NSF/ANSI/3-A Standard
for Food Processing Equipment

Hygiene requirements for the design of meat and poultry processing equipment

1 General

1.1 Purpose

This NSF/ANSI/3-A Standard establishes minimum food protection and sanitation requirements for the materials, design, fabrication, and construction of meat and poultry processing equipment. This Standard does not contain operator safety requirements.

1.2 Scope

This NSF/ANSI/3-A Standard applies to equipment intended for use in the slaughter, processing, and packaging of meat and poultry products, excluding hand held tools and mechanical belt conveyors. The requirements are to be applied by designers and manufacturers who in turn are to provide guidance to the users for the intended use of the equipment.

Excluded from this NSF/ANSI/3-A Standard are requirements for the uncontrolled egress of microbiological agents from the equipment.

1.3 Measurement

Decimal and metric (SI) conversions provided parenthetically shall be considered equivalent. Metric conversions have been made according to IEEE/ASTM SI 10.

2 Normative references

The following documents contain provisions that, through reference, constitute provisions of this NSF/ANSI/3-A Standard. At the time of publication, the editions indicated were valid. All referenced documents are subject to revision, and parties are encouraged to investigate the possibility of applying the most recent editions of the documents listed below.

3-A Accepted Practice, No. 604-04 – 1994, Supplying air under pressure in contact with milk, milk products, and product contact surfaces

1 3-A, International Association of Food Industry Suppliers, 1451 Dolley Madison Boulevard, McLean, VA 22101-3850
3 Definitions

For the purposes of this Standard, the following definitions apply.

3.1 associated equipment: All appurtenances associated with a piece of equipment, not defined as equipment, that are essential to the functioning of the equipment for it to hygienically process a product (e.g., fittings, piping, tubing).

3.2 bond: The adhesive or cohesive forces holding materials together. This definition excludes press fits and shrink fits.

3.3 cleanable: Designed to be readily freed from soil.

3.4 cleaned in place: Cleaning of equipment by impingement or circulation of flowing chemical solutions, cleaning liquids, and water rinses, without dismantling, into, onto, and over surfaces in equipment or systems designed for this specific purpose.

3.5 cleaning: Removal of soil.

3.6 coating: The results of a process where a different material is deposited to create a new surface. There is appreciable, typically more than 40 µ in (1 µ m), build-up of new material. The coating material does not alter the physical properties of the substrate. Coating processes include but are not limited to: chemical (conversion coatings), engineering plating (e.g., electrodeposition gold), thermal spraying (e.g., flame, plasma, arc spray), physical vapor deposition, chemical vapor deposition, and overlays and encapsulation.

3.7 consumer: The end user of the product (including domestic animals).

3.8 corrosion resistant material: Capable of maintaining original surface characteristics under prolonged contact with the intended end use environment and the normal use of cleaning compounds and sanitizing solutions.

3.9 crevice: A sharp, cleft-like, irregular opening of small depth that adversely affects cleanability.

3.10 dead space: Space wherein product, cleaning or sanitizing agents, or soils can be trapped, retained, or not completely removed during the operation of cleaning.

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2 American Society of Mechanical Engineers (ASME), Three Park Avenue, New York, NY 10016-5990


5 Institute of Electrical and electronics Engineers, Inc., 445 Hoes Lane, Piscataway, NJ 08854
3.11 **easily accessible:** A location that can be reached by an employee from the floor, a platform, or other permanent work area.

3.12 **easily removable:** Capable of being detached and taken away from the parent unit without or with the use of simple hand tools.

3.13 **hygiene:** The taking of all measures during product handling, preparation, and processing to ensure its suitability for use by humans or domestic animals.

3.14 **inspectable:** Designed such that all product contact surfaces can be made available for close visual observation.

3.15 **joint:** Junction of two or more pieces of material.

3.16 **equipment:** An assembly of parts or components, with the appropriate actuators, controls, and power circuits, joined together for a specific application, in particular for the processing, treatment, moving, or packaging of product.

3.17 **manual cleaning:** Cleaning by various methods that are manipulated by hand when the equipment is open or when partially or totally disassembled.

3.18 **microorganism (relevant):** Bacteria, fungi, yeasts, molds, spores, and viruses that are able to contaminate, multiply, or survive in a product and are able to be harmful.

3.19 **non-absorbent materials:** Those materials that under the intended conditions of their use do not retain substances with which they come in contact.

3.20 **non-product contact surface:** The exposed equipment surfaces that are not in contact with the product and from which product or other materials cannot drain, drip, diffuse, or be drawn (self-returned) into the product or product container.

3.21 **non-toxic materials:** Substances that, under the conditions of their use, are in compliance with applicable requirements of the Food, Drug, and Cosmetic Act of 1938, as amended.

3.22 **pest:** Mammals, birds, reptiles, vermin, and insects that can adversely influence the product.

3.23 **practical test:** Activities performed following a documented set of procedures and parameters used to determine an evaluation.

3.24 **product:** Any substance intended to be applied or taken into humans or domestic animals (e.g., by ingestion, injection, topical application, insertion).

3.25 **product contact surface:** Equipment surfaces that are exposed to the product and from which the product or other materials can drain, drip, diffuse, or be drawn (self-returned) into the product or product container.

3.26 **sanitization:** The application of cumulative heat, chemicals, or other approved agents on clean surfaces that is sufficient to reduce the population of disease organisms by at least 99.999% (5 log reduction).

3.27 **seal:** To close an aperture so as to effectively prevent the entry or passage of unwanted matter.

3.28 **self-draining:** The combination of design, construction, installation, and surface finish so as to prevent the retention of liquid except for normal surface wetting.

3.29 **sensors:** Devices or instrumentation attached to equipment for process monitoring/control.
3.30 **smooth**: The condition of a surface that satisfies hygienic requirements and is free of pits, pinholes, cracks, crevices, inclusions, rough edges, and other surface imperfections detectable by visual and tactile inspection.

3.31 **soil**: Any unwanted matter.

3.32 **sterilizable (equipment)**: Designed to be capable of being sterilized.

3.33 **sterilization**: A process that inactivates all microorganisms.

3.34 **surface treatment**: The results of a process whereby chemical compositions or mechanical properties of the existing surface are altered. There is no appreciable, typically less than 40 µ in (1 µ m), build-up of new material or removal of existing material. Surface treatments include but are not limited to: mechanical (shot peening, glass beading, polishing), thermal (surface hardening laser, electron beam), diffusion (carburizing, nitriding), chemical (etching, oxidation), ion implantation, or electropolishing.

4 **Materials of construction**

4.1 **General**

Materials shall be suitable for their intended use.

Surfaces of materials, coatings, and surface treatments shall be durable, cleanable, and if necessary, capable of being sanitized without breaking, cracking, chipping, flaking, delamination, erosion, corrosion, abrasion, and shall be resistant to the penetration of unwanted matter under intended use.

Equipment used in the slaughter, processing, and packaging of meat and poultry products shall be constructed of materials that will withstand the generally humid operating environment and high pressure, hot water cleaning with chemical cleaning agents.

4.1.1 **Unacceptable materials**

The following materials shall not be used in product contact surface areas or non-product contact surface areas:

- materials containing antimony, arsenic, cadmium, lead, or mercury;
- **metals containing selenium in excess of 0.50%**;
- materials classified as hazardous substances (such as carcinogens, mutagens and teratogens);
- asbestos and asbestos containing materials;
- wood;
- enamelware;
- porcelain;
- leather;
- uncoated aluminum and aluminum alloys; and
- uncoated anodized aluminum and aluminum alloys.
4.2 Product contact surfaces

In addition to the general requirements (see 4.1), materials used for product contact surfaces shall:

- be corrosion resistant to both product and cleaning/sanitization materials;
- be non-toxic;
- not contaminate or otherwise have any adverse effect on the product;
- be non-absorbent (except where technically or functionally unavoidable); and
- be temperature resistant to processing and heat treatments where necessary (e.g., freezing, heat-sterilization).

4.2.1 Metals

4.2.1.1 Product contact surfaces shall be:

- AISI 300 series stainless steel; or
- of stainless steel of a type appropriate for the application; or
- when necessary, stainless steel that has been hardened by heat treatment or precipitation hardening, including martensitic stainless steel; or
- other alloys that can be shown to be as corrosion resistant as austenitic stainless steel and are non-absorbent and non-toxic (see chart in Annex D); or
- other metals and metal alloys (including solder) suitable for the conditions of intended use; or
- carbon steel when used for cutting surfaces; or
- black iron pipe when used for the processing, storage, and transportation of fully rendered vegetable and animal fats.

4.2.1.2 Copper and copper alloys, bronze, brass, and zinc galvanizing shall not be used for product contact surfaces. These materials may be used in supply air and supply water lines or for gears and bushings used in non-product contact surfaces. Brass is acceptable for potable water systems.

4.2.1.3 Surface coatings and platings may be used if the base material is non-toxic. Coatings shall meet the requirements of 4.2.2.

4.2.2 Non-metals

Product contact surfaces shall be manufactured from or composed of substances that:

- may not reasonably be expected to result, directly or indirectly, in their becoming a component of food or otherwise affecting the characteristics of food, including the imparting of a color, taste, or odor to food; or
- are generally recognized as safe or have received prior sanction for their intended use; or
- are regulated as indirect food additives under the provisions of 21 CFR, parts 174-189; or
- are exempt from regulation as food additives under the provisions of the 21 CFR, part 170.39; or
can be demonstrated to be safe for the intended use, subject to the Food, Drug, and Cosmetic Act, Section 409(h)(1) [21 U.S.C. 348(h)(1)], Premarket Notification.

4.2.2.1 Elastomers and polymers having product contact surfaces shall be of such composition as to retain their surface and conformational characteristics when exposed to the conditions encountered in the environment of intended use and in cleaning and sanitization or sterilization.

4.2.2.2 Adhesives and the bonds created by their use shall be compatible with the surfaces, products, and cleaning/sanitizing materials in which they are in contact. All bonds shall be continuous and mechanically sound so that the adhesives do not separate from the base materials to which they are bonded.

4.2.2.3 Where materials having certain inherent functional purposes are required for specific application, product contact surfaces may be made of these materials (e.g., carbon, sapphire, quartz, fluorspar, spinel, ceramic materials).

4.2.2.4 Product contact surfaces may be modified by surface treatment or coating(s).

4.2.2.5 Gaskets, O-rings, etc., shall be non-toxic, non-porous, non-absorbent, and unaffected by food products.

4.2.2.6 Absorbent fabric may only be used for single use applications, e.g., single service filters.

4.3 Non-product contact surfaces

In addition to the general requirements (see 4.1), materials used for non-product contact surfaces under the conditions of intended use, shall:

- be of corrosion resistant material or material that is treated (e.g., coating, painting) so as to be corrosion resistant to both product and cleaning/sanitizing materials. When coated, the coating shall adhere;
- be non-absorbent (except where allowed under 4.2.2.6); and
- not contaminate or otherwise have any adverse effect on the product.

Parts removable for cleaning having both product contact and non-product contact surfaces shall be designed to ensure that hygiene risks are eliminated in accordance with the requirements for product contact surfaces.

5 Design and construction

5.1 Product contact surfaces

5.1.1 Surface texture

Surfaces shall be free of imperfections such as pits, folds, cracks, and crevices.

Surface textures shall have a maximum $R_a$ of 32 $\mu$ in (0.81 $\mu$ m). When necessary, due to functional needs, the following may be used:

- Glass-beaded or shot-peened surfaces shall have a maximum $R_a$ of 125 $\mu$ in (3.2 $\mu$ m).
- Coatings shall have a maximum $R_a$ of 200 $\mu$ in (5.0 $\mu$ m).
- Machined plastics shall have a maximum $R_a$ of 125 $\mu$ in (3.2 $\mu$ m).
Black iron pipe used for the processing and transport of fully rendered fats is exempt from surface texture requirements.

NOTE – The 2B mill finish on stainless steel sheet is also considered as smooth or smoother than a No. 4 finish. No further finishing is required if the finish is free of defects, such as pits, scratches, chips, or flakes in the final fabricated form.

5.1.2 Cleaning and inspection

Surfaces shall be cleanable. For equipment intended to be disassembled, the design shall ensure that product contact surfaces be easily accessible for cleaning and inspection, and the demountable parts shall be easily removable. Alternatively, equipment designed to be cleaned in place shall be designed so that product contact surfaces and all non-removed appurtenances thereto can be mechanically cleaned and are easily accessible and easily removable for inspection.

5.1.3 Sanitization and sterilization

Where appropriate, equipment shall be designed such that all product contact surfaces can attain the required sanitization or sterilization conditions.

5.1.4 Microbial ingress

Where appropriate (e.g., aseptic process), equipment shall be designed to prevent microorganisms migrating from the external environment onto product contact surfaces, either directly or via soils.

5.1.5 Draining

Surfaces of equipment intended to drain shall be self draining or be drainable (see figures B.1 and B.2).

5.1.6 Dead spaces

There shall be no dead spaces (see figure B.3).

5.1.7 Joints

5.1.7.1 Permanent metal-to-metal joints shall be continuously welded. Jointed surfaces shall be flush (see figure B.4).

5.1.7.2 Dismountable joints shall be flush and sealed at the product contact surface (see figure B.5).

5.1.7.3 Only in cases where welding or bonding is impractical, silver soldering, press fitting or shrink fitting may be employed where necessary for essential functional reasons.

5.1.7.4 Silver-bearing solder may be used for flushing joints and producing fillets for minimum radii requirements. In cases where welding is impractical, silver-bearing solder may be used for essential functions, such as mounting of cutting blades and cutting blade mounting pins and bushings.

5.1.7.5 Welding, press fitting, shrink fitting or soldering shall produce product contact surfaces with a smooth finish free of imperfections such as pits, folds, inclusions, cracks and crevices.

5.1.8 Coatings

Coatings shall be free from surface delamination, pitting, flaking, spalling, blistering, and distortion. Surface coatings and platings must remain intact. Surface coatings shall not crack or peel. Coatings and platings shall not be used on product contact surfaces that are not inspectable. Paint shall not be used on product contact surfaces or on parts having both product contact and non-product contact surfaces.
5.1.9 Internal angles, corners and grooves

Internal corners and angles of less than 135° in product contact areas shall have smooth and continuous radius \( \frac{1}{8} \) in (0.13 in, 3.2 mm) or greater. Lesser radii may be used for necessary functional reasons or to facilitate drainage provided these areas can be readily cleaned. The radii shall not be less than \( \frac{1}{32} \) in (0.031 in, 0.79 mm) except that the radius intersection of press-fits, shrink-fits, and flat sealing surfaces may be zero.

Internal three-plane intersections shall have a radius of \( \frac{1}{4} \) in (0.25 in, 6.4 mm) or greater.

Where used, grooves shall be wider than their depth.

5.1.10 Seals, gaskets, O-rings, joint rings

5.1.10.1 Seals, gaskets, O-rings and joint rings shall be designed to minimize product contact and be cleanable.

5.1.10.2 Excessive compression can cause damage to rubber components and can cause the elastomer to extrude into the product zone adversely affecting cleanability. Where an elastomer is used as a seal between solid surfaces, the compression of the elastomer shall be controlled (see figure B.7).

5.1.11 Fasteners

Fasteners (e.g., screws, bolts, rivets) shall be avoided. Where technically unavoidable, fasteners shall be cleanable (see figure B.8). There shall be no exposed screw threads or recesses.

Threads which may become product contact surfaces during dismantling operations should be designed to be cleanable, such as ACME 60° Stub, or equal, with not more than 14 threads per inch and a with a major diameter of not less than \( \frac{5}{16} \) in (0.31 in, 7.9 mm).

5.1.12 Process flow disruption caused by intrusions

Intrusions (e.g., springs, openings, perforations) shall be avoided except where functionally necessary.

Where necessary, such process flow disruptions and intrusions shall be cleanable in place or easily accessible for cleaning, sanitizing, and inspection.

5.1.13 Shafts and bearings

5.1.13.1 Where shaft seals are required, they shall be hygienic in design (i.e., packless) and shall be easily accessible for cleaning, sanitizing, and inspection.

5.1.13.2 Where a shaft passes through a product contact surface, the portion of the opening surrounding the shaft shall be protected to prevent the entrance of contaminants (see figure B.9).

5.1.13.3 Lubricated bearings, including the permanent sealed type, shall be located outside the product contact surface with adequate clearance open for inspection between the bearing and any product contact surface (see figure B.9).

5.1.13.4 Bearings or bushings having a product contact surface shall be avoided. When technically necessary, these bearings or bushings shall be of a non-lubricated or product-lubricated type (see figure B.10) and be cleanable. When a bottom support bearing or bushing is used, it shall not interfere with drainage of the equipment.

5.1.13.5 When provided, a shaft driving mechanism shall be securely mounted in a position that ensures a physical separation from product contact surfaces for cleaning and inspection.
5.1.14 Sensor and sensor connections

All sensors and sensor connections having product contact surfaces shall be installed to avoid crevices and dead spaces and be drainable (see figure B.3).

5.1.15 Other connections

All pipelines and other appendages entering the equipment shall be hygienically sealed and designed to prevent the ingress of soil.

5.1.16 Openings and covers

5.1.16.1 Panels, covers, and doors shall be so designed that they avoid any adverse influence (e.g., entry and/or accumulation of soil) and shall be cleanable (see figure B.11).

5.1.16.2 If any exterior flange is incorporated in the opening, it shall slope and drain away from the opening.

5.1.16.3 Covers shall be sloped to an outside edge(s).

5.2 Non-product contact surfaces

5.2.1 General

All equipment, supports, and framework shall be designed in such a manner as to prevent the retention of moisture and the ingress and harborage of pests and soils. All equipment, supports, and framework shall be designed in such a manner as to facilitate cleaning, inspection, servicing and maintenance. Equipment shall be designed such that non-product surfaces can attain the required sanitization or sterilization conditions.

Permanent metal-to-metal joints shall be continuously welded wherever possible; when not possible, permanent metal-to-metal joints shall be completely sealed. Permanent metal-to-non-metal or non-metal-to-non-metal joints shall be continuously bonded.

Equipment to be mounted without supports shall be designed to allow the installer of the equipment to mount flush and seal the equipment to the supporting surface (see figure B.13).

There shall be no dead spaces.

The possibility of adverse galvanic reactions between dissimilar materials shall be taken into consideration (see figure B.12)

5.2.2 Cleaning and inspection

Surfaces shall be cleanable. For equipment intended to be disassembled, the design shall ensure that relevant areas are easily accessible for cleaning, and inspection and the demountable parts shall be easily removable. Alternatively, equipment may be designed to be cleaned in place. Cleaned in place equipment shall be designed to allow access for inspection after cleaning.

5.2.3 Insulation

The insulation material shall be properly mounted and completely sealed to prevent the ingress of contaminants (e.g., moisture, pests).

5.2.4 Supports
5.2.4.1 Supports (e.g., legs) are to be smooth with rounded ends or with flat, load bearing feet suitable for sealing to the floor and have no exposed threads. Sufficient clearance around and under the equipment for cleaning and inspection shall be provided (see figure B.13).

5.2.4.2 Where casters are used, they shall be of sufficient size to provide sufficient clearance between the lowest part of the base and the floor for easy cleaning and inspection. Casters shall be easily cleanable, durable, and of a size that permits easy movement of the equipment.

5.2.4.3 Where the equipment is to be floor or wall mounted, supports shall be designed for sealing to the mounting space.

5.2.5 Product contact with equipment fluids

Equipment shall be designed, fabricated, and installed to prevent the ingress of unwanted fluids (e.g., lubricating and hydraulic fluids, signal transfer liquids) into the product.

5.3 Requirements for specific equipment

5.3.1 Pneumatic equipment

Exhaust air shall be piped below and away from product surface areas. Air directly contacting product or product contact surfaces shall meet the requirements of 3-A Accepted Practice, No. 604-04.

5.3.2 Equipment that uses a single pass water flush

Equipment that uses a single pass water flush shall have a drain that directs water to a non-product contact area.

5.3.3 Belts

Belts with fabric carcasses or substrate materials shall have edges sealed with an acceptable compound.

5.3.4 Spraying devices

Radii on spraying devices may be less than \( \frac{1}{32} \) in (0.031 in, 0.79 mm). When radii are less than \( \frac{1}{32} \) in (0.031 in, 0.79 mm), the internal angles must be cleanable and inspectable.

There shall be no exposed threads or crevices on product contact surfaces of high and low pressure spraying devices except where required for functional and safety reasons.

6 Instruction handbook, maintenance, and cleaning

6.1 Instruction handbook

The instruction handbook shall include the following items:

- installation instructions of the equipment and associated equipment:
  - Information shall be provided so that, after the equipment is installed, it maintains its hygienic integrity (e.g., drainability) and there is adequate access for servicing and cleaning (see figure B.14).
  - Measures shall be described on the use of the equipment so that when installed correctly the product is not exposed to factors that can lead to contamination.
- instructions for use.
6.2 Maintenance and cleaning

6.2.1 Maintenance

A system of measures shall be recommended to ensure that the hygienic integrity of the equipment is maintained during the intended life time.

6.2.2 Cleaning

The instructions shall specify typical routine procedures for cleaning, sanitizing, rinsing, and inspection for cleanliness and, where appropriate, sterilization. Recommended cleaning and sanitizing procedures, materials, implements, and agents shall be specified. Recommended cleaning and sanitizing procedures, materials, implements, and agents shall be compatible with the materials of construction. Where dismantling is required, specific instructions shall be provided.
### Annex A
(informative)

#### Table A1 – Categorization of equipment and associated equipment for intended use

<table>
<thead>
<tr>
<th>Hygiene level</th>
<th>Description</th>
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<tr>
<td>1</td>
<td>Equipment which, following a hygiene risk assessment, needs only to partially conform with the requirements of this Standard to meet the identified risk(s) and to produce safe product.</td>
</tr>
<tr>
<td>2</td>
<td>Equipment which, following a hygiene risk assessment, conforms with the requirements of this Standard, but requires planned disassembly for cleaning.</td>
</tr>
<tr>
<td>3</td>
<td>Equipment which, following a hygiene risk assessment, conforms fully with this Standard and can be cleaned without disassembly.</td>
</tr>
<tr>
<td>4</td>
<td>Equipment which, following a hygiene risk assessment, conforms fully with this Standard and has been designed for a specified heat, chemical or physical treatment to free the equipment from relevant microorganisms.</td>
</tr>
<tr>
<td>5</td>
<td>Equipment which, following a hygiene risk assessment, conforms fully with this Standard, will prevent microbial ingress and has been designed for a specified heat, chemical or physical treatment to free the equipment from relevant microorganisms.</td>
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Annex B
(informative)

Examples of good and bad hygienic design features

Figures B.1 to B.14 are examples of a particular problem with the objective of enhancing and illustrating the text of Sections 5 and 6. In many cases, alternative solutions, which are equally as hygienic, could be found. Poor examples of hygienic design are illustrated on the left hand side of the page (hygiene risk) and good examples on the right hand side (acceptable).

<table>
<thead>
<tr>
<th>Hygiene risk</th>
<th>Acceptable</th>
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<tbody>
<tr>
<td>Not drainable design</td>
<td>Drainable design</td>
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</table>

Figure B.1 – Drainage of vessels
Figure B.2 – Drainage of pipes
(a) mounting of sensors

(b) conveyor roller construction

Figure B.3 – Dead spaces
Hygiene risk

(a) welded joints

- a1) intermittently welded lap joint
- a2) continuously welded butt joint (ground and polished)
- a3) continuously welded lap joint

(b) bonded joints

Acceptable

Product

Figure B.4 – Permanent joints
Hygiene risk

(a) pipe couplings

Hygiene risk

(b) stirrer in product contact

Figure B.5 – Dismountable joints
Hygiene risk

It is important to limit the compression to prevent damage to the elastomer structure, resulting in loss of contact pressure.

The same problem will occur when due to ageing resilience is lost.

Acceptable

When compressed by 15%, 70° shore hardness rubber gaskets will provide a tight seal.

Figure B.6 – Internal angles and corners

Hygiene risk

High temperature

Temperature cycling will cause permanent leakage due to large differences between thermal expansion rates of metal and plastic (e.g., PTFE).

Acceptable

Non-resilient gasket material "flow" under pressure.

Low temperature

(Gap is not shown to scale)

Figure B.7 – Controlled compression and thermal expansion of elastomers
Hygiene risk

Acceptable

Figure B.8 – Design of fasteners
Hygiene risk

Acceptable

Figure B.9 – Shaft entry design

Hygiene risk

Acceptable

Figure B.10 – Product lubricated bearings
Hygiene risk

pivot cover

hinge

dead area

Acceptable

detachable cover

Hinged cover

Figure B.11 – Openings and covers

Hygiene risk

open cross-section

Acceptable

closed cross-section

open

with cladding

without cladding

Figure B.12 – Framework (supports)
Figure B.13 – Floor and wall mountings

Figure B.14 – Accessibility of equipment
Annex C
(informative)

Bibliography

NOTE – Figures B.1 - B.14 have been derived from the following texts.

Hygienic design of liquid handling equipment for the food industry. Technical Manual No. 17, Campden & Chorleywood Food Research Association, Chipping Campden, Gloucestershire GL55 6LD, UK.


Published in-full (in English) from: Campden & Chorleywood Food Research Association, Chipping Campden, Gloucestershire GL55 6LD, UK.

Other hygienic design texts are available from the organizations above and the 3-A Sanitary Standards Committees, 14151 Dolley Madison Boulevard, McLean, Virginia, USA 22101-3850
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Optional metal alloys

Optional metal alloys having the following compositions are examples considered in compliance with Section 4.2.1. This is not an all-inclusive list. Chemistries given are per ASTM specifications wherever possible and may deviate slightly from UNS chemistry. (Percentages are maximum, unless range is given.)

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- continued -
### Table D1 – Optional metal alloys

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**W** | 1.0 | 0.50 | Balance |
|**Ti** | | 0.25 | |
|**Al** | | | |
|**Other** | | | H=0.015 |
| | | | N=0.050 |
| | | | O=0.40 25 |

Metal alloys or metals other than the above may be as corrosion resistant as AISI 300 Series Stainless steel. This may be shown when metal alloys or metals are tested in accordance with ASTM G31 Laboratory Immersion Corrosion Testing of Metals and have a corrosion rate of less than 10.0 mil (250µm) per year. The test parameters such as the type of chemical(s), their concentration(s), and temperature(s) should be representative of cleaning and sanitizing conditions used in meat and poultry processing equipment. Alloys containing lead, leachable copper, or other toxic metals should not be used.
Annex E
(informative)

Schematic risk assessment procedure

START

Determine Limits of the Machine in term of Product and Process

Identify all Food Safety Hazards (See annex F)

Undertake a Risk Assessment (See annex G)

Can Hazard be Eliminated by Hygienic Design?

YES

NO

Can Hazard be Removed by Cleaning/Disinfection?

NO

YES

Provide Cleaning/Disassembly Instructions

Provide additional Instructions or Limitations to Use (See annex J)

Have Additional Hazards Been Created?

YES

NO

Additional Hazards to be Addressed?

YES

NO

Verify Compliance with Hygiene Requirements as Required (See annex I)

END

Classify According to Hygiene Levels as Required (See annex A)
Annex F
(informative)

Hazards

The hazards that can be associated with product handling, preparation, and processing can arise from:

– biological causes such as pathogens, spoilage microorganisms, or toxins (e.g. ingress or retention of bacteria, spores, viruses, yeasts/molds);

– chemical causes, including those from cleaning and sanitizing substances (e.g. lubricants, cleaning fluids); and

– physical causes including foreign materials arising from raw materials, equipment or other sources (e.g. allergens, pests, metals, materials used in the construction of the equipment).
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Strategy for selecting hygiene measures

The risk assessment strategy for selecting hygiene measures is applicable to both product and non-product contact areas. The basic strategy for selecting hygiene measures for the design of equipment shall include the following:

- identification of the process for which the equipment is intended;
- hazards associated with the product(s) produced (Annex F);
- risk assessment associated with each hazard identified (see below);
- design methods/measures which can eliminate hazards or reduce risks associated with these hazards (Section 5);
- identification of any other hygienic hazards, which can be introduced by methods used to reduce the risk associated with the hazard under analysis;
- means of verification of the effectiveness of the hazard elimination or the risk reduction method (Annex I); and
- description of residual risks and any additional precautions necessary in the information for use where applicable (Section 6 and Annex J).

This process is schematically represented in Annex E. After this process has been undertaken for all hazards identified, it may be applicable to define the item of equipment according to one of the hygiene levels described in Annex A in order to help clarify the intended use.
Annex H
(informative)

Elements of risk assessment

When undertaking the elements of the risk assessment, the following parameters are presented as guidance to the range and type of factors that shall be considered for the equipment and its associated equipment.

a) The intended use of the equipment: Will the equipment be used for one specific purpose only, for which the hazards are readily identifiable, or could the equipment be used for a wide range of products in many industries (e.g., a pump)?

b) The product type to be processed by the equipment: Will the product be already contaminated (e.g., a raw material) or will it be “preserved” or aseptic?

c) The degree of further processing: Will the product processed by the equipment subsequently undergo a further process which functions as a hazard elimination step (e.g., a heat treatment) or is the process for which the equipment is intended the final process?

d) Specific application of the product:

   – Is the product to be used by the consumer immediately after processing or is there a product shelf-life in which the severity of the hazard could increase (e.g., relevant microbial growth)?

   – Will the product be used by a specific consumer group to whom the hazard may present a more serious risk (e.g., an infant, elderly, or infirm person)?

e) The degree of cleaning, sanitization, sterilization, and/or inspection: Is the equipment to be cleaned sanitized, sterilized, and/or inspected after every use, routinely during the day, every day, or every week, etc.?

f) The use of the equipment: Is the equipment likely to be well maintained or used infrequently? Is it designed for high or continuous use? Is misuse forseeable?
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Annex I
(informative)

Verification of hygiene measures and test methods

Verification of compliance with hygiene requirements is undertaken using one or more of the following:

– examination of the functional specifications and drawings;
– examination of the fabricated equipment; and/or
– undertaking of specific practical tests (if available).

The methods of verification of hygienic design depend on both the original risk analysis (see Annex H) and the specific purpose for which the equipment was designed.

The majority of open product processing equipment is considered to be cleanable if its design complies with the requirements of Section 5 and of the specific standards. More complicated equipment may require assessment by means of a practical cleanability test.

The majority of closed product processing equipment is considered cleanable if the cleaning procedure can be verified by means of a practical test of the entire plant or its individual components. Some closed product processing equipment may be considered to be cleanable if its design complies with the requirements of Section 5.

Equipment designed to be sterilized or for aseptic production, usually for closed product processing, shall require practical testing.
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Annex J
(informative)

Additional information (limitations of use)

In the event of a hygienic design (Section 5) being unable to control the risk associated with a specific hazard identified (Annex F), or in the event of a product compromise, additional information shall be required. Additional information could include, for example:

- further monitoring, cleaning and disassembly instructions;
- specific processing conditions (e.g., controlled temperature environment); or
- limitations to the range of products that can be safely processed.
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