Hygienic Design

Hygienic Designed Scales

Less Contamination and Enhanced Profits

In today's global market, in an effort to ensure safety, weighing equipment construction must follow international guidelines based on EHEDG, NSF and 3-A standards. These standards encompass issues such as equipment surfaces, materials and design.

Contaminated processing equipment has been responsible for a number of major poisoning outbreaks. It also accounts for innumerable instances of product spoilage and quality defects.

In some cases, these events result from a failure to maintain, clean, or operate equipment hygienically; in others, the fault is found in the design of the equipment itself. Either way, the results can be catastrophic for consumers and nutraceutical producers.

To ensure safety of nutraceutical products, equipment used for its processing must be designed and installed according to requirements of sanitary design organisations Equipment must allow efficient cleaning and sanitizing, and surface materials must resist exposure to corrosive nutraceutical products and cleaning chemicals.

This paper highlights several of the the most important nutraceutical processing equipment aspects that are relevant to bench- or floor-scale design to ensure nutraceutical safety, reduce spoilage, and enhance profits.

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METTLER TOLEDO

1 Nutraceuticals contact surfaces

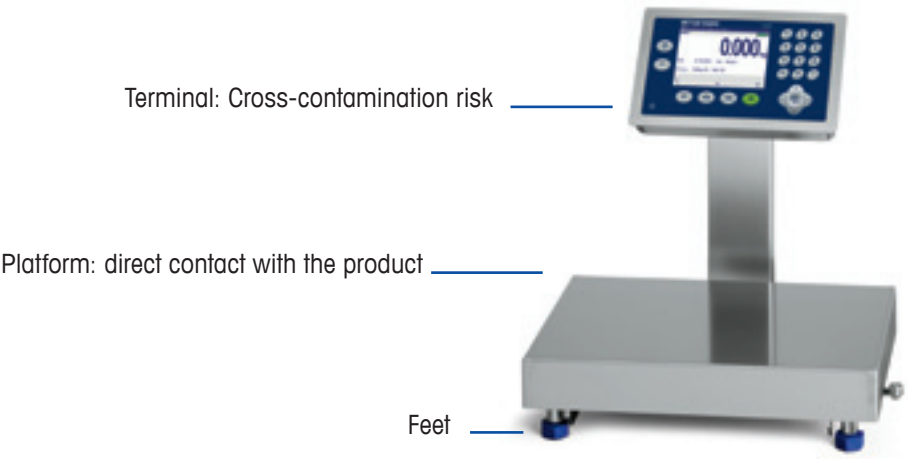
A nutraceutical product contact surface is defined as a surface in "direct contact with nutraceuticals, or raw material residue or where nutraceutical product or raw material residue. Because contamination of these surfaces can result in nutraceutical product contamination directly, rigid sanitary design criteria must be met.

Non-product contact surfaces include equipment parts such as feet, supports, and housings that do not contact nutraceutical product directly. However, contamination of these surfaces can cause indirect contamination. They must also be included when considering sanitary design. Risk analysis can help define areas with indirect or cross-contamination potential.

Generally, particularly if a structure is coated with metal alloy or non-metal (ceramic, plastic, or rubber) the final surface must be:

- Smooth
- Impervious
- Free of cracks and crevices
- Corrosion-resistant
- Durable and maintenance-free
- Nontoxic
- Nonporous
- Nonabsorbent
- Non-contaminant
- Cleanable
- Nonreactive

3A Standards also require that such coatings maintain corrosion resistance and be free of surface delaminating, pitting, flaking, chipping, blistering, and distortion during the equipment's intended use. Similarly, if any other modification or process is used in fabrication– such as welding, bonding, or soldering – it should be done using appropriate materials and in a manner that ensures the final surface meets the same sanitary design criteria.



2 Materials

A variety of materials are used in the construction of industrial equipment. These materials vary in their properties with regard to workability, compatibility and sanitary design features. Depending upon the application, various metals as well as non-metals such as plastics and rubber are used.

Hygienically designed portable bench scale feet: Example of non metal material in a scale, feet without open threads

Metals

Stainless steel is the preferred general-use metal for nutraceutical contact surfaces because of its corrosion resistance and durability in most nutraceutical applications. In general, the properties of the stainless steel alloy are related to its relative levels of chromium which offers corrosion resistance; and nickel which adds strength.

3A Standards also provide specifications regarding alloys and other coatings used in fabrication.

ANSI, DIN/EN designations of stainless steels commonly used in industrial equipment:

ANSI	DIN/EN	Typical analyses					
		C%	Cr%	Ni%	Mo%	Ti%	N%
304L	e.g.: DIN 1.4307 (EN X2CrNi18-9)	< 0.03	18	9			
316L	e.g.: DIN 1.4435 (EN 2CrNiMo18-14-3)	< 0.03	18	14	3		
410	DIN 1.4006 (EN X12Cr13)	< 0.12	13	< 0.75			
409	DIN 1.4512 (EN X2CrTi12)	< 0.03	11.5			< 0.65	
329	DIN 1.4460 (EN X3CrNiMoN27-5-2)	< 0.05	27	5.5	1.7		< 0.20

Non-metals

A variety of non-metal materials find application in nutraceutical product contact surfaces such as probes, gaskets, and membranes. Non-metal materials used in contact surfaces include:

- **Plastics, rubber, and rubber-like materials**
  These should be high purity grade and meet requirements designated under 3A Sanitary Standards or EHEDG.
- **Ceramics/glass**
  Ceramics are used primarily in membrane filtration systems; glass may be used as a contact surface. These applications are limited due to breakage potential.
- **Paper**
  Has been used over the years as a gasket material in piping systems designed for daily disassembly. Paper is considered a single use material.
- **Wood**
  is highly porous and difficult to clean and should be avoided. More details on polymeric materials, elastomers, adhesives, lubricants, and other non-metallic materials can be found under Chapter 9 "Additional resources".

In general, non-metal surfaces may lack the corrosion resistance and durability of metal surfaces, so maintenance programs should include frequent examination for wear and deterioration and be replace as appropriate.

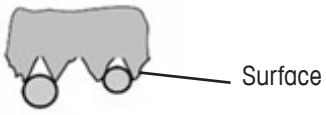
3 Surface texture and/or finish

If a surface is ground, polished, or textured in any way, the final result must be smooth, durable, free of cracks and crevices, and meet the sanitary design requirements described in the previous section.

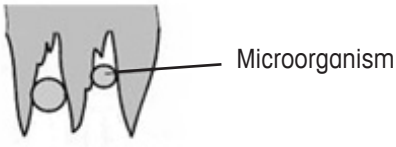
Large contact surface areas should have a finish roughness (Ra) of 0.8 µm or better. However, cleanability strongly depends on the applied finishing technology, which can affect surface topography.

A roughness of Ra >0.8 µm is acceptable if test results have shown that the required cleanability is achieved through other design features or procedures such as a high-flow cleaning agent rate. Specifically, in the case of polymeric surfaces, hydrophobicity, wettability and reactivity may enhance cleanability.

Hygienic design



Hygienic risk



Product contact surfaces should have finsih a roughness of Ra < 0.8µm

4 Functional requirements

Equipment used in processing of nutraceutical products should be easy to maintain. This ensures it will perform as expected and prevent microbiological problems.

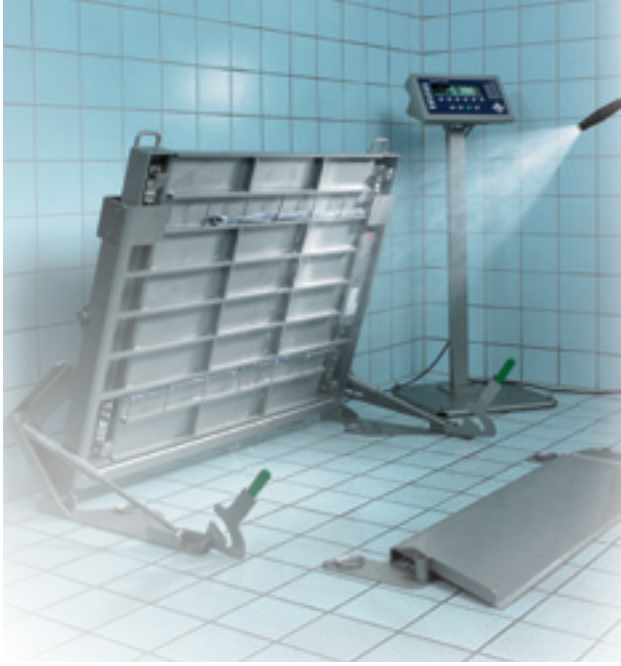
Poorly designed equipment requires more severe cleaning and prolonged cleaning time. This can include aggressive chemicals and longer cleaning/ decontamination cycles which results in higher costs, reduced production availability and shorter equipment life.

Easy-clean equipment, on the other hand, allows high-pressure washdown, reduces costs, and shortens cleaning time.

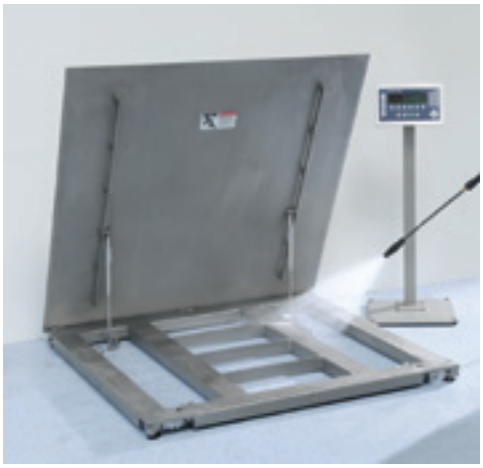
- Full stainless-steel construction
- Continuously welded and completely closed column, no disturbing cables
- Platter with smooth surface, brushed (ra < 0.8 mm)
- Ingress protection IP68/IP69k

5 Construction and fabrication

Design of equipment used in nutraceutical production and fabrication should avoid sharp corners and crevices. Mated surfaces must be continuous and substantially flush. Construction should allow for easy disassembly for cleaning and inspection.



Liftable floor scale with easy cleaning access



Floor scale with hinged load plate where contamination and corrosion have no chance due to high-quality material, hermetically seal-welded tubes and smooth surfaces

6 Internal angles / permanent joints

Internal angles should be coved or rounded with defined radii as shown in the accompanying figure. Equipment standards state appropriate radii for specific equipment applications and components.

For example, radii requirements stated in the 3A Sanitary Standards indicate that "all internal angles 135 degrees or less should have a minimum radius of 1/4 inch (6.35 mm)". EHEDG defines it in a similar fashion: "Corners should preferably have a radius equal to or larger than 6 mm; the minimum radius is 3mm. Sharp corners (≤90°) must be avoided."

Hygienic risk

Hygienic design

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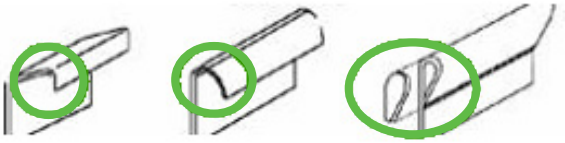

7 Testing

A series of EHEDG test methods for assessing the hygienic characteristics of equipment is available under Guideline EHEDG No. 2A (Additional resources).

8 Summary

The primary intent of international standards organizations such as 3-A, EHEDG and NSF, is the application of sanitary principles in nutraceutical equipment manufacturing to ensure product safety. Even with subtle differences among a reputable equipment manufacturer such as METTLER TOLEDO will implement these principles when designing bench and floor scales.

Hygienic design and high-quality materials ensure that machines can be cleaned quickly and with less costs. This leads to fast shift changes, fewer cleaning agents and an overall reduced risk of product contamination.

9 Additional resources

The following resources provided additional information on hygienically designed equipment specifications.

- European Hygienic Equipment Design Group (EHEDG)
  www.ehedg.org
- The National Sanitation Foundation (NSF)
  www.nsf.com
- 3A Sanitary Standards
  www.3-a.org
- Food and Drug Administration
  www.fda.gov
- METTLER TOLEDO Hygenic Design
  www.mt.com/hygienic-design

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