make sure that you have minimal moisture and product buildup in different product zones. In an ideal world, the processor wants to increase productivity and run the lines as efficiently and safely within the regulated timeframe. If, for example, the processor operates a wet process that adds moisture all the time, there likely will be increased microbial counts on the conveyor. Designing the conveyor or other equipment parts to minimize product buildup and moisture allows the production run to be increased to the extent allowed by regulation and to maximize the benefit of the operation during that time while minimizing any type of quality defect.

Principle 8. Hygienic Design of Maintenance Enclosures. *Maintenance enclosures (e.g., electrical control panels, chain guards, belt guards, gear enclosures, junction boxes, pneumatic/hydraulic enclosures) and human machine interfaces (e.g., pushbuttons, valve handles, switches, touch screens) must be designed, constructed and be maintainable to ensure food product, water, or product liquid does not penetrate into, or accumulate in or on the enclosure and interface. The physical design of the enclosures should be sloped or pitched to avoid use as a storage area (Figure 3).*

Engineers involved with the EDTF stressed the importance of this principle, noting that there are many equipment installations whereby an ideally designed piece of equipment is placed adjacent to an electrical box (a perfect harborage place for water leakage) and/or pushbuttons that are not cleanable. This principle not only addresses product contact surfaces, but the entire asset represented by the piece of equipment. This moves the consideration beyond the surface to ensure that all of the maintenance enclosures and other connections to the equipment are appropriately designed and also can be cleaned and sanitized.

Principle 9. Hygienic Compatibility with Other Plant Systems. *Design of equipment must ensure hygienic compatibility with other equipment and systems (e.g., electrical, hydraulics, steam, air, water).*

Ensuring the hygienic compatibility of the equipment with other systems is both a processor responsibility to the equipment manufacturer as well as an equipment manufacturer responsibility to the processor. The processor wants to make sure that equipment introduced into a facility is designed and built to be usable with the plant systems. Processors can communicate to equipment manufacturers the established electrical, hydraulic, steam, compressed air and oil filtration and water systems information to assist in improved design strategies prior to the equipment being built and arriving at the plant.

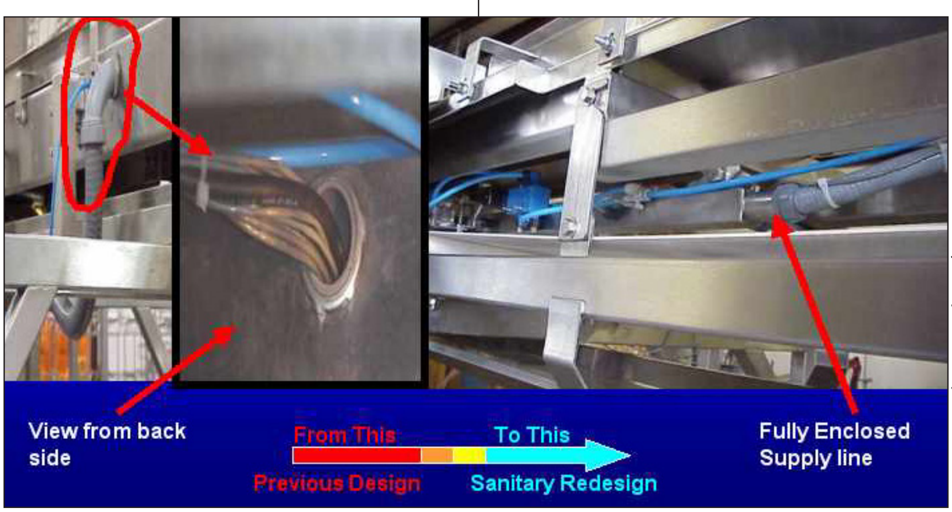


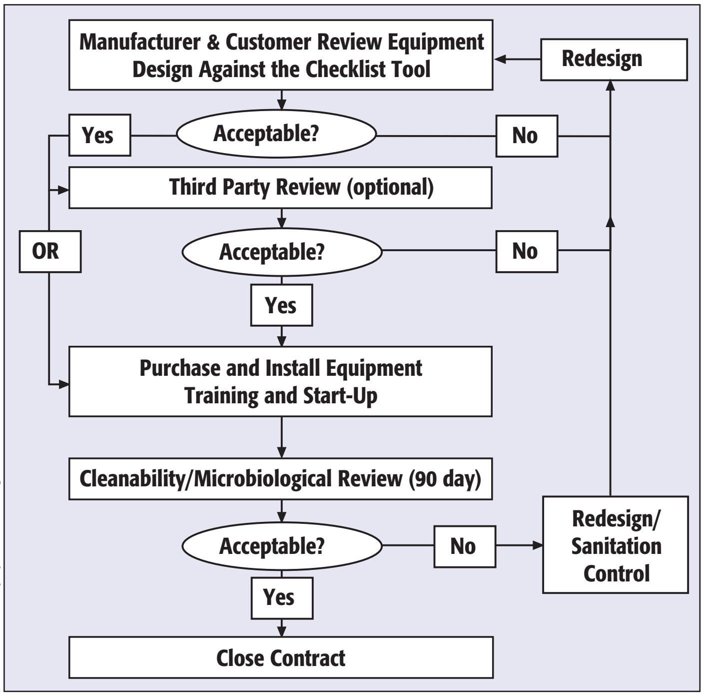
Figure 3. Principle 8: Hygienic Design of Maintenance Enclosures.

Principle 10. Validate Cleaning and Sanitizing Protocols. *The procedures prescribed for cleaning and sanitation must be clearly written, designed and proven to be effective and efficient. Chemicals recommended for cleaning and sanitation must be compatible with the equipment, as well as compatible with the manufacturing environment.*

Equipment manufacturers are not cleaning procedure experts; their manufacturing facilities resemble machine shops teeming with lathes and metal shaping equipment. It is a rare equipment manufacturing operation that would have the ability to wash a piece of equipment, much less sanitize it. However, food processors utilize cleaning and sanitizing systems everyday, and can provide useful insight as to the best way to clean and sanitize equipment in given plant environments. This principle recommends that the equipment manufacturer work with the individual processor during the equipment design stage, so that by the time the equipment is being constructed, the equipment company will have a fairly good vision of how the equipment can be cleaned and sanitized in a processing plant. When it is delivered to the processing plant, the processor also will have a clear vision of what needs to be done to successfully clean it.

Charting A Standardized Course

The sanitary equipment process flow chart for design review illustrates the interaction of the processor and the equipment manufacturer to achieve the benefits of an industry model approach within the framework of the 10 Principles of Sanitary Design (Figure 4). As an example, let's say that a food company wants to purchase a new loader from an equipment manufacturer. The two companies begin the design review process for this piece of equipment by using the checklist tool created by AMI that allows for consistent evaluation of



Source: AMI Equipment Design Task Force

Figure 4. Process flow chart for design review.

equipment by both processors and manufacturers. Figure 5 shows a portion of the checklist developed for the review of Principle 1: Cleanable to a Microbiological Level. Both the food company and the equipment supplier will go through these equipment checklists, which are based on the 10 Principles of Sanitary Design, and if they determine through this preliminary review that the equipment is welldesigned in accordance with the sanitary design principles, the process continues to Phase 2. If not, the equipment goes back to redesign.

At Phase 2, the processor now has the option of going to the USDA AMS or NSF International, both of which offer a service for third-party evaluation of equipment for sanitary design. If this option is exercised, the third-party reviewer will look at the piece of equipment in question as an additional check to verify that the equipment incorporates the desired sanitary design elements. In most cases, the equipment will be acceptable if the equipment manufacturer and the processor use the checklist tool to conduct a preliminary inspection. Again, if at any one of these review steps the parties find the equipment unacceptable, it goes back into a redesign phase.

If the equipment is acceptable following Phases 1 and 2, the processor purchases and installs the equipment in the plant. The significant aspect of Phase 3 is the 90-day period of cleanability and microbiological review by the processor in a real-world environment. In this way, the processor is able to actually test the sanitary design of the equipment in the individual plant environment, something that cannot be accomplished in the equipment manufacturer's facility as discussed earlier. During the 90-day period, the food company runs product on the new equipment and applies the appropriate cleaning and sanitizing protocols. The processor can now better determine whether the equipment is, in fact, microbiologically cleanable; for example, whether any unfriendly organisms have found harborage and at what location, or whether organisms are easily removed by routine cleaning and sanitizing.

If after the 90-day in-plant period the equipment is deemed acceptable in terms of sanitary design criteria, the processor closes the contract. If the equipment is not acceptable, either the equipment manufacturer must redesign to address the problem or the processor must develop a sanitation control that will augment a reduction in the microbial counts for that piece of equipment. For example, the parties may determine that the types of belts used need to be reconfigured or that the finish on a piece of stainless steel allows for the creation on niches, and therefore the piece needs undergo redesign. If the processor identifies an area that is extremely difficult to access and clean, it may indicate the need to redesign that specific area.

Principle 1. Cleanable to a Microbiological Level

	Reference	S	M	U
1.1 Equipment is designed to be constructed & maintained in a cleanable condition to prevent the ingress, survival & multiplication of microorganisms (measured post-installation).	NSF 5.1			
1.2 All surfaces are cleanable as measured by <1 CFU per 25 square centimeters, <1 CFU per 10 mL when the item is rinsed, acceptable RLU (device specific) when measured by residual ATP, and/or negative for residual protein or carbohydrate when using swabs to detect residual protein or carbohydrate (measured post-installation)	AMI			
1.3 All surfaces are accessible for mechanical cleaning & treatment to prevent biofilms formation (measured post-installation)	AMI			

Source: AMI Equipment Design Task Force

Figure 5. Sample portion of checklist tool used in sanitary equipment design review.

Conclusion

The goal with the AMI 10 Principles of RTE Equipment Design is continuous improvement with the robustness of our sanitation, cleaning and food safety programs. The EDTF team members and their family of processors firmly believe in working with the equipment suppliers to develop equipment with the best design that will be an enabler to deliver quality and food safe products to our consumers and customers. ■

__Joe Stout, RS__, was with Kraft Foods for 29 years and held a variety of positions in quality and sanitation. In 2010, after 10 years as director of global product protection, sanitation and hygienic design, he retired and founded Commercial Food Sanitation (CFS). CFS offers services for the food industry similar to those Joe performed at Kraft. Stout can be reached at Joe.Stout@cf-san.com.

Acknowledgment

The author would like to thank the members of the AMI Equipment Design Task Force. More information on the AMI 10 Principles of Sanitary Design can be found at www.meatami.org.

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METTLER TOLEDO

By Roy Curiel

Hygienic Design of Equipment in Food Processing

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Problems caused by microbial contamination of foods tend to be expensive, particularly if these result in recalls. As a result of the development and application of increasingly mild preservation technologies, processed foods become more sensitive to microbial (re)contamination, requiring greater control of the manufacturing process. One way to achieve this added control is to "build" hygiene into the equipment used in the food manufacturing facility from the start.

The hygienic design of equipment plays an important role in controlling the microbiological safety and quality of the products made. A hygienic factory should prevent products from having high microbial counts, from containing toxins of microbial origin, and from containing residues of chemicals used for cleaning and disinfection. In addition, the hygienic facility should prevent food from being contaminated with other non-food substances, such as lubricants, coolants and antimicrobial barrier fluids, as well as from containing foreign bodies, such as pieces of metal, plastic, packing material and insects or other vermin, or parts thereof. This may appear a complex task, but with increased activity by international standard-setting organizations more specific and workable information on this topic is now available to the food industry.

Standards and Guidelines

There is an increase in the involvement of regulatory and advisory bodies in the area of hygienic processing and hygienic design. In the European Union (EU), specific legislation, such as the Machinery Directive 98/37/EC and the Council Directive 93/43/EEC on the hygiene of foodstuffs, requires all food handling to be performed under hygienic conditions.[1-2] In the framework of the machinery directive, many technical committees (TC) continue many efforts with regard to the preparation of standards.

For example, the TC 153 has prepared the general hygiene standard EN 1672-2: Food Processing Machinery, Part 2: Hygiene Requirements.[3] This European standard sets common requirements in respect of risks to hygiene arising from the use of the machine and process. It primarily covers general aspects of hazards to the food created by the machine in order not to introduce hazards to the consumer of the food. Other specific requirements currently being prepared or already published include standards pertaining to food processing equipment, such as planetary mixers (prEN 454); food processors and blenders (prEN 12852); beam mixers (prEN 12854); chop cutting machines (prEN 13870); cube cutting machines (prEN 13871); and dough mixers (EN 453:2000).

In addition, the International Organization for Standardization (ISO) TC 199 has prepared a standard titled, "Hygiene Requirements for the Design of Machinery."[4] This international standard specifies hygiene requirements of machines and provides information for the intended use to be provided by the manufacturer. It applies to all types of machines and associated equipment used in applications where hygiene risks to the consumer of the product can occur. However, it does not cover requirements relative to the uncontrolled egress of microbiological agents from the machine.

The European Hygienic Engineering and Design Group (EHEDG) has developed similar design criteria and guidelines on the hygienic design of equipment and hygienic processing.[5-22] The EHEDG has links with the Comité Européen de Normalisation (CEN), 3-A Sanitary Standards, NSF International and ISO. As these international standard-setting organizations continue efforts to specify hygienic design requirements, food processors will be able to more effectively select and introduce such equipment into their facilities.

Selected Hygienic Design Criteria and Requirements

There are several aspects of designing hygiene into equipment that should be considered by the food processor before reengineering or introducing process equipment into the plant. In general, construction materials that may come in contact with food should not be able to make a food product toxic. Equipment must be designed to be self-drainable to make it possible to remove all residues of products and chemicals. To be cleaned without difficulty, surfaces must be smooth and free from crevices, sharp corners, protrusions, and shadow zones. When surfaces are not clean, microorganisms may be protected from destruction by heat or chemicals.

Selected criteria and basic requirements for a variety of hygienic equipment characteristics provide an overview of areas that can be addressed by food manufacturers:

Materials of construction. Materials used for the construction of a food processing plant must fulfill certain specific requirements. Product-contact materials must be inert to the product under operating conditions, as well as to detergents and antimicrobial chemicals (sanitizers) under conditions of use. They must be corrosion-resistant, mechanically stable, and such that the original surface finish is unaffected under all conditions of use. In addition, non-contact materials shall be mechanically stable, smoothly finished and easily cleaned. The reinforcement in plastics and elastomers should not be allowed to contact the food product.

Surface roughness. Product contact surfaces should be smooth enough to be easily cleanable. The roughness (or smoothness) of a surface usually is expressed in µm, as Ra-value.[23] Generally, the cleaning time required increases with surface roughness. The American 3-A Sanitary organization and the EHEDG specify that food contact surfaces have a maximum roughness of Ra = 0.8 µm. To achieve this quality of surface, polishing or other surface treatment may be required. Cold-rolled stainless steel sheet material, used for vessels and for piping, usually has an Ra-value between 0.2 and 0.5 µm, and thus, further treatment is not needed. According to the EHEDG, rougher surfaces can be acceptable if tests have shown that the required cleanability is achieved. Porous surfaces usually are unacceptable. To be cleaned without difficulty, surfaces must not only be smooth but also free from crevices, sharp corners, protrusions and shadow zones. This applies not only when equipment is new, but during its entire functional lifetime.

Crevices. Crevices cannot be cleaned, and as such, will retain product residues that may effectively protect microorganisms against inactivation. In some cases, crevices are unavoidable. This may be the case if slide bearings must be in contact with product; for example, as bottom bearings of top-driven stirrers or as bearings in scraped-surface heat exchangers. The presence of slide bearings should be considered when writing procedures for cleaning and disinfection. These procedures may require instructions for both partial or total dismantling of equipment, or for increased cleaning times.

In most cases, crevices are the result of incorrect choices when designing (or selecting) equipment. When parts of equipment must be mounted together, metal-to-metal contacts (other than welds) must be avoided because they leave very narrow and deep crevices. Elastomers should be used between metal components, but not in the form of O-rings in standard O-ring grooves, as this, too, will create crevices. The elastomeric material must be mounted in such a way that the seal is at the product side and excessive compression is prevented to avoid destruction of the elastomer. This can be achieved by including design features that align the surfaces of the various parts and provide a metal stop.

Screw threads. The use of screw threads and bolts in the product area should be avoided. Where unavoidable, the crevices created should be sealed, at minimum (Figure 1).

Sharp corners. Sharp corners in the product area should be avoided. Exceptions are constructions where the sharp corner is continually swept, such as in lobe pumps. Welds should not be made in corners, but on the flat surfaces, and must be smooth (Figure 2).

Dead areas. There is a significantly reduced transfer of energy to the food residues (soil) in dead areas in process equipment that is placed outside of the main flow of cleaning liquids than there is to the soil in the main flow. Such areas are difficult to clean, and therefore, should be avoided. If unavoidable, their presence should be taken into account when devising the cleaning procedures. Typical shadow zones, for example, can be found in the legs of T-pieces in pipelines, which are used to mount sensors such as pressure gauges.

Drainability of equipment and process lines. To make it possible to remove all chemicals from process equipment, the equipment must be designed to be selfdrainable. Thus, surfaces and pipes should not be completely horizontal, but slope toward drain points. There should be no ridges that may hamper draining. Where it is not possible to build equipment in such a way that proper draining is possible, procedures must be designed to ensure that residues of cleaning and disinfection liquids can be removed in another way. The method used should be well documented with clear instructions. Draining also is important, even in cases where no chemicals are used, because many microorganisms can easily grow in residual water, needing only minute amounts of nutrients to multiply.

Top rims of equipment. The design of the top rims of product-containing equipment must avoid ledges, where product can lodge and that are difficult to clean (Figure 3). Open-top rim design must be rounded and sloped for draining. If the top rim is welded to the wall, the weld must be flush and polished to provide a smooth surface. In this case, the rim must be totally closed.

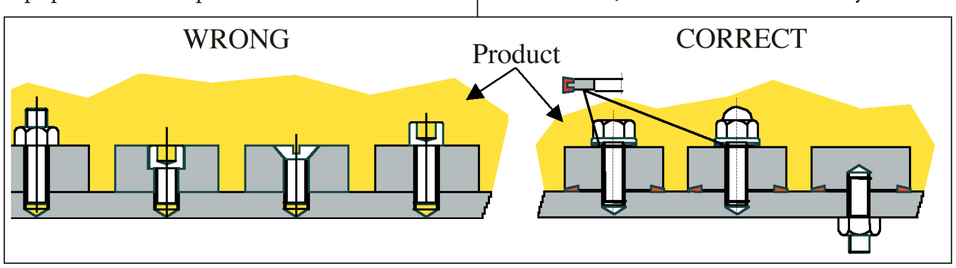

Figure 1. Examples of unhygienic fasteners (left) where soil is trapped in crevices at the metal-to-metal contact surfaces and screw threads.

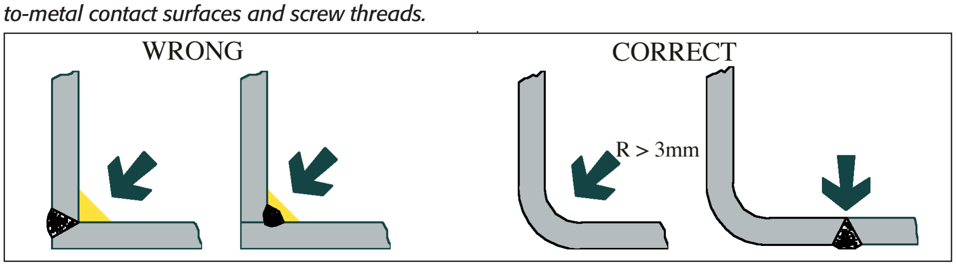

Figure 2. Internal angles and corners should be radiused and welds should not be made in corners.

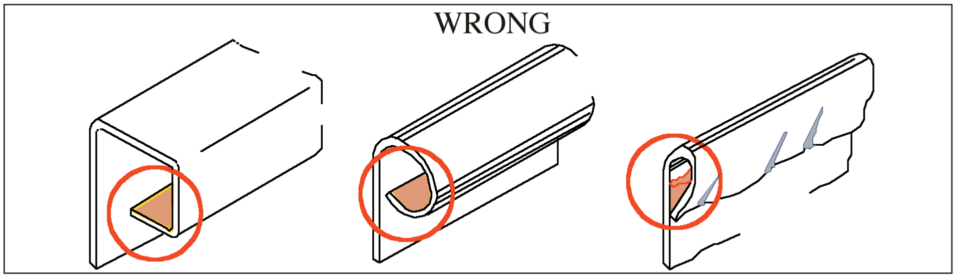

Figure 3. Unhygienic top rims of equipment where soil can be retained and thus, indirectly affect the product.

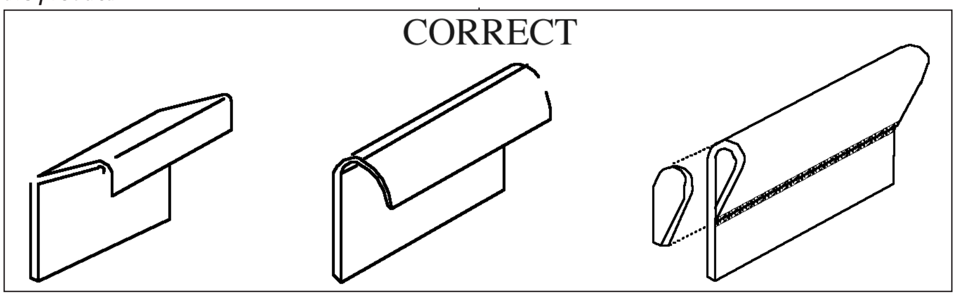

Figure 4. Examples of hygienic top rims.

The weld must be continuous and any holes must be sealed by welding, gaskets or plastic caps (Figure 4).

Mandoor covers. Mandoor covers intended to protect the food products may accumulate dirt, which will enter the product in the vessel when the lid is opened. Policy should specify that no tank is opened during production unless absolutely necessary.

Shaft passages and seals. Shaft passages and seals may leak product to the outside of the line. Microorganisms may then multiply in the product and grow back to the product side. In the case of dynamic seals, such as those for shafts of valves, pumps and mixers, the movements of the shaft will assist the transfer of product to the outside and the transfer of microorganisms to the product side. This applies to reciprocating shafts, and to a lesser extent, to rotating shafts, the latter always displaying some axial movement. Reciprocating shafts can be sealed by means of flexible diaphragms or bellows. To prevent the ingress of microorganisms in rotating shafts, double seals with microbiocidal barrier liquids should be used. If not replaced in a timely manner, however, such barriers may become a growth medium for microbes..

Hygienic design in food processing plays an important role in controlling the microbiological safety and quality of the products made. This will prevent products from having undesirably high microbial counts, containing toxins or chemical residues, or from contamination from other non-food substances. A factory designed with hygienic requirements in mind, and with process lines correctly built with hygienic equipment that is properly operated and maintained, will produce food products that are safe and of excellent microbiological quality. ■

Roy Curiel *can be contacted at curiel.roy@gmail.com.*

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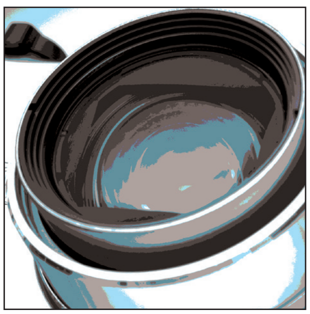
Snapshots in Sanitary Equipment: Developing an Eye for Hygiene

By Donald J. Graham



The old adage "a picture speaks a thousand words" is a well-used truism for a reason: Often, seeing something in a visual form sparks a much faster "Aha!" moment than one might experience during the more complex process of reading. When you think about the scientific and engineering tomes that we in the food safety and sanitation profession read—not to mention regulatory codes, compliance documents and standards guidelines, company best practices policies, and more—it is also easy to understand why it is desirable to use pictures to tell a story.

We all work in fast-paced manufacturing and food handling environments that don't leave as much time as we may want to peruse the latest white papers or studies, and yet we are responsible for a wide range of activities that assure the safe production and delivery of foods to our customers. In addition, although we are in our food plants day in and day out, we do not always really see what's happening on the floor. Humans tend to become innured to the environments in which they routinely work and as a result, may not notice very slight changes in that environment over time. This tendency can pose a significant disadvantage to a food production company when the overlooked element is a food safety hazard.

Equipment is the lifeblood of the food processing plant and the industry understands the important role that the machinery itself can play in enhancing food safety through improved sanitation. But like many items in our daily environment, we may pass by production lines, blenders, piping and compressors every day without really seeing the potential or existing problems posed by unhygienic and/or poorly positioned equipment and auxiliary machinery parts. Sanitary design and sanitation are partners—because if the equipment is not designed and built to be cleaned, it's not going to get cleaned. If it is designed and built to be cleaned, sanitation will be more efficient and effective, increasing the food safety quotient. Understanding this is the first step to a successful, food safety payback outcome when plant sanitarians, engineers and maintenance crews discuss the purchase, upgrade, or renovation of processing and food-contact equipment.

Of course, the critical second step is to become more aware of what you may not be seeing when you look at existing equipment and components in order to make more informed choices, avoiding investing in poorly designed new equipment. Here, we'll provide some of the core questions you should ask of yourself, your sanitation, engineering and maintenance colleagues, and your equipment suppliers during the decision-making process, and illustrate with photographs some of the common sanitary design problems that may exist in your plant.

Exposure to the Basics

Sanitary equipment design is defined as the engineered design of food handling, processing, storage facilities and equipment to create a sanitary processing environment in which to produce pure, uncontaminated, high-quality products consistently, reliably and economically. The universal guideline that is most useful to the food industry in this regard is Good Manufacturing Practices (21 *CFR* Part 110), *Sec. 110.40, Equipment and utensils*, which reads:

(a) All plant equipment and utensils shall be:

- adequately cleanable
- preclude adulteration with lubricants, fuel, metal fragments, contaminated water, or any other contaminants
- installed and maintained as to facilitate the cleaning
- corrosion-resistant when in contact with food
- made of nontoxic materials and designed to withstand the environment of their intended use

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

(c) Equipment that is in the manufacturing or food handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

The American Meat Institute's (AMI) 10 Principles of Sanitary Equipment Design also provides manufacturers and food handlers with clear and straightforward guidance, no matter what type of food you are processing or serving, The 10 principles state that equipment considered "sanitary" should be:

1. Cleanable to a microbiological level
2. Made of compatible materials
3. Accessible for inspection, maintenance, cleaning and sanitation without special tools
4. No product or liquid collection areas
5. All hollow areas hermetically sealed
6. No niches
7. Must be able to operate in a sanitary manner
8. Hygienic compatibility with other plant systems
9. Be able to validate cleaning and sanitizing protocols

Both the GMP and AMI guidance documents provide a good foundation for understanding what questions should be asked and answered when considering new equipment buys and existing equipment renovation or replacement decisions.

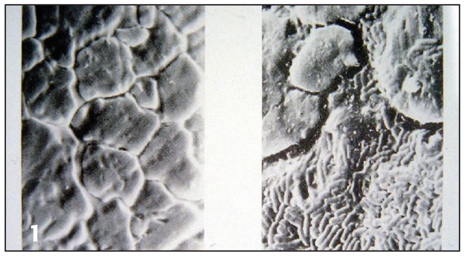
The Questions You Need to Ask: Exposing Problems

Although there are many questions that, when asked and answered, will provide insight into the sanitary equipment decision-making process, these 10 queries are certainly among the priorities to be considered.

1. Do the food contact materials meet the FDA criteria for surfaces?

There are five criteria that can be gleaned from relevant U.S. Food and Drug Administration (FDA) regulations. Simply put, food contact surfaces must be non-reactive with the product, noncontaminating of the product, noncorrosive, non-absorbent of any kind of liquid, and above all, cleanable, to ensure prevention of biofilm formation and harborage niches for microorganisms, allergen-containing residues or other chemical contaminants. The importance of these five criteria is obvious when we look at **Photos 1** and **2a/b**.

As shown in **Photo 1**, at high magnification, we see on the left a section of stainless steel plate as it was first received direct-



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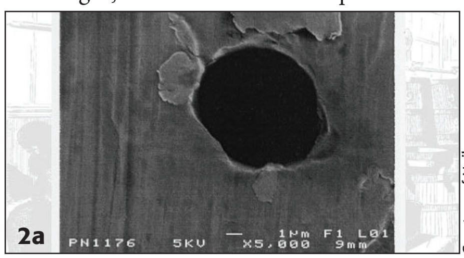
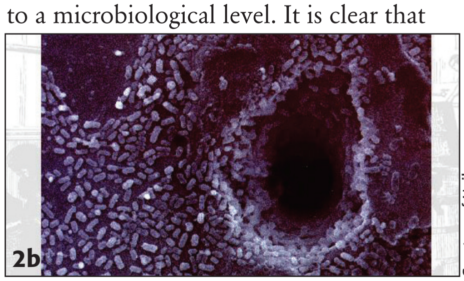
ly from the mill; note the cracks and crevices. On the right, after some time of use in a food plant, we can see that microbes have entered and settled into those cracks and crevices. If microbes take hold and survive on equipment for long enough, they exude a biofilm that is extremely difficult to remove. And, an incorrectly designed or manufactured piece of equipment can harbor a lot of bacteria. **Photo 2a** shows a microscopic hole in a stainless steel heat exchanger; **Photo 2b** shows the prolifer-



2a

Courtesy of Unilever.

ation of bacteria in that hole when if less than adequate action is taken to clean to a microbiological level. It is clear that



2b

Courtesy of Unilever.

when unabated, these microorganisms will continue to grow and can easily reach the sterilized or pasteurized side of a unit.

Of course, microorganisms are not the only food hazards that hygienically designed equipment helps to address. Look around the plant. Is the equipment paint-free? Remember, you want food contact surfaces to be non-contaminating of the product in food production areas. Paint is not a good because it can peel and get into your product and without the protective coating, allow the equipment or component to rust (**Photo 3**). Peeling can be caused by a variety of things, detergents, hot water spray, or even just jarring a painted component with a cart and knocking

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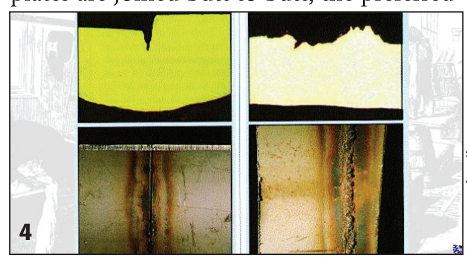
the paint off. It may sound obvious but existing equipment that is painted should be replaced to avoid these inevitable problems.

2. Are all welds in the food contact zone sanitary welds, and is the product zone free of overlap welds?

Certainly, improper welds on processing equipment and parts are among the most common and problematic hurdles to good sanitation results. **Photo 4** shows two welds on flat stainless steel plates. On the left, we see a butt weld in which the plates are joined butt to butt, the preferred



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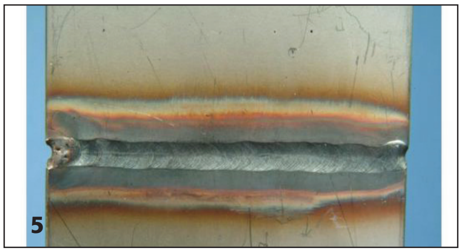
Courtesy of Unilever.

weld style since there is by definition no overlap, which can result in flexing. Flexing can cause cracking, allowing soils, microorganisms and unwanted residues to get underneath the overlap, which are difficult to remove through sanitation methods. Althought the butt weld on the left is nice and even, it can still collect microbes because it is not ground and polished to a smooth finish to which bacteria cannot strongly adhere. The criteria for a good butt weld is that the weld is ground and polished to the same texture as the adjoining pieces. The "globular" weld on the right is unhygienic to a greater degree since there are more crevices and depressions in which microbes and chemical residues can take hold.

Photos 5, 6 and 7 illustrate a sanitary butt weld. In the first photo, we see a flat plate welded on one side without backer rod—and the depression that is a hiding place for microbes and soils. In the second shot, the plate is welded with backer rod but it has not yet been ground and polished and thus still poses some food safety



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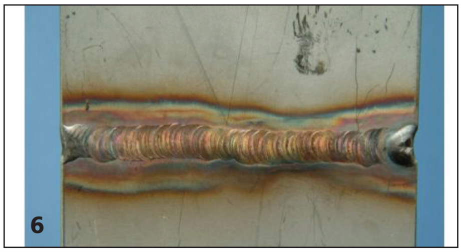

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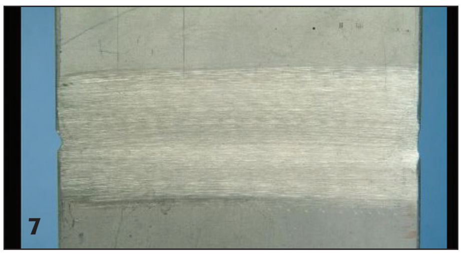

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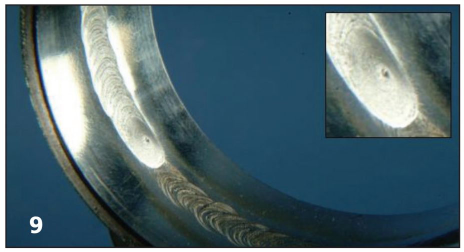
risk. Finally, we see the ground and polished sanitary weld.

What should you look for in the sanitary design of pipe welding? When a stainless steel pipe is welded, an inert gas is introduced into the pipe's interior and then welded on the outside to prevent oxidation inside the pipe. However, if the gas pressure inside is inadequate, the weld will penetrate and and result in a lumpy surface, as shown in **Photo 8**, where the application of ID Argon purge gas was insufficient. When this occurs, there will be niches where the microbes can hide and the clean-inplace

8

(CIP) system won't touch it, no matter which way the product is flowing. One way to check the integrity of the interior pipe weld is to insert a boroscope so you can view it upon completion of the weld. If it passes initial inspection, you can continue to spot check the various welds. But if it fails, you may want to require the contractor to boroscope every weld at his expense.

Other pipe weld problems occur when there is a pit at the end of the weld (**Photo 9**), which is caused by too rapid termination of the weld. If the pit actually goes all the way through that stainless pipe, it will become a niche in which soils, microbes



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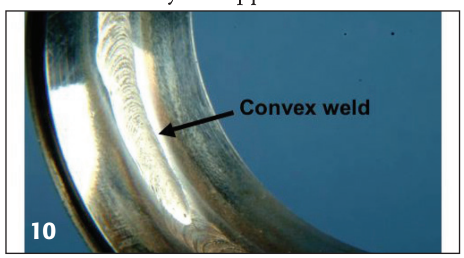
and other residues can collect and will be very difficult to remove. **Photo 10** shows another example of a niche-friendly weld, a convex weld on ID whose uneven surface is caused by the application of too



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much heat on the outside of the pipe. In addition, make sure equipment is free of stitch or spot welds, which is probably one of the most common welds done in food processing plants–and one of the biggest sins. **Photo 11** shows a lap joint with a stich weld where we can see that crack or gap that can be a hotspot for *Listeria* or other microorganisms that we don't want

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gaining a foothold in our plants. Spot welding should be avoided because of the large gap that occurs where two pieces of metal come together. And you can't get the two pieces apart because they are welded, making it hard to clean. This type of seam either needs to be eliminated or redone using a continuous, smooth weld to prevent bacteria.

Photo 12 shows an acceptable hand weld of a pipe interior. The weld is even and smooth, which makes the pipe more cleanable and allows product to flow prop-

12

erly. However, the best way to weld a pipeline is to use an automatic orbital welder since it controls the gas pressure inside the pipe, as well as the heat and speed, and thus is very efficient (**Photo 13**).

A final note related to welding and plant sanitation. If you have ever seen an area or component of stainless steel

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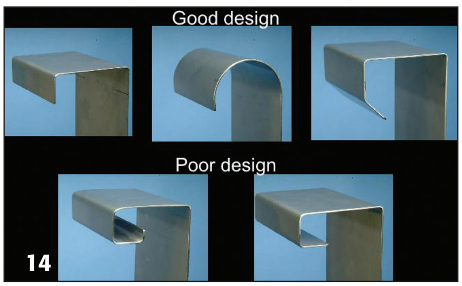
equipment become rusty, it is likely due to cross-contamination caused by grinders and polishers. If maintenance has used these tools on mild steel elsewhere in the plant, as soon as they touch a stainless weld any contaminants thereon will impregnate that iron into the stainless weld and it will turn rusty. So, stainless welding equipment, including the stainless rods, the grinders and polishers, should be dedicated to the stainless steel surfaces only.

3. Are horizontal food contact/zone surfaces free of recessed fasteners?

When Allen heads, Phillips screw heads or other fasteners are recessed, they become nonhygienic because those recesses cause solid traps, metal-to-metal contact and dead spaces. If there is a depression on a horizontal surface, it will become a holding place for moisture and other soil–all the nutrients needed for bacteria to grow. To avoid this, you want to fasten nuts on the bottom side of the product contact surface so you don't have anything on the product side, and bolt it in from the bottom or put in a gasket to seal it. Make sure that all nuts (cap, wing or other) are mounted on the outside of the equipment so that if a nut vibrates loose, it will fall onto the floor. If the nut is on the inside, it could fall into your product the bolt will stay in place in the hole and you won't suspect that the nut is missing. The nuts themselves should be polished stainless steel with no exposed threads and bolt threads should be covered to eliminate grooves and provide fewer places for bacteria to cling.

4. If there are any rolled edges on the equipment in product or splash zones, are they rolled so they do not exceed 180 degrees?

If you've got stainless steel tables in your plant where product is placed, stick your hand under them. Many times you'll come up with a handful of glop because the there is an edge underneath that is an excellent hiding place for soils and debris (**Photo 14**, poor designs, bottom) that frequently is not cleaned and sanitized. All equipment should be inspected to check for these edges. Of the good designs shown



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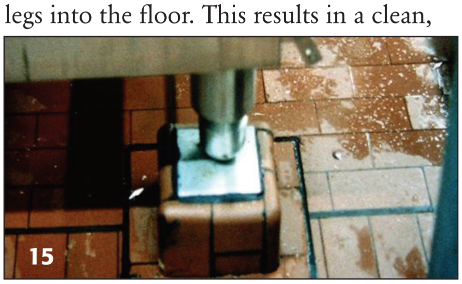
here (**Photo 14**, top), the middle picture is the best since it has structural integrity and no lip where debris can hide and settle.

5. Are the equipment legs designed so there are no areas for moisture or debris to collect? Are they easy to clean around?

Take a look at **Photo 3** again. This is an excellent example of why equipment floor supports can be sites where soils can accumulate. As shown, it is nearly impossible to clean when the legs are bolted to the floor or elevated incorrectly, allowing gaps for moisture and debris to collect. It is best to elevate equipment legs so you can clean the equipment (**Photo 15**), or you can put cones on each leg and weld them on as shown in the diagram (**Photo 16**) to eliminate nooks in blot heads that put the legs into the floor. This results in a clean,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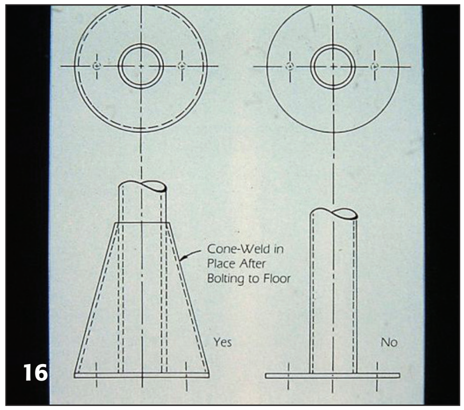
sloped surface that can be easily cleaned.

6. Are all control panels mounted on support posts, framework or standoffs with space behind them (1-2 inches) for adequate cleaning?



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You don't want control panels (or anything for that matter, including signage, pipes, equipment, etc.) right next to the wall because if you can't see behind it, you can't clean it. In fact, cockroaches love to get behind electrical panels. Control panels should either be caulked or a standoff should be used. The latter is recommended, with the standoff set at about a half-inch to an inch from the wall, so you can see behind any control panel and you can clean behind it, especially in process areas. If caulking is used in a refrigerated area, you may have a little trouble with mold growth.

Photo 17 shows how a support post solves this problem, creating the space for the sanitation crew to see behind and underneath the control panel for effective cleaning. This isn't expensive to do, and can be done in existing plants.

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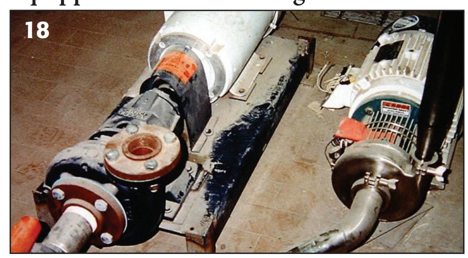
Also, control boxes and other switch boxes should have sloped tops to prevent moisture from settling on top of the door itself. These boxes should also be free of piano hinges, which are big dirt collection areas. Try to renovate these by replacing with strap hinges, which have fewer surfaces to clean, or use stainless steel food-grade struts.

7. Are motors, bearings and drive components mounted on easily cleaned supports?

Electric motors are famous for attracting dirt and dust and it is very hard to clean out that type of debris, as shown in **Photo 18**, when these are placed on a solid base. **Photo 19** illustrates how a motor can be elevated by mounting it on rails so that soils will fall through to the floor where you can sweep or mop them away.

8. If any compressed air is used in product contact zones, is the line equipped with a coalescing filter and air filter at (99.99% efficiency at 0.2 microns) located downstream from pressure regulators or other potential contaminating devices?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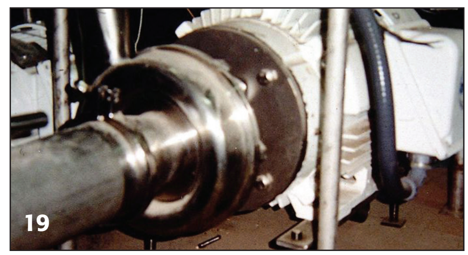
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This is a sanitation problem, especially if compressed air is used in product contact areas. The compressed air lines themselves can be a significant area of bacterial growth. Why? Although compressed air is dried to a pressure dew point below the lowest ambient temperature to prevent moisture accumulation in air lines, moisture can develop if there are no filters, particularly if the lines go through a refrigerated area, then through a warm area, back into a refrigerated area. Condensate will form in the pipes and that's all the elements needed for bacterial growth.

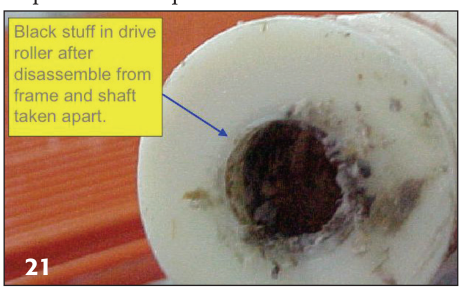
If you've got a compressed air line that comes into product contact, like the air overrun, ensure that compressed air intended for direct product contact is filtered to at least a 0.3 micron level by installing good HEPA or other filters (**Photo 20**) at any point of use in the plant.

9. Are all carry and return rollers on

conveyers solid rollers or slides rather than hollow tube rollers?

20

Hollow rollers have end caps that will allow moisture to get into the interior. Logic tells us that if it can get in, it can get out again and will contaminate the belt that it is rolling on. **Photo 21** is telling, showing an example of the type of debris that can accumulate in a hollow roller and why it is important to require solid rollers or slides



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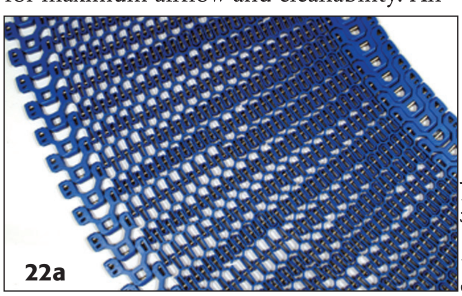
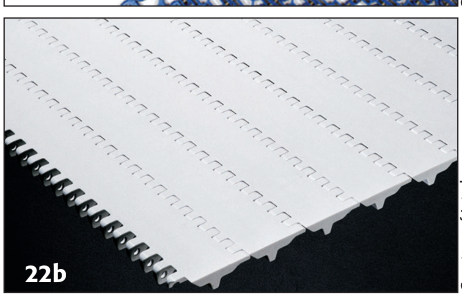
for belt returns.

Conveyor belts should also be hygienically designed for greater assurance of cleanability. Many belting manufacturers have introduced innovative conveyor belts that have a basis in sanitary design. These types of spiral, turn curving or other belting (**Photo 22a-c**) feature open-module designs or double slotted links, which allow for maximum airflow and cleanability. An



22a

Courtesy of Intralox



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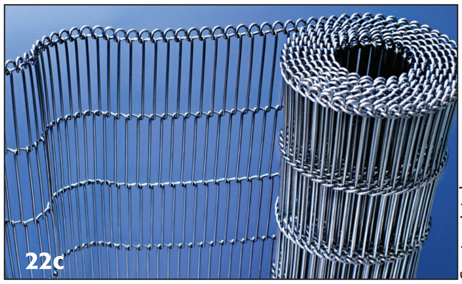
Courtesy of Intralox



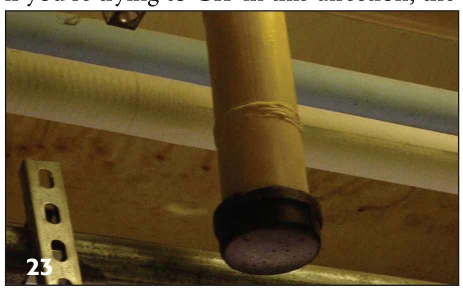
22c

Courtesy Intralox

open design permits improved access to the rods to flush out soils and chemical residues.

10. Is the piping system free of deadlegs greater than two pipe diameters?

These (**Photo 23**) can be deadly, pun intended. According to information published by Unilever, we can see what happens in a deadleg. As shown in **Photo 24**, if you're trying to CIP in this direction, the



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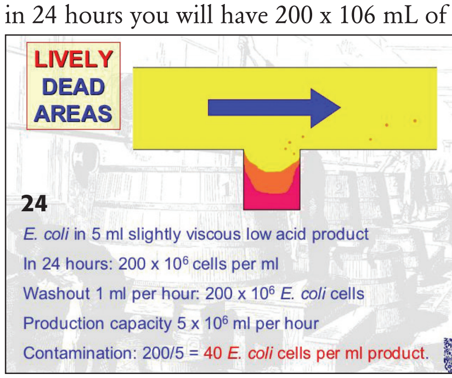
blanked off T-intersection will fill up because the CIP solution will take the path of least resistance. If *E. coli* is introduced into 5 mL of slightly viscous, low-acid product, in 24 hours you will have 200 x 106 mL of



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Courtesy of Unilever.

E. coli cells. When you washout one mL per hour of the 200 x 106, and if your production capacity is 5 to 106 mL per hour, you will end up with contamination of 200/5, which equals 40 *E. coli* cells per mL in product, just sitting in that deadleg area and easily transferred throughout the line. Hence, get rid of deadlegs.

It is recommended that if you cannot eliminate deadlegs, they should be no larger than two pipe diameters–and one pipe diameter is better–depending on your product flow. If you've got a pinch point, it should be sloped back from either direction. At minimum, place an elbow at the point of the T-intersection.

Good Composition, Great Sanitary Picture

These 10 questions are just the beginning of the list that can be asked to get a clear picture of the sanitary equipment design elements that you should consider when planning to purchase or renovate processing and food handling equipment. A picture may be worth a thousand words, and it can also be worth thousands of dollars in costsavings to the operation by preventing food hazards more efficiently and increasing the efficiency of the sanitation program. ■

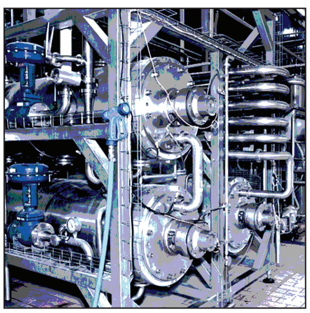
Donald J. Graham*, was president of Graham Sanitary Design Consulting, Ltd. He was one of the industry's leading experts on the application of sanitary design principles to food processing facilities.*

Don was past-president of the Missouri Food Processors Association and a member of the Food Processors Institute Curriculum Committee; the Institute of Food Technologists; the International Association of Food Protection; a charter member of the Institute for Thermal Processing Specialists. He was also an Editorial Advisory Board member of Food Safety Magazine*, and the author of numerous industry publications.*

Many of the photos published in this article were taken by Don in the 1,300 plants he visited throughout the world during his career.

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

By Ron Schmidt, Ph.D.



Reprinted from *Food Safety Magazine*, December 2012/ January 2013

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 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.

> "Increased use of corrosive chemicals in *L. monocytogenes* control programs has created new challenges for food equipment manufacturers..."

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.

> "Improved hygienic design enhances cleanability, decreasing the risk of biological (pathogens), physical and chemical (e.g., allergens) contamination."

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.*

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Progress in the Hygienic Design of Food Processing Equipment

By Huub Lelieveld

A few decades ago, it was difficult for food processors to obtain hygienic equipment because only a few companies built such equipment. Most manufacturers of equipment for the food industry maintained that their equipment was good, as they never received complaints from their customers. When I was with Unilever, we had a meeting with about 25 equipment manufacturers from all over Europe. I expressed my amazement at their consensus of opinion and told them that if they never heard complaints, they weren't listening, because at Unilever, we heard complaints from many of our food companies. After many such discussions, the equipment manufacturers agreed to work with the food industry to improve equipment design. This was the start of the European Hygienic Engineering and Design Group (EHEDG).[1]

EHEDG today has sections in most European countries and, increasingly, in countries on other continents. EHEDG produces guidelines that are intended to clarify how to avoid mistakes in the design of equipment that may lead to uncontrolled growth of microbes, leading to unacceptable risks of spoilage, food poisoning and even death. In addition, several books have been published with the same objective, providing more detail and references to the underlying research. Since then, hygienic design of food processing equipment has progressed enormously, and there is a large choice of hygienic equipment on the market, much of which has been EHEDG-certified.[2] If all of this information is available, why then does equipment still cause food poisoning incidents?

The issue apparently is that the *availability* of information differs from the *application* of information. Although there are many responsible companies that indeed try to apply this information, other companies find it too expensive and knowingly take risks, assuming that accidents happen elsewhere but not in their company. This reasoning still applies to equipment manufacturers that make designs that are cheaper to produce but present a hygiene risk. That might even be acceptable if they would admit this to the users of the equipment, who then could take this into account when deciding on cleaning regimes and frequencies. It does, however, also apply to some food processors that could buy hygienically good equipment but knowingly buy cheaper, less hygienic equipment.

In the EU, it is compulsory to use hygienic equipment in food handling. Governments also have a food safety responsibility here, because knowing that not every company complies with the law, there should be adequate inspections. When a food poisoning incident takes place and the investigation concludes that the equipment is the source of the incident, the equipment manufacturer often claims innocence, because it is not responsible for the correct operation of the equipment. The food company also claims innocence because it trusted that the equipment purchased met the legal requirements and hence was adequate. The food inspection authority cannot be made responsible because there is never the capacity to inspect everything everywhere. Hence, even when an incident has resulted in deaths of consumers, nobody is responsible, little is learned and another incident is right around the corner.

There is one essential requirement that applies to all three parties: The employees who are made responsible for the design of the equipment, for purchasing and operation of suitable equipment and those responsible for inspection should all have been trained appropriately. This, on the one hand, is a matter of proper education before actual employment and, on the other hand, continuous education on the job. This is a crucial point but it's grossly underestimated in many situations.

Some Pertinent Examples

Meat processing:

When I visited a sausage processor to help find the source of a recurring contamination of the final product, I asked to dismantle a temperature probe in the process line. This was done after the cleaning-in-place of the process line and therefore reluctantly, because dismantling may contaminate the cleaned and disinfected line. To the amazement and shame of the company staff, the temperature probe, assumed to be of hygienic design and shiny in appearance (it certainly *looked* clean), had several crevices that were full of spoiled product residue. The line had recently been "approved" by an inspector of the local food safety author-

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ity. The inspector had not opened anything in the process line, and the company had trusted the supplier of the temperature probe (and other line components) that it was indeed hygienic and thus without crevices that could not be cleaned.

Dairy processing:

When I visited a dairy plant with a persistent contamination of the final product that occurred consistently within a few hours after the start of production, it appeared that several valves in the process line, when removed for inspection after cleaning-in-place and taken apart for a thorough inspection, smelled very bad. The reason appeared to be that milk had accumulated behind a membrane and was badly spoiled; shortly after the start of production, this spoiled milk residue began to release microbes, contaminating the final product. The valves had been selected from a catalog of a renowned equipment company as "aseptic" and were also expensive (meaning that the food company had no intention of taking risks by choosing cheaper designs). Replacing the valves by another type solved the problem.

Frozen novelty processing:

In an ice cream company, the final product regularly appeared not to be properly pasteurized, although the temperature had been correct every time—the temperature sensor had been inspected and calibrated several times. The residence time had been properly calculated, meaning that the number of plates on the plate heat exchanger (PHE) frame was correct. Moreover, at the beginning, when the plant was commissioned, everything looked fine and the microbiological test results were excellent.

To determine the cause of the problem—a variety of microbes surviving pasteurization—various components of the line had been taken out for inspection and looked clean after cleaning-in-place. After a few days, all components had been thoroughly inspected. Not, however, the PHE. The assumption was that the PHE could not be the problem, because it was the pasteurizer and it came from a reliable manufacturer with a long history of good designs. The cleaning procedure recommended by the producer was carefully followed: Every day, the cleaning was done twice before pasteurization was resumed. Moreover, it was assumed that taking apart the PHE would do more harm than good, because disassembly might damage the gaskets and plates, and it would take hours to reassemble the PHE. But after cleaning (twice), the PHE was dismantled. To the embarrassment of the company's staff and the representative of the PHE supplier, most of the plates proved to be extremely dirty, with brownish, sticky residue on the surfaces on the product side of the plates. It could easily be seen that as a consequence, the "free" volume between the plates was much less than would be the case if the plates had been clean. Thus, the effective volume of the holding section of the PHE was a fraction of the intended volume, and the holding time a fraction of what it was supposed to be. By manually cleaning the plates and thereafter changing the cleaning procedure so that it could cope with the product to be pasteurized, the problem was solved and did not reoccur.

> "In the EU, it is compulsory to use hygienic equipment in food handling."

Fish processing:

In the Netherlands in 2012, about 23,000 people became ill and 4 died as a result of eating salmon contaminated with *Salmonella* Thompson;[3] the cause appeared to be the presence and multiplication of *Salmonella* in the porous sides of supports made from polyvinyl chloride used to transport the salmon on a conveyor belt. The porous sides retained moisture (likely containing fish proteins), enabling microbes to multiply.[4] This was an oversight in the design that could have been avoided if the designer had understood the hazard, which has been discussed in many publications, such as *Hygiene in Food Processing*.[5] There are many more examples, such as an outbreak of listeriosis associated with Jensen Farms cantaloupes in the U.S. in 2011 and *Salmonella* Typhimurium infections associated with peanut products, also in 2011 (cited by Schmidt and Pierce[5]).

Preventing Food Safety Incidents

The staff of manufacturers of equipment for the food industry should have knowledge of hygienic design, meaning they should also have learned the basics of microbiology. Similarly, the staff of food companies should be aware of the microbiological problems that may be caused by wrongly designed or wrongly used equipment. They should have been trained in reading technical drawings. Food safety inspectors will have knowledge of microbiology, as often they are veterinarians. While their education often includes the "construction" of animals, it does not usually encompass the construction of equipment. Therefore, it cannot be expected that a food safety inspector can judge whether a food factory is hygienic or not and should not be given that task before he or she has been adequately trained. Hence, the education of safety assurance managers, engineers who design food processing equipment and veterinarians (or professionals with other backgrounds) who are appointed as food safety inspectors should include training before they are expected to carry out such responsibilities. In addition, we can learn from incidents, meaning it should be made compulsory to publish the results of the investigations of the causes of food safety incidents.

Finally, the design of equipment and process lines should be a joint activity of equipment manufacturers and food processors. Together, they should write the specifications and the operation procedures for the product that is to be made with the equipment. Only in this way can the industry reduce the frequency of equipment-related causes of foodborne illnesses. ■

***Huub Lelieveld** is president of the Global Harmonization Initiative. He is also a member of the Editorial Advisory Board of* Food Safety Magazine.

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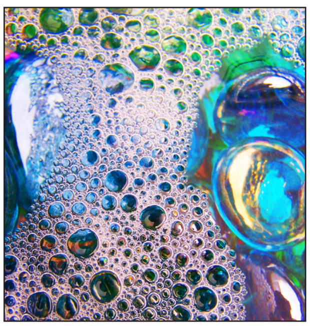
Using Sanitary Design to Avoid HACCP Hazards and Allergen Contamination

By Donald J. Graham



The question has been asked, "Shouldn't allergens be considered the fourth hazard in a Hazard Analysis and Critical Control Points (HACCP) program, rather than simply a chemical hazard as they are currently defined? While arguments ensue about the classification of allergens with regard to food safety, quality assurance and quality control, practical programs must be developed to ensure that foods, residues and ingredients containing allergens do not contaminate non-allergen-containing foods. Although just 1-2% of adults (along with about five million American children) are affected by allergens, they can be life-threatening to a small percentage of people. Since 1994, recalls attributed to allergen contamination or mislabeling have increased dramatically. The "Big 8" allergens in the U.S. make up about 90% of the allergens of concern in foods:

- Peanuts or peanut derivatives such as pieces, protein, oils, butter, flavor, and mandelona nuts (an almond-flavored peanut product).
- Tree nuts (almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios and walnuts) or their derivatives (nut butters and oils, proteins, pieces, etc.)
- Milk or its derivatives (milk caseinate, whey, isolates, milk protein concentrates, yogurt, powdered milk products).
- Eggs or derivatives (frozen yolks, egg white, egg powder, and egg protein isolates, etc.).
- Crustaceans (including crab, crayfish, lobster, prawn, and shrimp), shellfish (including snails, clams, mussels, oysters, cockle and scallops), or their derivatives such as extracts.
- Fish and fish products.
- Soy or its derivatives, including lecithin, oil, tofu, and protein isolates, etc.
- Wheat or its derivatives, (flours, starches, and brans).

In addition, Canada and the European Union list sesame seeds, celery (celeriac) and sulfites as allergens.

Allergens are naturally occurring proteins with many characteristics of interest to food safety and quality assurance professionals who aim to prevent or control them. Allergens are organic, but not living organisms that are water insoluble, only slightly acid soluble (according to some sources), and alkali soluble. Allergens are difficult to remove when baked onto a surface, such as wheat protein in a finish dryer, because they are heat resistant, as well as resistant to proteolysis and to extremes in pH. By considering these characteristics when developing an allergen control program for the food processing environment, food safety, sanitation and quality assurance teams can better incorporate the elements of sanitary equipment and facility design to avoid both HACCP hazards and allergen contamination.

Sanitary Design Elements: Outside and In

Under close examination, one finds that there are many similarities in measures used to control conventional chemical, microbiological and physical hazards in a food plant and to control potential contamination by allergen residues. However, there are some striking differences. For example, one of the significant differences between allergenic materials control and microbiological hazard control is the application of heat. Microbes can be controlled by the use of hot water, but heat will not remove allergen proteins, which have to be removed

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by scrubbing, detergents, or in the case of dry cleaning, by a good vacuum system. Thus, a facility and equipment designed for thorough cleaning and sanitizing is key to successfully controlling potential allergen contamination.

Sanitary design for control of physical, chemical and microbiological hazards starts outside of the facility. Whatever contaminants are found outside of the plant will try to get inside the plant, especially insects, rodents, birds and windborne microbes contained on dust particles. Keeping contaminants out is a function of designing the driveways, truck docks, access doors, roofing materials, heating, ventilation and air conditioning (HVAC) systems, and, believe it or not, the landscaping.

Truck dock areas and doors are an important consideration when it comes to sanitary design because they are one of the frontline defenses in the pest control program. Modern docks are equipped with dock seals. Trucks back up to the door and engage the seal. This effectively prevents the entrance of insects and as long as the plant is under positive pressure with air flowing out of the openings that do occur around the seal dust contamination is kept out. Dock seals also can replace (where allowed by USDA) overhead canopies. Overhead canopies, or roofs over dock doors, require constant monitoring to prevent bird nesting and roosting due to the high potential of birds entering the plant as a result of leaving the door open after the truck leaves. Dock leveler plates should be lined with brush seals to discourage rodents from entering the leveler pit and up through the space between the plate and the inside floor.

A relatively new development in dock levelers is the vertical lift plate. The design of this type leveler plate eliminates the pit when the door is closed, thereby preventing any pests from getting under the plate. The recommended dock doors are the vertical lift type. The second choice is the overhead door type, followed by the rollup type with no housing. Housings become great nesting places for various insects, and if they are already in place, should be routinely monitored for insect infestation.

Clearly, the more contaminants are prevented from entering the plant at the outset, the less cleaning and sanitation problems are faced on the inside of the facility.

Once inside the facility, sanitary design can be applied to floors, walls, ceilings, equipment and HVAC systems for both microbial control and allergen control.

Floors. Floors are the most abused surface in a food processing facility. Floors are exposed to mechanical abuse, chemical abuse, temperature abuse, and any other type of abuse that can happen to a floor. Food processing areas should have floors covered with an appropriate type of coating, such as a good monolithic or a brick material. Plain concrete floors soon spall and the exposed aggregate creates an excellent hiding place for microbial contamination (Figure 1). Severely spalled floors can be rinsed, foamed, rinsed, sanitized and still show positive microbial swabs. These organisms can be splashed onto equipment and can be tracked around the facility by processing personnel. Allergenic materials or spilled ingredients containing allergens also can lodge in the aggregate material and then spread through the facility by similar means. As such, floor coverings should be smooth, non-absorbent and easily cleanable.

Figure 1. (Left) Plain concrete floors will spall and the exposed aggregate creates an excellent hiding place for microbes. (Right) Floor coverings should be smooth, non-absorbent and easily cleanable.

Walls. Although not as critical as floors, walls also require a smooth, non-absorbent surface to prevent microbial growth (mold, yeast, bacteria) and absorption of materials containing dust from allergen ingredients. The surfaces should extend from floor to ceiling and be easily cleanable. There are a number of new materials on the market that will fill the bill. Today, there are gel-coated reinforced fiberglass panels from a number of suppliers that are being used in food processing facilities, as well as in pharmaceutical facilities. The more sensitive the product being processed, the more attention must be paid to the wall surfaces.

Anything hung on the facility's walls should be hung with a minimum of one inch of space between the back of the item and the wall surface. This allows for improved cleaning access and keeps areas behind electrical boxes, switches and equipment hangers from becoming a habitat for insects or niches for microbial growth and allergen residues to reside.

Ceilings. Some areas within a food processing facility are better off without any kind of a ceiling in place rather than a drop 2x4 panel ceiling (Figure 2). Ceilings serve the purpose of preventing contaminants–dust, condensate, paint chips, etc.–from falling from the roof supports or from the underside of the roof into the product in process or on finished product. Typical drop ceilings, as shown in Figure 2, more often than not exhibit the problem seen in the picture. They are fine when new and the panels are glued or clipped down; however, when something above a drop ceiling requires repair or maintenance, access to it is through a panel and this is problematic. Repositioning of such panels is difficult and the air in both areas becomes contaminated through loose or misplaced panels. In addition, the area above the panels is not accessible for pest control measures to be efficiently taken.

Good sanitary design recommends a walk-on type solid ceiling, at least over the processing area where product is exposed. All utilities can be kept above the ceiling and accessible from outside the process area. Horizontal runs below the ceiling are eliminated and only vertical drops of utilities to the equipment below are apparent.

Heating Ventilation and Air Conditioning Systems. Some time ago, the U.S. Food

Figure 2. Typical drop ceilings may crack or be repositioned improperly, resulting in reduced contaminant control and/or increased air contamination in the plant.

and Drug Administration (FDA) made the statement that "airborne contamination is strongly suspected as the cause of some pathogenic contamination." Unfortunately, this suspicion has been proven true in some well-known cases. Sanitary design of HVAC systems has become a focal point in the renovation, as well as in the initial design of food processing plants today. Emphasis is being placed on positive air pressure in the processing/packaging areas where micro-sensitive product is being produced in addition to high filtration of incoming air.

Outside air is full of dust particles that carry microbes, and these particles must be kept out of the areas where exposed product is being packaged or processed. Positive pressure also will help keep contaminated air from entering sensitive areas by way of the raw material handling areas of the plant. Product flow is counter to airflow in a facility that has a properly designed and installed HVAC system.

Allergen contamination also is affected by the design of the HVAC system. If the product or product ingredients contain one or more of the allergens previously described, or are added during production and are dusty, the escaping dust can contaminate adjoining lines or other food contact surfaces in the processing room. Therefore, a hood system should be considered. A hood system to capture escaping dust will require a sufficient incoming flow of air to provide positive pressure in the room while the hood system is removing sufficient air containing the allergenic dust. Incoming air must be filtered. The most common filters found in air handling systems in food processing plants are approximately 35% efficient at 50 to 100 microns. The recommendation for good food safety is to use filters that are 95% efficient at 5 microns. This level of filtration will filter out dust particles carrying microbes and will also trap the dust particles carrying allergens from any dust in recycled air.

Equipment. One of the most significant ways in which using a sanitary design approach can help to prevent microbial contamination and carryover or cross-contamination by allergenic ingredients is in designing processing equipment that is more easily cleaned and sanitized. Equipment designed with hygienic goals in mind is fast becoming an area of concern to all stakeholders in the food industry, from regulators to processors to equipment manufacturers. FDA has stated it will be concentrating on the cleanability of processing equipment during the agency's strengthened inspections of food processing facilities. Industry also is working with equipment manufacturers to establish sanitary equipment design guidance in a proactive effort to offer basic tenets, flow charts and checklists to help in the evaluation of effective sanitary design attributes. For example, the American Meat Institute's (AMI) 10 Principles of Sanitary Design is a set of working principles that provides guidance to both equipment manufacturers and ready-to-eat (RTE) meat and poultry processors on elements of improved sanitary design under a general standard (www.meatami.org). The International Fresh-cut Produce Association (IFPA) is in the process of developing a Sanitary Design Checklist for use by its members when specifying processing equipment used in fresh-cut produce operations (www.freshcuts.org).

In general, there are several criteria to consider and specify in processing equipment. Overall, processors should look for equipment with food contact surfaces that are non-absorbent, non-corrosive, non-reactive with the product, non-contaminating and cleanable. These criteria apply both to preventing microbial contamination and to aid in removing allergen residue between products or production runs. Other important criteria include purchasing equipment with no internal horizontal ledges, hidden or hard-to-clean areas, or recessed fasteners such as Allen head screws on horizontal surfaces. The design should not limit access to the interior of the equipment for cleaning and sanitation. Existing equipment should be modified to make it accessible for cleaning and visual inspection.

In an ideal situation, a processor will operate dedicated lines and dedicated facilities to reduce allergen cross-contamination risk. In operations where this is not feasible, the processor can adopt some per-line measures, including some equipment design functions, that will reduce the risk of cross-contamination by allergen-containing product to non-allergen-containing product. Some of these measures are eliminating crossovers of conveyer lines; dedicating re-feed systems; installing adequate lighting for better visual inspection to detect allergen residue; and ensuring that maintenance tools used in raw and finished product areas are dedicated as "allergen-contact" or "non-allergen contact," and kept separate. Designing production lines to isolate allergen addition points is another measure measure that can be taken on a per-line basis.

Operational Considerations

On an operational basis, scheduling allergen-containing product runs at the end of the production day, controlling rework, and lengthening production runs go a long way toward effective control of allergen carryover. Other operational procedures include implementing strong prerequisite programs and sanitation standard operating procedures (SSOPs) in the sanitation program, and using appropriate cleaning methods such as wiping, scraping, vacuuming, detergent/water wash (no compressed air blows) with the proper cleaning and sanitizing chemicals. When cleaning a line on which allergen-containing materials are run and that is next to a line that is not used to process non-allergen-containing product, the lines can be isolated by installing shrouds or curtains to avoid splash. Another possible way to reduce allergen carryover risk is to use high-volume/low-pressure (house pressure) water because of the high potential of splash contamination and the creation of aerosols containing microbes and/or allergen containing residues. Thus, previously cleaned equipment and adjacent equipment can become contaminated with these airborne residues. As indicated earlier, the use of high-volume air hoods to capture any allergen-containing dust generated either by line operations or by the cleaning of an allergen line can help minimize cross-contamination. These procedures, combined with the correct design of the HVAC system, will go a long way in preventing air contamination of adjacent lines.

Sanitation and sanitary design go hand-in-hand to improve the food processor's food safety and quality assurance aims. Designing a facility to meet or exceed sanitary design criteria will make the sanitation program easier, more efficient and faster to execute. Good sanitation is necessary to prevent contamination from potential HACCP hazards and from allergen carryover. Using sanitary design as a way to control microbes has been a subject of discussion and action for a number of years. While using sanitary design to control allergen carryover is a fairly recent design criteria subject, it is one that is rapidly evolving as newer and more rapid allergen residue tests are perfected. With the attention being paid to allergen awareness by the regulatory agencies, processors, the media, trade publications, this area of design criteria will continue to evolve. All of these criteria should be a part of any sanitary design document developed for new plants, additions to existing facilities, and/or for the renovation of existing facilities. It is much easier to incorporate these design elements during the planning stages than it is after the facility has been "cast in concrete." ■

Donald J. Graham*, was president of Graham Sanitary Design Consulting, Ltd. He was one of the industry's leading experts on the application of sanitary design principles to food processing facilities.*

Don was past-president of the Missouri Food Processors Association and a member of the Food Processors Institute Curriculum Committee; the Institute of Food Technologists; the International Association of Food Protection; a charter member of the Institute for Thermal Processing Specialists. He was also an Editorial Advisory Board member of Food Safety Magazine*, and the author of numerous industry publications.*

Many of the photos published in this article were taken by Don in the 1,300 plants he visited throughout the world during his career.

Hygienic Design of Food Processing Facilities

By Frank Moerman, M.Sc.

Increasing consumer demand for fresh foods has led to the development of processing and preservation methods that have minimal impact on either the nutritional or sensory properties of foods. Freshly prepared foods often contain less salt, acid, sugar, additives and preservatives. Since the use of mild preservation technologies primarily results in pasteurized products, hygienic processing equipment and a hygienic process environment are needed to prevent microbial, chemical and physical contaminants from affecting these products while preventing product exposure to sources of filth (pests, dust, etc.). Combating product contamination may occur not only at the equipment level but also at the factory level. Incorporation of hygienic design into your food processing facility can prevent development of pests and microbiological niches; avoid product contamination with chemicals (e.g., cleaning agents, lubricants, peeling paint, etc.) and particles (e.g., glass, dust, iron, etc.); facilitate cleaning and sanitation and preserve hygienic conditions both during and after maintenance. The facility infrastructure can be so designed and constructed that it cannot contaminate food products, whether directly or indirectly.

Barrier Technology

To control food safety, providing barriers to food contamination is a generally applied concept. The first barrier refers to outside premises, such as fencing, to prevent unauthorized access to the facility. The access of transport vehicles with raw materials and end-products, personnel, domestic and non-domestic animals should be monitored and controlled. Factory site drainage and storm water collection must be sufficient; areas within a 3-m perimeter of the factory must be kept vegetation free to avoid pest breeding and harborage sites; a 10-cm thick concrete curtain wall around the factory foundation at least 60 cm below ground discourages rodents from entering the building; effluent treatment plants and waste disposal units should be sited such that prevailing winds do not blow microbial and dust aerosols into manufacturing areas.

The second barrier concerns the closing of factory buildings. All entrances/exits (i.e., window and door openings, openings for vents, air circulation lines, floor drains, etc.) must be designed for control over access, flow or exit of personnel, raw and finished food products, air, process aids (process water, process steam, food gases, etc.), waste, utilities (plant cooling and heating water, plant steam, compressed air, electricity, etc.) and pests (insects, birds, rodents, etc.). Floor drains must be screened to avoid rats from entering the food plant via sewers; ventilator openings, including vents in the roof, shoul be screened to prevent the entry of roof rats, insects and birds; gaps at the entrances of electrical conduits, process and utility piping, which are convenient pathways for roof rats, must be closed.

The third barrier is the segregation of restricted areas (zones) within the plant, each of which have different hygienic requirements and controlled access. The fourth barrier is the processing equipment (including storage and conveying systems), which must have an adequate hygienic design and must be closed to protect the food product from external contamination.

Zoning: A Cornerstone In Prevention Of Food Contamination

Zone B is an area in which a basic level of hygienic design requirements suffices. It encompasses areas in which products are produced that are not susceptible to contamination or that are protected in their final packages. A B0 zone is the area outside the buildings within the perimeter of the site where the objective is to control or reduce hazards created by unauthorized personnel entry and hazards created by water, dirt, dust and presence of animals. B1 zones include warehouses that store both raw materials and packed processed products, offices, workshops, power supply areas, canteens and redundant buildings/rooms. The objective for a B1 zone is to control or reduce hazards created by birds and pests.

Zone M is an area in which a medium level of hygiene suffices. It includes process

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areas where products are produced that are susceptible to contamination, but where the consumer group is not especially sensitive and where no further microbial growth is possible in the product in the supply chain. In this area, product might be exposed to the environment, during sampling and during the opening of equipment to clear blockages. The objective for zone M is to control or reduce the creation of hazardous sources that can affect an associated area of higher zone classification. Another objective is the protection of the interior of food processing equipment from contamination when exposed to the atmosphere.

Zone H applies to an area where the highest level of hygiene is required. A "High Hygiene" room, which, in food processing is the equivalent of a cleanroom, must be completely contained. Zone H is typical for open processing, where even short exposure of product to the atmosphere can result in a food safety hazard. Products and ingredients that are processed or stored and are destined for a highly susceptible consumer group (e.g., infant nutrition), are instant in nature or ready for consumption. They must be handled in a refrigerated supply chain, as they are susceptible to growth of pathogenic microorganisms. The objective for H zones is to control all product contamination hazards and to protect the interior of food processing equipment from exposure to atmosphere. Filtered air must be supplied to this area.

These areas should be limited in size, must have a simple equipment layout to facilitate process, cleaning and maintenance operations and should have utilities located outside. However, investing in an enclosed line that brings barriers very close to the product is more logical than trying to create a complete cleanroom around a partially open line.

Zoning and the establishment of barriers to ensure that product of acceptable hygienic quality is produced should only be applied where their use will help significantly to protect products. Designing the entire factory as a cleanroom is not the purpose of food area segregation to protect both product and consumer. Zoning and barrier technology must be applied in an appropriate and consistent way, thereby avoiding unnecessary investment.

Construction of Facilities: Appropriate Layout

The layout and design of the food factory must be adapted to the hygienic requirements of a given process, packaging or storage area. The interior of the factory must be designed so that the flow of material, personnel, air and waste can proceed in the right direction. As they become incorporated into food products, raw materials and ingredients should move from the 'dirty' to the 'clean' areas. However, the flow of food waste and discarded outer packaging materials should be in the opposite direction. Before building begins, simulation of the flow of people, materials, products and waste can help the designer determine the most appropriate place for installing the process equipment and where the process and utility piping should enter the process area. Even the simulation of maintenance and cleaning operations can be useful to determine the most appropriate factory layout. Graphical computer-aided design and 3D visualization programs can help in the hygienic design, positioning and routing of processes, process supports and utility systems. These programs allow the observer to "walk through" the facility, seeing the inside of the facility from different angles and locations. To save building and renovation costs, potential problems can be solved before the onset of construction. Additionally, in the development of high hygiene areas, computational fluid dynamics can help simulate and visualize expected airflows.

> "Zoning and the establishment of barriers...should only be applied where their use will help significantly to protect products."

To meet a possible increase of processing activities within the food plant in the future, the building and its food processing support systems should be designed so they can either be expanded, or another building and/or utilities can be added. Oversizing the main utility systems is a common practice. If possible, the factory should also be made adaptable (i.e., the ability to modify the production area for other manufacturing purposes) and versatile (i.e., the ability to do different things within the same room).

Construction of Facilities: Pest Prevention

To exclude flooding and the entry of rodents, factories should be built at a higher level than the ground outside. Exterior doors should not open directly into production areas, and windows should be absent from food processing areas. The number of loading docks should be minimal and be 1–1.2 m above ground level. Preferably, outside docks should have an overhanging lip, with smooth and uncluttered surfaces that are sloped slightly away from the building to encourage water runoff. Areas beneath docks should not provide harborages for pests, should be paved and should drain adequately. To provide protection for products and raw materials, docks can be shielded from the elements by roofs or canopies. However, these structures can become a serious sanitation problem due to roosting or nesting of birds. Bird spikes or nets can solve that problem. To prevent the entry of insects, dock openings should be provided with plastic strips or air curtains, and external lighting to illuminate these factory entrances should be placed in locations away from the factory building. Intruding insects can still be attracted and killed within the food factory by strategically positioned ultraviolet (UV) light electric grids or adhesive glue board traps.

Construction of Facilities: Interior Hygienic Design

Construction Materials

Construction materials for equipment and utility piping should be hygienic (smooth, non-absorbent, non-toxic and easily cleanable), chemical-resistant (to product, process chemicals, cleaning and sanitizing agents), physically durable (unbreakable, resistant to steam, moisture, cold, abrasion and chipping) and easy to maintain. Materials used to construct process and utility systems located in the non-food contact area may be of a lower grade than those applied in the food contact zone. Surfaces that are frequently wet should not be painted as the paint can crack, flake and chip.

Lead, mercury and cadmium should not be used within the factory. However, as part of many electric components, it is very difficult to exclude their presence. In the food contact area, electric components must always be enclosed in junction boxes, casings, closed cable housings, cabinets, etc. or should be installed in non-product contact zones or in technical corridors. Alloys for food contact may only contain aluminium, chromium, copper, gold, iron, molybdenum, nickel, platinum, silver, titanium, zinc, carbon, etc. However, zinc, copper, aluminium, bronze, brass, carbon and galvanized and painted steel have poor resistance to detergents, disinfectants, acidic food and steam and must be avoided in food contact areas.

"The layout and design of the food factory must be adapted to the hygienic requirements of a given process, packaging or storage area."

Polytetrafluoroethylene, polyethersulfone, polyvinylidene fluoride, phenol-formaldehyde, ureaformaldehyde, melamine-formaldehyde, epoxy and unsaturated polyester resins are used in the construction of electric components, while other plastics like polypropylene (PP), low-density polyethylene (PE), polyvinyl chloride (PVC), polyurethane (PU), ethylene propylene diene monomer (EPDM), silicone, etc. are applied as jacket materials for electrical cables or for the construction of pneumatic hoses and compressed air tubing. PP, PE and PVC are also used to construct drain pipes, while shields of polycarbonate can protect the food area below light sources from shattered glass after accidental breakage of lamps. Silicone, nitrile, PU, EPDM and butyl rubber are largely used as materials for gaskets, seals, etc. Epoxy is widely used as floor, wall and ceiling coatings. Remember that many plastics perform differently at -25 °C than they do at 20 °C.

Integration of Piping

Utility piping in technical corridors or zone H areas should be integrated into wall compartments or the ceiling. If this is not possible, it is recommended to use open racks, fixed to the ceiling, or walls and columns close to the ceiling. However, sufficient clearance must be provided between pipe runs and adjacent surfaces so that both are readily accessible for cleaning and maintenance. The pipe racks must be designed hygienically to minimize the presence of horizontal ledges, crevices or gaps where inaccessible dirt can accumulate.

Food processing support piping should be directly routed from service rooms to process areas and should always be logical and simple. The amount of utility piping should be minimized and should have—like process piping—a slope of 1/200 to 1/100. Especially in process, hot water and process steam piping, standing "pools" of liquid that can support the growth of microorganisms must be avoided. To remove condensate, steam traps should be located at all low, convenient points along any extended pipe length. Steam purges for relief of steam condensate in a drain should be closely connected to that drain. In open systems, the steam vapor coming out of a drain can cause humidity and odor problems within the factory. Discharge of condensate from the system should be via an air break to prevent back-siphonage. Neither process nor utility piping should have dead legs.

Like process piping, utility piping should be grouped together in easily accessible pipe trains whenever possible. The points of use should also be grouped, in an attempt to minimize individual ceiling drops. Vertical entrance of piping into the equipment or equipment jacket is more hygienic than horizontal utility piping runs. Running of process and utility piping over open equipment in food preparation areas cannot be accepted, and nesting of ductwork should be avoided. Piping should not clutter the ceiling. When necessary, suspended racks that run over a product zone shall be equipped with a drip pan that protects the product zone below and can be readily removed for cleaning. Bumper guard construction can also be installed in heavy traffic areas to protect piping from external mechanical forces.

Piping should be installed at least 6 cm from walls and floors to encourage thorough cleaning around it. Piping in corners should be avoided, as it hampers thorough cleaning. Process equipment shall be installed such that enough space is provided to facilitate pipe cleaning.

As piping (utility and process) can affect or disrupt the airflow pattern in zone H rooms, a fog test can control airflow patterns. The geometry of the utility piping can destroy the desired air pattern (e.g., piping with a square or rectangular profile is less favorable than circular). Square and rectangular shapes create turbulence and depressions where dust can accumulate, but cylindrical profiles make cleaning easier.

Penetration of Piping through Walls, Ceilings and Floors

Piping that transports dirty fluids should not run in the vicinity of or cross utilities that transport process aids, especially if these process aids are in direct contact with the food to be processed. Like process piping, food processing support piping should run unidirectionally, with the support piping running from the cleanest area toward the least clean areas. Support systems should deliver a certain process aid first in the process area with the highest hygienic risk (zone H) and last in the zone of lowest hygienic risk (zone L).

Pipeline penetration through walls, ceilings and floors should be minimized, as holes in these areas can lead to sanitation problems and can invite the entry of insects and rodents. Openings in floors for pipes should be guarded with a sleeve to avoid spill of cleaning solutions onto a lower floor. When several pipes penetrate the floor, a larger curbed floor can replace several pipe sleeves to improve the cleanability of the surrounding process environment. However, that curbed floor may create a large opening where pests may harbor, and where dirt, water, etc. may accumulate. It must be a completely closed curb with a cover that leaves no gap around the penetrating piping.

Holes in walls for pipe traverse need not to be sealed waterand air-tight when both sides of the wall are in rooms of the same hygienic zoning, but any opening should be large enough for access and cleaning. However, if a wall separates rooms of different hygienic zoning, all holes for pipe traverse must be sealed. The exterior surfaces of the pipes that traverse walls or ceilings should then have water- and air-tight contact with the wall or ceiling. Foaming-in-place is an appropriate method to close the gaps formed between pipe surfaces and walls as are the applications of plastic caps around the piping and flashing flanges. If running of process and utility piping through walls or ceilings in zone H rooms cannot be avoided, the apertures through the walls and ceilings shall be properly closed against air leakage, as they give excessive air volume losses which may affect product.

> "Hygienic food factory design starts with the selection of an appropriate location and the application of a hygienic building concept that prevents the entry of pests."

Sanitary Insulation of Piping

Hot piping should not run in the neighborhood of piping that transports cold food products, cold process water, etc. The warm-up of these cold liquids can give rise to the growth of food pathogens. Insulation of hot piping is required, not only to economize on energy, but also to prevent excessive heating of the food production environment above acceptable temperatures. Poorly insulated ethylene glycol and cold/chilled water piping can sweat or be covered with ice, resulting in dripping water. To avoid ingress of dust, vermin, etc. into the insulation, it is highly recommended fully welded metal cladding or plastic covering be installed. It should be impossible to walk on the insulation during maintenance. Damage to insulation can be inhibited by covering the pipe insulation with a smooth, hard, non-electrostatic, plastic cover, rather than steel sheet cladding.

Hygienically Designed Transfer Panels

Flexible hoses can be used for performing transfers within a given process area. However, hoses are impractical to perform transfers between rooms, especially if these rooms have a different level of "cleanliness." To make connections between different processing units in adjacent rooms, the use of hygienically designed transfer panels is recommended. Interconnection between the different ports should be made with sanitary U- and J-bends. Piping behind the transfer panel and the panel ports must be sloped to ensure proper drainage of residual liquid toward a drain pan. For the same reason, the whole transfer panel can tip a little bit forward. Ports should be capped when not in use to prevent any potential spill or contamination.

Chemical and Wear-resistant Floors

Floors should be sloped toward drains and provided with curbed wall floor junctions, with the curbs having a 30-degree slope to prevent accumulation of water, dust or soil.

Concrete flooring, including the high-strength granolithic concrete finishes, are especially suitable in warehouses where excellent resistance to heavy traffic is critical. However, untreated concrete can be dusty if dry and highly susceptible to damage from water and acids when wet. Concrete flooring is not recommended for high-care production areas, because it can spall and absorb water and nutrients, allowing microbial growth below the surface.

Epoxy flooring provides a durable, seamless, chemical-resistant and readily cleanable surface. However, over time the coating can crack and buckle due to exposure to cleaning chemicals or wear caused by heavy traffic. Once this happens, moisture pockets under the coating can create a microbiological niche.

Tile flooring is an excellent surface for food plants. However, with heavy wear and in more aggressive cleaning environments, tiles may lose some of their grouting, allowing the penetration of water beneath them. Plastic or asphalt membranes may be laid between the underlying concrete surface and the tiles. Brick floors also may be satisfactory but tend to be somewhat fragile and, unless vitrified, permit water penetration.

Welded PVC sheets have excellent chemical resistance. However, they are not suitable in hot and wet areas, and the welded PVC may be damaged by heavy cart traffic. Steel plates may be used on balconies, for example, and on loading docks and walkways in the vicinity of the process. However, they may corrode and are difficult to bond to concrete. Wood floors are satisfactory in packing and warehouse areas; however, the wood should be impregnated and coated with a durable plastic such as PU. Generally, wood floors may become worn, porous and absorbent, requiring expensive maintenance, and thus are not typically installed in modern food plants.

Pocket-free Drains

Drains should have appropriate capacity to avoid "ponding" of water and hence contamination in the area to be drained. The drain bodies must be free of pockets that can hold food soil; otherwise, they will cause odor problems. Only drains with an internal P-trap and atmospheric break should be used. Ptraps create a water-lock that keeps sewer gases out of the plant.

Balanced Air Supply and Exhaust System

Exhaust systems should have sufficient capacity to remove excess heat, dust, vapor, aerosols, odors and bioburden from process rooms. However, a positive overpressure must always be maintained. The supply of filtered air in the room by the heating-ventilation-air conditioning system must thus be large enough, otherwise the exhaust system will attempt to draw the required amount of air from adjacent less clean areas through doorways and windows. Exhaust fans must be located outside the building to maintain a negative pressure in the portion of the duct system located within the building. If they are installed in the exhaust hood, the exhaust air is pushed through the duct and not pulled out. By pushing vapors, fumes, etc. through that duct, the system puts the exhaust duct under positive pressure, which can force dirty air back into the room through holes and gaps in the duct work.

Hygienically Designed Lighting

Lighting must illuminate horizontal and vertical working surfaces evenly, without causing glare and at an intensity of about 300–500 lux at normal working height. Walls and ceilings should be light-colored because that permits fast detection of dirt and soil on their surfaces. In contrast, dark-colored walls and floors require additional lighting.

Preference should be given to lighting mounted on ceilings rather than on walls, because process equipment, storage racks, etc. can form shadows that make cleaning and inspection of floor, walls or ceilings difficult. For the same reason, overhead piping may not obstruct lighting.

Selected lighting should produce little heat and UV light to prevent attraction of insects. Because high-intensity discharge lamps (metal halide, and high- and low-pressure sodium lamps) have high penetration depth, they are used as high-bay lighting in warehouses; fluorescent luminaires are preferred as low-bay lighting, giving good illumination with less glare when covered with a prismatic cover or opalescent diffusing panel.

Lighting systems and their supports may not create horizontal ledges, legs or surfaces. To avoid projections that can accumulate dust, they can be built into the ceiling or wall with a hermetically closed seal, a procedure that is typical for cleanroom areas where lamps are changed via the technical area.

Hygienic Supply and Application of Electricity

In zone M areas, installing individual cables or multiple cables of small diameter, sharing the same route, in conduits is recommended. When two or more cables partly share a common route but go to different termination points, the creation of unsealable openings that allow the cable(s) to enter or exit the conduit is possible. However, this practice is only recommended for short distances. For long distances, straight line, non-bundled electric cables should be mounted on wire trays, preferably separated from each other. Vertical cable trays are less prone to dust accumulation, and are more accessible for inspection and cleaning. The use of horizontal racks for electrical cabling should be minimized, or they should be protected by a removable lid or installed vertically (on their side) to minimize horizontal surfaces.

When two or more cables partly share a common route, but go to different termination points, unsealable openings allowing cable(s) to enter or exit the conduit should be avoided. Conduits should be suitably sealed at both ends with a proprietary cable/sealing gland where a cable does pass through. In the food contact and splash areas, cables can also be protected from dirt, penetrating liquid and damage by encapsulating them in hermetically closed cable housings. However, the use of pipe rather than conduit should be discouraged because of the difficulties in maintaining the integrity of the piping system at cable entries and exits. Cable mounting in pipes still creates a hollow body and hence a hygienic risk.

Electric components should be enclosed in dust- and watertight cabinets or field boxes with all connections made at the bottom. Connections of cables and wires to housings must be sealed. The enclosures should be spaced away from equipment or walls and should be provided with an easily drainable 30° top roof. The heat generated by the electrical installations within these enclosures, and concomitantly the dust that penetrates the electrical installation during its cooling by means of fans, should be ventilated toward a technical area or a central ventilation system.

Control Panels

Control panels with high ingress protection rating should be provided with hygienically designed control and indicator devices. However, the more modern and hygienic membrane panels or touch-screen display panels now often replace these older, non-computer-based control panels.

Conclusions

Many food manufacturers only make use of the classic food preservation approach to control food safety. In the past two decades, however, the European Hygienic Engineering & Design Group has demonstrated that hygienic design of food process equipment and factories can contribute significantly to enhanced food safety. Hygienic food factory design starts with the selection of an appropriate location and the application of a hygienic building concept that prevents the entry of pests. The factory layout must permit the correct flow of materials, waste, air and personnel without compromising food safety as well as the installation of hygienic zones that offer maximal protection to the food produced. Process equipment and process and utility piping must be designed from food-grade materials that are compatible with the food product produced and the cleaning agents and disinfectants applied to sanitize the production environment. To avoid the introduction of new contaminants, equipment and piping must be hygienically integrated within the factory's premises. Walls, ceilings and floors must have an appropriate finish, lighting must provide sufficient illumination and drains should guarantee proper drainage to facilitate cleaning and to maintain hygienic conditions within the factory. The aim of this article is to serve as an introduction to proper hygienic food facility design. ■

Frank Moerman *received his M.Sc. in bioengineering from the University of Ghent in Belgium. In 2002, he became a member of the European Hygienic Engineering and Design Group (EHEDG) responsible for Belgium. More about EHEDG can be found at www.ehedg.org.*

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Best Practices in Facility Design

By Kenneth L. Fry, PE, LEED® AP

As the population continues to grow and more and more households rely on prepared foods as a healthy and convenient way to feed their families, food safety has become a top consideration in virtually every business decision in the food processing and manufacturing industries. The U.S. Centers for Disease Control and Prevention estimates that each year, roughly 1 in 6 Americans (or 48 million people) gets sick, 128,000 are hospitalized and 3,000 die of foodborne diseases (Table 1).

Of the known pathogens, norovirus accounts for roughly 50 percent of the recorded cases of foodborne illnesses. This pathogen is easily transmitted by handling contaminated product and then handling noncontaminated product, or by processing a product on a contaminated surface. What this boils down to is that this prevalent pathogen can be minimized or eliminated by proper facility plumbing design and by stringent hand-washing and sanitation protocols for your facility.

So how do we design a facility that minimizes the possibility for contamination, encourages frequent handwashing and allows for ease of sanitizing your processing areas? The Code of Federal Regulations, Title 21, Chapter 1, Parts 110 and 111, addresses Good Manufacturing Practices for manufacturing food and touches briefly on the subject, stating the following:

Subpart B–Buildings and Facilities

- Sec. 110.20 Plant and grounds

Be constructed in such a manner that floors, walls and ceilings may be adequately cleaned and kept clean and in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food contact surfaces or food packaging materials; and that aisles or working spaces are provided between equipment and walls, and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food contact surfaces with clothing or personal contact.

- Sec. 110.37 Sanitary facilities and controls

Plumbing. Plumbing shall be of adequate size and design, and adequately installed and maintained to:

- Carry sufficient quantities of water to required locations throughout the plant.
- Properly convey sewage and liquid disposable waste from the plant.
- Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste onto the floor.
- Provide that there is not backflow from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water for food or food manufacturing.

While the regulations give general guidelines of what good manufacturing processes include, they don't provide any details as to how to meet these standards. So how do we apply these guidelines in the real world?

Part 1: Constructing Cleanable Facilities

Most manufacturers have an idea of what a cleanable facility should look like: rooms constructed with insulated metal panels, washable ceilings and light fixtures, steam or hot water hose stations that provide adequate coverage for wash down, etc., but the devil is in the details. As it relates to plumbing, here's what we would expect in a wash down-type facility:

- All piping mounted to the walls and ceilings using stainless steel standoffs to

	Illnesses	%	Hospitalizations	%	Deaths	%
Known pathogens*	9.4 million	20	55,961	44	1,351	44
Unspecified agents	38.4 million	80	71,878	56	1,686	56
Total	47.8 million	100	127,839	100	3,037	100

**Thirty-one identified; content source: CDC, National Center for Emerging and Zoonotic Infectious Diseases and Division of Foodborne, Waterborne, and Environmental Diseases*

Table 1: Estimated Annual Number of Domestically Acquired Foodborne Illnesses, Hospitalizations and Deaths Due to 31 Pathogens and Unspecified Agents Transmitted through Food

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minimize the trapping of dirt and debris behind the pipe and allow for cleaning behind the pipe. Best practice is a minimum standoff of 1 inch or big enough to get your hand behind to clean.

- All insulated piping is provided with a washable jacket, typically a white PVC wrap. Closed-cell insulation such as Armstrong Armaflex should be used to prevent moisture absorption.
- For hose stations that have a stainless steel or high-density polyethylene backer board, the perimeter of the board should be caulked to prohibit contaminants from getting behind it. The same detail would apply to standoffs, sinks and other items affixed to the wall or ceiling.
- All plumbing fixtures (floor drains, floor sinks, hand sinks and compartment sinks) should be constructed of stainless steel and have radiused corners wherever two planes meet to prevent the build-up of contaminants. All drains should have removable grates and sediment baskets for ease of cleaning.
- All condensate drains should be properly trapped and have piping unions to allow for ease of disassembly and cleaning.

Determine how your facility will be cleaned and provide the proper infrastructure to support your plan. Will there be clean-in-place? Will the wash down be chemical or hot-water based? Will 140 °F hot water be adequate, or will you need 180 °F for sanitizing or kosher production areas? Decisions like these will greatly impact the design of your system.

Part 2: Providing Adequate Water Flow

The one complaint we hear over and over is the lack of adequate hot water temperature and flow during a facility wash down. Another is that there is insufficient water pressure to operate a boot wash or some other piece of equipment. The approach to solving these common issues is twofold: 1) Evaluate your available water service pressure and flow to design the possibility of a problem out of your plant and 2) thoroughly evaluate the procedures at your facility to get a true understanding of your needs under operating conditions. You might be surprised to find that you really need a lot more hot water than you thought you did. So here's how you can avoid these problems down the road.

Ensuring adequate pressure in your plant:

- Prior to building or expanding your plant, order a new flow test that will tell you what your available pressure and flow are. Don't rely on an old flow test, as there could have been changes to the service upstream that affect your service pressure.
- Size your service and backflow prevention device to minimize pressure drop from the get-go.
- If the available water pressure is borderline or, worse, inadequate, install a domestic water pressure booster pump as part of your system. This relatively inexpensive pump will provide good insurance against problems down the road.

> "So how do we design a facility that minimizes the possibility for contamination… and allows for ease of sanitizing your processing areas?"

Ensuring adequate flow in your plant:

- Do a thorough analysis of your water demands. Does your blast freezer have a water defrost? Will the wash down of your plant happen in all areas simultaneously or will it be staged to happen at different times? How many hose stations will you run at one time? Use this information to determine your peak demands.
- Size all the piping in your plant to flow at 4 feet per second or less. This will reduce pressure drop and not tax the system.
- Assume 8 gallons per minute for each hose station when calculating your demand to ensure adequate hot water capacity.
- For hot water systems, size your boiler with a high enough recovery rate to meet the peak demand. Include hot water storage tanks to stretch your system's capacity. Consider making provisions to install an additional boiler in the future. The cost will be minimal and an upgrade will be easy if your needs increase in the future.
- Provide a hot water recirculating system as part of your hot water system. Not only is this required by the International Energy Code if your point of use is 100 feet or more away from the hot water source, but it will ensure hot water is quickly available for handwashing and utensil cleaning, which will keep your U.S. Department of Agriculture inspector happy.

Part 3: Providing Adequate Drainage

Of all the things you need to get right in your new/expanded manufacturing plant, this is the biggie. Not only will poor drainage lead to potential contamination issues, it could also lead to slip-and-fall injuries and create a maintenance nightmare if things don't drain properly. A little thought and planning upfront with your facility manager, engineer and architect will go a long way in making your facility safe and sanitary.

Here are the keys to keeping your facility manager and inspectors happy:

- Provide the right type of drain to do the job. Do you need only small area drains for wash down and incidental spills, or do you plan to empty the tilt kettle on the floor? Will the drain experience only foot traffic or are you running hand trucks and forklifts in the area? Select a drain that can handle the duty required.
- Will your facility produce grease waste or solids during production? These types of waste require separate dedicated waste systems with interceptors to mitigate the contaminants. Position the interceptors in a location that allows for ease of servicing.
- Never use less than 4 inch-diameter piping for process waste. Although the International Plumbing Code allows for a pitch shallower than 1/8 inch per foot on a 4-inch pipe, never go below that.
- If your waste is going to be 140 °F or

above, PVC piping cannot be used. Cast iron is a recommended material in these cases.

- Pitch the floors to the drain. While this is more difficult in renovation scenarios, it can be done. If it is just not possible or too expensive to have a true pitched floor, leave an area 12 inches around the drain slightly depressed to help capture the flow.
- If you intend to reuse an existing waste system in your plant, reach out to your plumber and have the lines scoped to determine the condition, location and pitch of the pipes. I have seen too many instances where trying to save money and reuse existing piping has led to serious drainage issues once the plant was back in operation and all the newly installed floors had to be ripped up to make a repair.
- Make sure your indirect waste receptors are sized adequately for the anticipated flow. Floor sinks need to be large enough and deep enough to ensure that there is no splashing or backup at full flow.
- Never run waste piping below a freezer. At best this will lead to poor flow and clogging issues, at worst to pipe fractures and leakage.

Part 4: Preventing Cross-Contamination

So you've done all your homework and designed a facility that has adequate pressure, plenty of hot water and nary a puddle to be seen. Good for you, but you're not there yet. We need to get this plant across the finish line and eliminate any potential for cross-contamination. This can be as benign as improper handling of food or as serious as contaminants getting into your domestic water system that could lead to recalls or massive shutdowns as you try to figure out where the problem lies. By focusing on the key areas where most problems occur, you can minimize your exposure to a catastrophic event.

Again, proper planning and design of your plumbing systems can be your best defense in avoiding any issues with cross-contamination in your processing plant. Here are the areas to focus your attention on:

- Provide indirect connections for the waste from any plumbing fixture that is used to prepare, process or store food. Make sure the air gap is a minimum of 1 inch, two pipe diameters or as required by code. This also applies to the condensate lines from the evaporators in your cold storage rooms.
- Provide boot washers, foamers and handwash stations at all entrances to the processing areas. Consider automatic systems that do not allow entry until proper sanitizing has taken place.
- Ensure that any equipment that is connected to the domestic water system has the proper backflow protection (BFP). The American Society of Sanitary Engineering has written standards specifying what type of BFP is appropriate for what application, as does the International Plumbing Code.
- Keep plant waste systems totally separate from the sanitary waste system. Consider having a separate "raw" waste system from the "finished" waste system.

Summary

While designing a state-of-the-art manufacturing facility can be a daunting challenge, with a little planning upfront and by focusing on key aspects of the plumbing system design, it is relatively simple to have a plant that is safe from contamination and easy to maintain. It is important to get all the stakeholders involved early to determine what the flow and process looks and feels like so your plumbing infrastructure will meet your and your customers' needs. Taking the time to review your sanitation process upfront will ultimately save you time, money and headaches in the future as your business grows. ■

***Kenneth L. Fry, PE, LEED® AP**, is a partner at BD Engineering LLC.*