



Hygienic Design Enhances Food Safety, Brand Protection, Regulatory Compliance...and the Bottom Line

KOLLMORGEN[®]

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The ability to adopt and successfully carry out an effective sanitation program is largely determined by facilities and equipment that are constructed in alignment with sanitary design standards.

What is Hygienic Design?

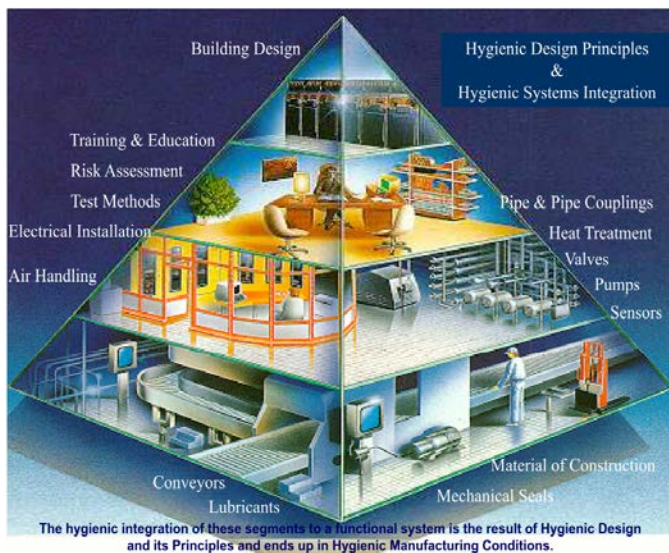
Sanitary design is the use of clearly defined methods and specifications for the design, fabrication, and installation of facilities and equipment, which when integrated, allow for timely and effective cleaning of the entire manufacturing asset. It entails the design of equipment and layout of facilities in line with hygiene-oriented standards that allow for good cleanability and surfaces that are resistant to daily exposure to corrosive food products and cleaning and sanitizing chemicals.

Equipment that does not meet basic sanitary or hygienic design principles, or is installed or used improperly cannot be adequately cleaned and sanitized. Reducing the time required for proper cleaning and allowing for optimization on the use of water and chemicals are also tangible benefits of incorporating hygienic design into food manufacturing operations.

While most benefits are obtained by selecting appropriate materials for the construction of facilities and equipment and avoiding dead spaces that are inaccessible or hard to reach where food residues can be trapped, there are generally accepted broader principles of sanitary design that, when adopted, support effective cleaning and disinfection of equipment, therefore minimizing the risk of cross-contamination of food. Ensuring accessibility for inspection, maintenance, cleaning and sanitation; eliminating liquid collection and hollow areas, and avoiding microbial and food residue harboring niches created by design (e.g., maintenance enclosures), operation, or by improper welding, are part of the ideal set of design criteria.

Food product contact surfaces should be cleanable, smooth, free of cracks and crevices, nonporous, nonabsorbent, non-contaminating, nonreactive, resistant to corrosion, durable, maintenance free, and nontoxic. Non-food product contact surfaces should also be considered when embracing sanitary design, as these have the potential to cross-contaminate food by frequently being in relative close proximity to the exposed product. Generally accepted principles of sanitary design of food facilities include the use of hygienic construction materials, hygienic zoning, appropriate layout, pest prevention, sanitary insulation of piping, and the installation of chemical and wear-resistant floors.

Separating raw from ready-to-eat food and dissimilar processes based on a risk assessment, in addition to strictly following personnel hygiene and cleaning and sanitation protocols, provides the best protection against incidents of cross-contamination. The validation of cleaning and sanitation processes is an industry best practice and should consider compatibility of chemicals with the equipment and the manufacturing process.



Source: Knuth Lorenzen, President of EHEDG

Principles of Sanitary Design

In general, accepted principles of sanitary design should contribute to enhancing the functionality of equipment and facilities while reducing the potential threat of product cross-contamination.

Standards and Guidelines

Guidelines and standards for sanitary design of equipment and facilities have been proposed and developed by multiple organizations, including the

3-A Sanitary Standards, Inc. (3-A SSI)¹, the North American Meat Institute (NAMI)², the European Hygienic Engineering and Design Group (EHEDG)³, the National Sanitation Foundation (NSF)⁴, Underwriters Laboratories (UL)⁵, and the Grocery Manufacturers Association (GMA)⁶. Organizations such as: 3-A SSI, NSF and UL issue standards, while others such as EHEDG and GMA have contributed with guidelines for hygienic design. International trade associations such as the International Dairy Federation (IDF)⁷ and others like the International Standards Organizations (ISO)⁸ are also generally involved in reviewing equipment hygiene standards. Occasionally, they review collaborative work done by some of the standards-issuing organizations (e.g., 3-A SSI and NSF worked together towards development of standards for meat and poultry equipment).

Some standards (i.e., 3-A SSI) are actually required by many state and local regulations, and there are voluntary certification programs that require third-party verification before a particular logo or insignia for some of the standards can be used.

Government agencies typically inspect food equipment for sanitary design, fabrication and installation, and in some instances have a process in place to pre-approve equipment for use in specific applications (e.g., meat, poultry, dairy).

While these standards and guidelines can vary in depth and content, they all aim to define sound elements of design that allow for easier access to facilitate cleaning and avoid microbial harborage niches as well as prevent physical and chemical hazards from becoming adulterants in the food produced.

Importance of Hygienic Design for Food Safety & Quality

A number of factors contribute to the cleaning and sanitation challenges faced by food manufacturers today which result in increased overall risk to food

safety. Changes in lifestyles have led to consumers expecting convenience and at the same time more natural, less processed items. Microbial adaptation to environmental pressures represented by sanitizers, storage temperatures and thermal processes, along with longer production times and less time for sanitation, have resulted in the need to come up with faster and more effective sanitation protocols, which in turn require easy access to all areas within the equipment and facility, as well as less harborage niches within these to save on time, water and chemicals.

The ease and level of cleaning of equipment and manufacturing facilities are directly related to potential for cross-contamination (e.g., microorganisms or allergens) and other undesired safety and quality effects on food. Regulations, industry standards and best practices demand that equipment and facilities must be hygienically designed so that they can be easily and thoroughly cleaned. Sanitary design must facilitate removal of microbial contamination along with any physical and chemical food residues, and that includes both product contact and non-product contact surfaces.

Dave Kramer, former Vice President of Engineering for Sara Lee Foods, once said that “the first principle of sanitary design is that the facility and equipment must be cleanable to a microbiological level”, and that “food facilities and equipment must be constructed – and able to be maintained – to ensure that they can be effectively cleaned and sanitized over their life”. Kramer also pointed out that several factors should be considered at the sanitary design planning stage, including traffic, airflow, temperature, moisture, nutrients, pH, and any competing microbial flora⁹.

Allowing for proper cleaning and sanitation enables safe food processing. This is why adhering to sanitary principles of design for both facilities and equipment can present significant benefits from an operational, regulatory and even reputational risk reduction standpoint.

¹ <http://www.3-a.org/>

² <http://www.meatami.org/>

³ <http://www.ehedg.org/>

⁴ <http://www.nsf.org/>

⁵ <http://ul.com/>

⁶ <http://www.gmaonline.org/>

⁷ <http://www.fil-idf.org/>

⁸ <http://www.iso.org/>

⁹ <http://www.foodprocessing.com/articles/2005/124/>

Resources & Industry-driven initiatives

The equipment and facility design process is much more effective in reducing the overall risk of food contamination events when it is carried out collaboratively between food manufacturers and equipment fabricators. That includes drafting specifications and standard operating procedures that aim to improve the ability of companies to ensure sanitary conditions in the food manufacturing environment. The process is also aided if both the original equipment manufacturers and their customers have a deep understanding of microbiology and the conditions that result in ideal niches for microbes to thrive.

For many years, resources such as *Engineering for Food Safety and Sanitation*¹⁰, a book written by Thomas Imholte, constituted the sole references available for the hygienic design and construction of food equipment and facilities. Today there are also guidelines and checklists published by organizations such as 3-A Sanitary Standards, Inc. (3-A SSI), the Baking Industry Sanitation Standards Committee (BISSC)¹¹, the National Sanitation Foundation (NSF), the European Hygienic Engineering and Design Group (EHEDG), and the Grocery Manufacturers Association (GMA) for further incorporation of hygienic design into both facilities and equipment. More recently, OEM's and food manufacturers engaged in a collaborative effort to reach an agreement on equipment design. This joint initiative, known as One Voice (OpX Leadership Network¹²), resulted in the development of a risk-based framework to define the appropriate hygienic specifications for the manufacture of low moisture foods. A similar approach could be applied to define common needs and expectations of both OEM's and food manufacturers across all food platforms.

All these resources can effectively assist equipment manufacturers and food industry personnel in understanding the proper elements of sanitary design to mitigate the risk of product adulteration with microbiological, physical or chemical contamination. Academia and the leading chemical companies (e.g., Ecolab) also play an important role in conducting research and communicating findings that lead to improvements in the selection

of materials of construction, better understanding of microbial attachment to various surfaces, and other critical factors that impact the ability of end users to maintain optimal sanitary conditions in the food handling environment.

Incorporating Sanitary Principles of Design Help Food Processors Meet Regulatory & Third-party Requirements

Joe Stout, former Director of Sanitation, Kraft Foods, and current President, Commercial Food Sanitation, indicates that “the key goal of sanitary design principles is to increase the probability that every square inch of processing plant equipment can be properly cleaned to a microbiological and allergen-free level every day”. Besides this being the expectation from most customers in the industry today, the requirements for considering sanitary design criteria are contained within Good Manufacturing Practices (GMP's), specifically Title 21 CFR parts 117.20 Plant and Grounds, 117.35 Sanitary Operations, 117.37 Sanitary Facilities and Controls, and 117.40 Equipment and Utensils. Incorporating hygienic design is thus a requirement of GMP's in food production.

While the food regulatory agencies in the United States do not regulate food processing equipment, they do regulate its sanitary use. As a key element of the Food Safety Modernization Act (FSMA)¹³, the Preventive Controls for Human Foods Rule will require each facility registered with the Food and Drug Administration (FDA) to prepare and implement a written food safety plan (FSP). The FSP will have to be focused on identifying and controlling risks specifically for each product, following this approach:

- Identify all potential risks (microbiological, chemical, physical)
- Determine which risks require a preventive control
- Develop preventive controls to manage those risks
- Have a monitoring program that documents that risks are being controlled
- List the expected corrective actions
- Verify that the systems are working

¹⁰ ISBN 0-9671264-0-1

¹¹ <http://www.bissc.org/>

¹² <http://www.opxleadershipnetwork.org/>

¹³ <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

- Reanalyze the FSP when something significant changes or at a minimum once every three years

As an example of the application of these principles, sanitation has been identified by FDA as a preventive control requiring food processors to develop and maintain written cleaning and sanitation procedures for all food-contact equipment and food-contact surfaces if they are needed to prevent cross contact with allergens or cross contamination with pathogens. The written procedures must define the scope, cleaning or sanitation objective, management responsibility, monitoring, corrective actions, and recordkeeping associated with the cleaning or sanitation procedure.

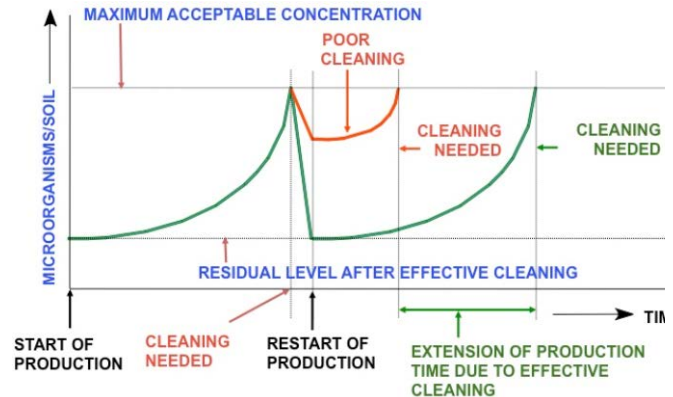
Furthermore, FDA considers that environmental testing, for an appropriate microorganism of public health significance or for an appropriate indicator organism, is particularly useful as a verification measure for preventive controls (i.e., sanitation) in operations where contamination of food with an environmental pathogen is determined to be a significant hazard. In addition, various food safety management schemes recognized by GFSI¹⁴, such as SQF and BRC, include environmental testing as part of their requirements.

Dave Kramer noted that “if you can’t see it and you can’t reach it, you can’t clean it or sample it”; therefore, incorporating sanitary principles of design in food manufacturing environments enables compliance with regulatory requirements and industry adopted standards, as well as meeting consumer and customer demands. Elimination of niches in machinery where pathogens can harbor reduces the risk of contamination.

The True Cost of Hygienic Design

There is a clear intersection between hygienic design and the bottom line for food manufacturing companies. Manufacturing costs are increased due to additional chemicals, water and labor that are needed to effectively clean and sanitize equipment and facilities that are difficult to clean. Higher operating costs are also incurred due to reduced life expectancy and increased maintenance required by equipment that is not hygienically

designed. Conversely, in addition to maximizing operational cost efficiencies, hygienically designed equipment and facilities enable effective cleaning, which allows for less downtime and therefore more time available for production (higher Overall Equipment Effectiveness, OEE).



Courtesy: Huub Lelieveld, GHI

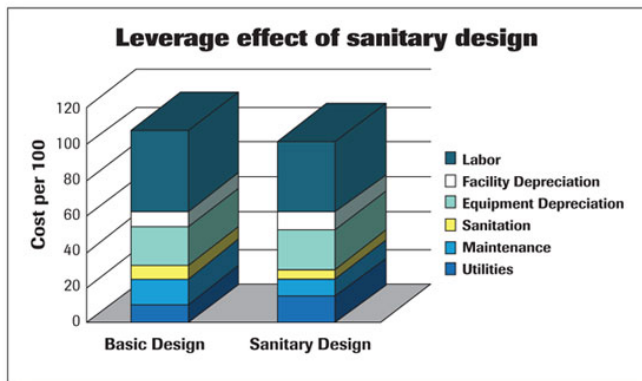
The upfront cost of food manufacturing equipment does not always correlate with its level of adherence to sanitary design. When evaluating the return on investment (ROI) for equipment and facilities designed in alignment with sanitary principles, it is best to consider it over the service life of the equipment and from an operational perspective, rather than from a capital purchase perspective.

It is typical for companies to expect short timeframes for positive return (payback) on investments of this nature, typically in the range of 2-3 years. When cost-cutting measures are enforced, the upfront cost of equipment becomes a decisive factor, and savings afforded by modifications to equipment buying and facility layout decisions may result in designs that do not fully align with the standards, guidelines and best practices recognized today.

The impact of failing to incorporate hygienic design into equipment and facilities is wide-ranging, as it negates a multitude of benefits that includes savings in not only chemical and water utilization but also reduction in cleaning time and environmental monitoring supplies. Additional benefits include reduced product non-conformances (less product on hold, reworked or destroyed), reduced number of complaints from

¹⁴ <http://www.mygfsi.com/>

consumers, and overall mitigated risk of a recall due to adulterated product.



Source: David C. Dixon, LLC (copied from Food Engineering Magazine)

Product Safety at Post Foods, and current Senior Director of Food Safety, The Acheson Group, helps us realize via the following example how incorporating hygienic principles into a facility design can also be a driver of multi-year operational efficiency gains:

Sloped floor to prevent water collection (upfront cost): \$1.2M

If not sloped, 22 employees × 1.25 hours per day × 220 days required to drain the floor = 6,050 hours/year

6,050 hours/year × \$30.00/hour fully loaded pay rate = \$181,500/year to squeegee water to a drain

Payback Period of \$1.2M divided by \$181,500/year = 6.61 years

A properly sloped floor would have lasted much longer than this, with savings of \$181,500 on manufacturing costs every year thereafter!

Substantial savings can be recouped when we look beyond upfront cost and the initial capital expenditure into a more comprehensive picture from an ongoing operational perspective.

Sanitary Design Helps Protect Brands

Improper sanitation has been cited frequently as the root cause of food poisoning incidents and a significant number of food-related recalls.

Investigations reveal that many of these incidents have had a connection with deficiencies in facility and machinery design, and thus the industry has realized that closely adhering to sanitary design criteria can dramatically reduce the risk of experiencing similar events.

When it comes to the true cost of not adopting sanitary principles of design, one must consider that damage to the reputation of the company, lost sales, idle time at the plant for cleaning, and extra costs associated with a potential food safety incident will almost always outweigh the cost of any preventive measures implemented, such as aligning with industry and government guidelines for hygienic design of equipment and facilities.

Recent history presents us with a relevant example that led to the deadliest outbreak of foodborne illness in the United States since 1924. Jensen Farms, a now bankrupt cantaloupe growers' farm in Holly, Colorado, was the source of a national *Listeria monocytogenes* outbreak in 2011 that, according to the Centers for Disease Control and Prevention (CDC), resulted in a total of 146 persons infected in 28 states, 30 deaths, and one miscarriage from a woman who was pregnant at the time of illness¹⁵. In its assessment of the factors that led to the preventable spread of the pathogenic bacteria, the FDA cited multiple factors related to poor facility and equipment design as well as negligent food safety management practices, including the fact that the packing facility's design allowed water to pool on the floor near equipment and employee walkways, that the packing facility floor was constructed in a manner that made it difficult to clean, and that the packing equipment was not easily cleaned and sanitized as evidenced by dirt and product buildup in certain areas¹⁶.

While ensuring food safety is a critical aspect of food manufacturing, product recalls occur due to a variety of reasons ranging from allergen cross-contact to microbiological contamination. In response to the potential negative impact to public health and damage to the reputation of companies, hygienic design guidelines for facilities and

¹⁵ <http://www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/120811/index.html>

¹⁶ <http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm276247.htm>

equipment have been developed as described before.

Sanitary design of equipment and facilities is no longer just a concern for manufacturers of high-risk foods such as ready-to-eat meats or salads, but food producers in low moisture and dry environments have also embraced hygienic design as a key component of their food safety risk mitigation strategies. Rather than being considered

as an afterthought, it is now incorporated into the early stages of equipment purchase decisions and facility building or modification processes. OEM's are partnering with clients to understand their needs and satisfy their requests for specific hygienic features being considered when designing equipment, with One Voice representing the best example of this trend as of today.

Conclusion

Sound sanitary design cannot be secondary to the functionality of equipment. While food manufacturers have a responsibility with respect to cleaning and sanitation, they must collaborate with equipment and facility engineers early in the design process to ensure that these critical programs within a food safety management system can be executed effectively to protect public health, protect their brands and optimize operations. Furthermore, companies that embrace sanitary design can drive significant savings over the service life of the equipment, which can represent a competitive advantage.

ABOUT KOLLMORGEN

Kollmorgen is a leader in the design and manufacture of hygienic motion control products used in food processing and packaging. Elimination of niches and covers in equipment and designing the devices for long life in the sanitation environment are key objectives of the designs. Much of this work is inspired by working with end users to maximize the impact for OEE and reducing the risk of food recalls. The Kollmorgen Advisory Board for Food and Beverage is a collaborative juncture with Virginia Tech Food Science & Technology whose objective is to drive high-value improvements in sanitation and hygienic equipment design.

For more information visit www.kollmorgen.com, email support@kollmorgen.com or call 1-540-633-3545.