10 hygienic design principles for food manufacturing equipment

An introduction to applying hygienic design principles to chocolate and bar manufacturing equipment

A PTL eBook

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INTRODUCTION

Between a rock and an unhygienic place

Plant engineers in a food manufacturing business, whether consumer packaged goods or co-packers, can be caught in a tough situation. Because the need for hygienic production outcomes is without question, it has become something of a ‘hygiene factor’ i.e., something you simply must have to be competitive in the food manufacturing business.

At the same time, production targets still remain and drive most engineers’ operational goals. Hygienic equipment design therefore becomes critical. What sort of production equipment will minimize the possibility of contamination from pathogens or allergens, while enabling maximum production capacity through faster cleaning times?

In this eBook we provide an introduction to the subject of hygienic design of food manufacturing equipment, from the factors driving changes, regulatory response and industry requirements, as well a look at best practice in terms of equipment design.

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The factors driving change

It's enough to make you sick

In the US market there has been growing awareness over the last decade of the risks of food borne diseases, and a significant regulatory response has followed. According to data available from the Center for Disease Control and Prevention (CDC), every year around 10 million Americans become ill from known pathogens (e.g. campylobacter, salmonella), resulting in 55,000 hospitalizations. If you add in all food related incidents, i.e. including those where pathogens are not always known, the figures rise to 48 million people being sick, with almost 128,000 requiring hospital treatment.

Estimated annual number of domestically acquired, foodborne illnesses, hospitalizations, and deaths due to 31 pathogens and the unspecified agents transmitted through food, United States

Foodborne agents	Estimated annual number of illnesses		Estimated annual number of hospitalizations		Estimated annual number of deaths	
	Number (90% credible interval)	%	Number (90% credible interval)	%	Number (90% credible interval)	%
31 known pathogens	9.4 million (6.6–12.7 million)	20	55,961 (39,534–75,741)	44	1,351 (712–2,268)	44
Unspecified agents	38.4 million (19.8–61.2 million)	80	71,878 (9,924–157,340)	56	1,686 (369–3,338)	56
Total	47.8 million (28.7–71.1 million)	100	127,839 (62,529–215,562)	100	3,037 (1,492–4,983)	100

www.cdc.gov/foodborneburden/2011-foodborne-estimates.html

The official response to this issue has been the introduction of the Food Safety Modernization Act (FSMA) in 2011 and its implementation since. This gave the Food and Drug Administration (FDA) wider powers over the way food is grown, harvested and processed.

What has this meant in a practical sense? Progressively, the FDA has been requiring all food facilities registered under section 415 of the Food, Drug and Cosmetic Act to comply with the FSMA and particularly the modernized Current Good Manufacturing Practices (CGMPs)[1]:

- Hazard analysis: the discipline of considering any known or reasonably foreseen hazards in your production.
- Preventative controls: measures put in place to mitigate against hazards, divided across process controls, food allergen controls, sanitation controls and other measures.
- Oversight and management of preventative controls: making sure these controls are applied. Using a mix of monitoring, corrections and corrective actions, and verification.
- Supply chain program: hazard identification and preventative controls through the supply chain where relevant.
- Recall plan: a written plan if a product has to be recalled.

What about allergens?

It's important to note that the FSMA includes allergen contamination as an explicit part of good practice - it is not just about food borne pathogens. That's because although only around 1% of American adults (as well as five million children) are affected by allergens, there is increasing awareness that a number of these can be life threatening. Allergens are usually grouped into the 'big eight' and all of their derivatives. Peanuts; tree nuts (almonds, cashews, pine nuts etc); milk; eggs, crustaceans (crab, lobster etc); fish; soy and wheat.

1 FSMA Final Rule for Preventative Control of Human Food

The shift from response to prevention

The role of equipment

Seen as the biggest change to food regulation in over 70 years, a key shift that the FSMA and subsequent enforcement guidelines was implemented from requiring manufacturers to respond to food safety incidents, to being proactive about preventing them. Given food safety incidents cost an estimated[2] of $USD 77.7 billion in 2012, investing in preventative action has been seen as a worthwhile investment.

Consequently, there has been greater involvement from regulatory and advisory bodies in the area of hygienic processing and the equipment that is key to that. The International Organization for Standardization (ISO) has issued a statement called 'Hygiene Requirements for the Design of Machinery,'[3] last updated in 2018. It applies to all types of machines and associated equipment used in applications where hygiene risks to the consumer of the product can occur. Many countries have adopted their own standards based on this international guide.

Then there are various industry organizations worldwide with a specific focus on the area, undertaking research on best practice, providing resources and training. These include:

- 3-A Sanitary Standards, Inc an independent, not-for-profit corporation dedicated to advancing hygienic equipment design for the food, beverage, and pharmaceutical industries.
- European Hygienic Design Group a non-profit consortium of equipment manufacturers, food producers, suppliers to the food industry, research institutes and universities, public health authorities and governmental organizations.

2 The cost of food safety, University of Florida
3 https://www.iso.org/standard/23748.html

Particularly relevant to food manufacturing businesses is the standard developed by 3-A SSI and the National Sanitation Foundation (NSF/3-A/ANSI 14159-1) called 'Hygiene Requirements for the Design of Meat and Poultry Processing Equipment'. Increasingly industries like chocolate and bar manufacturers have recognized these standards as applicable to their own sector. The basic requirements of NSF/ANSI/3-A 14159-1 – 2010 are harmonized with ISO 14159 which is the primary hygienic design standard listed in the Official Journal of the European Union for the EU machinery directive 2006/42/EC.

Manufacturers of food processing equipment have responded to the FSMA by trying to pro-actively build good hygiene features into the equipment they make, rather than expecting food manufacturers to respond to incidents. That's because equipment lies at the heart of any manufacturing operation, so in many ways these machines drive a food business' ability to confidently output food products that are free of pathogens and allergens.

What constitutes hygienic equipment design?

10 principles for food manufacturing equipment

As a plant engineer, how do you know manufacturing equipment is designed with hygiene in mind? Since being developed in the early 2000s, the American Meat Institute's (AMI) principles[4] of hygienic design for food manufacturing equipment in meat and poultry industries have been recognized across other food businesses. These principles are now seen as a good fit for manufacturers of products like chocolate and bars.

The AMI specify 10 underlying principles:

Principle 1

Equipment can be cleaned to a microbiological level.

Equipment must be able to be effectively and efficiently cleaned and sanitized over the lifetime of the machinery. The ability to remove all food materials is critical to this, including preventing bacterial ingress, survival, growth and reproduction.

Principle 2

Equipment is made of compatible materials.

Materials used for the construction of equipment needs to be compatible with the food product, the environment they operate in, to cleaning and sanitizing chemicals, and to the standard methods of cleaning and sanitation. That means inert, corrosion resistant, nonporous and non-absorbent equipment materials.

4 Sanitary Equipment Design Principles, AMI

Principle 3

Machines are accessible for inspection, maintenance, cleaning and sanitation.

Accessibility by an individual without tools is key to efficient sanitation. That means all parts of the equipment need to be readily accessible for inspection, maintenance, cleaning and/or sanitation. Equipment design can optimize hygiene by making disassembly and assembly straightforward for non-technical staff.

Principle 4

No product or liquid collection in equipment.

Food product, water, or product liquid cannot accumulate, pool or condense on the equipment or product zone areas, so machinery needs to be self-draining.

Principle 5

Hollow areas of equipment are hermetically sealed.

Hollow areas of equipment like frames or rollers can be high risk areas when it comes to contamination. They must be eliminated where possible or otherwise permanently sealed. Bolts, studs, mounting plates, brackets, junction boxes, name plates, end caps, sleeves and other such items need to be continuously welded to the surface of the equipment and not attached via drilled and tapped holes.

Principle 6

Equipment do not have niches.

All parts of food manufacturing equipment need to be free of niches such as pits, cracks, corrosion, recesses, open seams, gaps, lap seams, protruding ledges, inside threads, bolt rivets and dead ends. This also means that welds are continuous and fully penetrating.

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.

Principle 8

Maintenance enclosures are also hygienic.

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.

Principle 9

Ensuring hygienic compatibility with other systems in your plant.

Design of equipment needs to factor in compatibility with other equipment and systems (e.g., electrical, hydraulics, steam, air, water) in terms of hygiene.

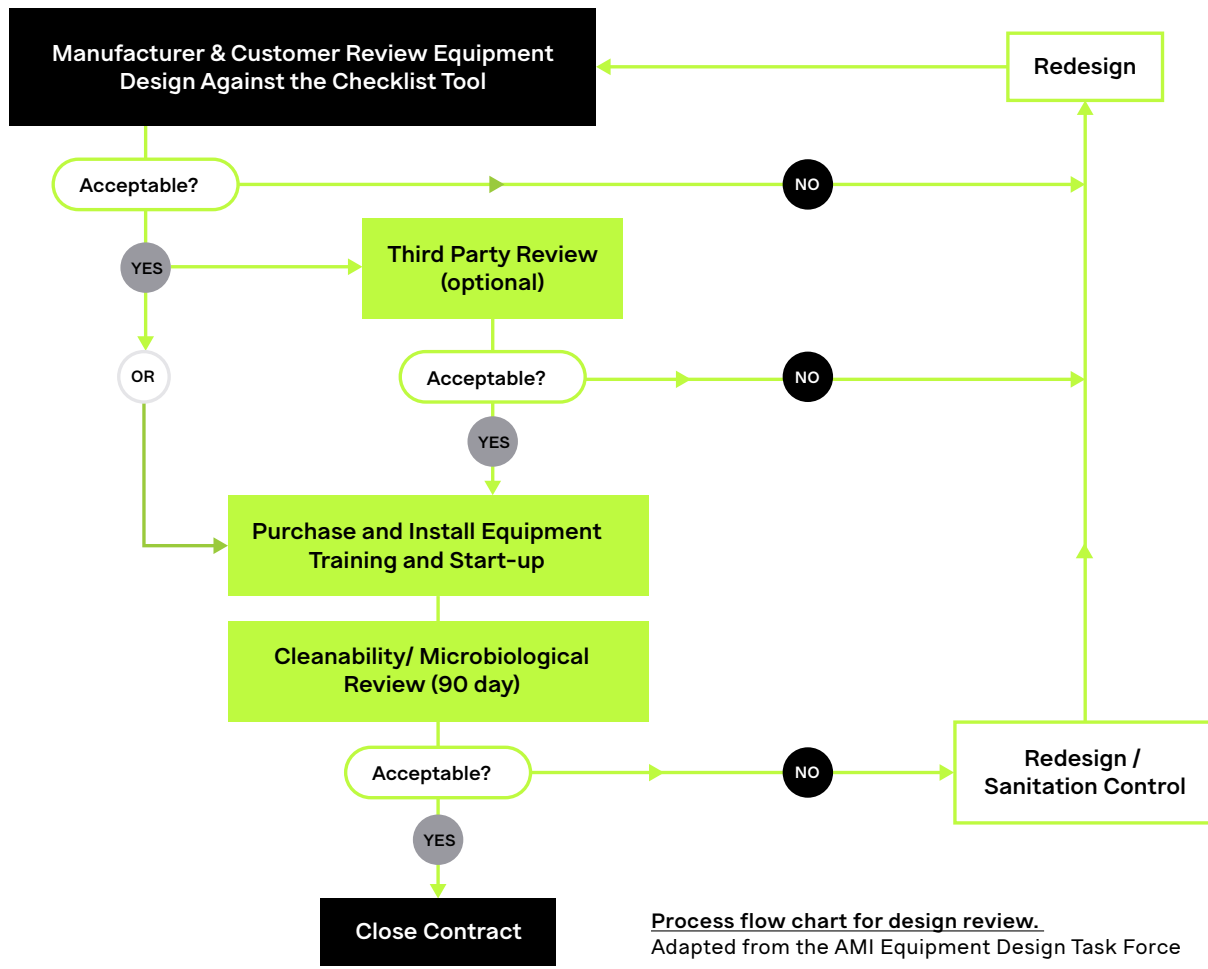
Principle 10

Validate cleaning and sanitizing protocols.

Procedures for cleaning and sanitation must be written, designed and tested to be effective. Chemicals recommended for cleaning and sanitation must be compatible with the equipment, as well as compatible with the manufacturing environment.

New equipment adoption checklist

The AMI has also developed a checklist to help manufacturers and their equipment suppliers to apply the 10 principles to the purchase of new machinery.



Process flow chart for design review.
Adapted from the AMI Equipment Design Task Force

The PTL way

"PTL's equipment and approach to customer service enables us to create a competitive advantage. By being open to our modifications and design change requests, we can create superior solutions for customers and gain increased flexibility in our operations. Their equipment reliability and exceptional sanitary design are outstanding."

Fred Grep
Director of Engineering
Hearthside Food Solutions

What about the production of chocolate and bars? The 10 principles can be applied to our industry. We emphasize the importance of hygiene when it comes to equipment design. At PTL, we understand this better than anyone, and it is a governing factor in how we design and build our equipment.

For example, the ability for people to execute effective sanitation without tools is fundamental to success. Backed with the right sanitation process and culture, that means machinery will be cleaned effectively with a much lower risk of any damage to a machine and the consequent delays to production. For products such as cold formed bars with coatings or not, there is no kill-step to kill contamination, so thorough cleaning processes are essential. Additionally any residual moisture can also lead to chocolate solidifying and binding in machines.

Our reputation has been built on the promise of creating innovative machinery together with our customers. This is underpinned by:

- A core focus of living and breathing chocolate and bars.
- Product development driven by customer-focus and innovation.
- Service attitude that is consultative and expert.
- Commitment to minimizing risk while maximizing output.

All our equipment is designed to several international standards; our focus goes beyond the equipment itself, as sanitation and hygiene are primary factors for us. We make sure that:

- Any equipment we design and build does not allow for bacterial build-up. Our attention to detail, no matter how minute, ensures that, if properly cleaned, contamination points are eliminated.
- The materials we use to build the equipment always meet strict industry allergen standards.
- We know that washing on-line can be troublesome. For example, chocolate needs a large amount of hot water and the drains must have fat traps to collect fats before they enter the waste system. This is much better done in a single dedicated wash down area, and machines are taken there for cleaning. Water is contained in the area, and not allowed to contaminate other parts of the facility. Our equipment offers fast and easy changeovers and wash-down options. Cleaning is more contained with this method.
- We ensure that all surfaces are smooth, sharp edges are removed, and operator safety is paramount.
- Non-product contact surfaces are also designed with hygiene in mind because even with the highest standards of containment, bacteria can still travel from one part of the facility to another.

We provide direction and guidance on how best to clean the equipment post-deployment, to ensure that hygiene standards are always met.

Conclusion

Further reading for a deeper look

Hygiene design of your food manufacturing equipment is not enough. Machinery must be designed and constructed with the prevention of sanitation issues in mind, but also with the reality that production facilities have to maintain output. It's combining those sometimes conflicting aims that production engineers must battle with, and ultimately partner with the right suppliers to achieve the best outcomes.

As a follow on from this introductory eBook, we suggest you download Hygienic Equipment Design for Low-Moisture Foods. PTL was involved in authoring this report, which is a collaboration of equipment manufacturers and large multinational manufacturers.

The objective of the report is to utilize existing industry standards, guidelines and information to define a process that allows consumer packaged goods and original equipment manufacturers to reach consensus of design criteria for hygienic equipment for low-moisture food manufacturing.

It covers process issues like risk assessment, hygienic zoning and cleaning methods. In terms of equipment, the report looks at materials and methods of design and construction, referencing other food industries like meat and poultry with a long history in this area.

Download the report