

Working Group for Machinery and Equipment in the Confectionery Industry

Hygiene Requirements for Machinery and Equipment in the Confectionery Industry

2nd Edition April 2002

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1.0 Scope and Purpose

This recommendation shall inform and explain designers and operators of confectionery machinery how to build, operate and maintain machinery and equipment from the hygiene point of view.

The recommendation describes rules for construction and operation of confectionery production equipment which are suitable to protect the consumer against the risk of infection or food-borne illness.

The information is based on the relevant laws and regulations. However, they cover a much more comprehensive field because they state precisely application-related details for the confectionery sector. But they do not release either the designer or the operator from their diligent care and responsibility for their products.

Another goal of this recommendation is the improvement of the dialogue between manufacturer of machines and equipment and user. The editors welcome any suggestions as well as proposals for improvement or amendments.

The recommendation is based on today's state of knowledge. At least parts of this recommendation might become invalid due to advanced developments, other findings, or modified or new laws and regulations.

2.0 Definitions

2.1 Machine zones

For confectionery machinery there are certain machine zones which require different technical and hygienic considerations.

2.2.1 Product zone

All areas in which food is processed, transported or stored and all surfaces coming into contact with food.

2.1.2 Splash zone

All areas outside the product zone in which product parts no longer useable for food production and other material might accumulate.

2.1.3 Non-product zone

All areas without any contact with either product or product parts.

2.2 Terms

This list contains only such terms not explained otherwise or which need a more precise definition in this context.

2.2.1 Accessibility

Easily accessible

All machine parts which can be reached without tools or with a maintenance key.

Hardly accessible

All machine parts which can be reached by use of additional tools only.

2.2.2 Removability

Easy to remove

Machine parts which can be removed by operating staff without tools.

Hard to remove

Machine parts which can be removed by authorized personnel using specific tools only.

2.2.3 Cleaning

Cleaning is defined as the removal of product residues and foreign material. It is required for hygienic, technical and visual reasons.

2.2.4 Contamination

A contamination of the product to be manufactured or processed by undesired foreign matters or microorganisms.

2.2.5 Disinfection

Inactivation of a wide range of microorganisms. It must be guaranteed that no pathogens are present any more after disinfection.

Precondition for an effective disinfection is proper cleaning because dirt particles might cover microorganisms and protect them from direct contact with the disinfectant. Furthermore, dirt might limit the effectiveness of a disinfectant.

2.2.6 Nearly sterile

This means that the number of microorganisms present is so low that there is not risk for product or persons at any time.

Remark:

From the microbiological point of view this term is not very specific. Whether a product or ambient air or similar can be considered as "nearly sterile" is highly depending on the type of application. For example for milk a total plate count (TPC) of 5000 is nearly sterile while the same value for lactose would be considered as highly loaded.

2.2.7 Sterile

Free from viable microorganisms capable of multiplication and active viruses.

2.2.8 Dead space

Space which can not be flushed during cleaning, thus it does not come into contact with cleaning liquid or steam.

2.2.9 Toxic

Specific health-damaging influence of toxins on human organism.

Contrary to most poisons formed by living organisms, toxins are mainly water-soluble poisons with specific effect even at low concentration.

2.2.10 Corrosion

Destruction of material surface by chemical or electro-chemical impacts.

3. Materials

The material used for the individual machine zones can be seen from the table.

All materials used for product or splash zone have to fulfill the following requirements: No matters are allowed to migrate from the surfaces of these materials into the product except for technically inevitable proportions which do not harm health, odor, or taste.

Materials/sealings	Product zone	Splash zone	Non-product zone
1. Stainless steel (see steel definition, e.g. DIN 1.4031, 4541, and 4571)	P	P	P
2. Aluminum/alloys	Y	P	P
3. Steel	Y	Y	P
4. Cast steel	Y	Y	P
5. Gray cast iron	Y	Y	P
6. Copper	Y	Y	P
7. Brass	X	Y	P
8. Bronze	Y	Y	P
9. Chrome-containing coatings ¹	Y	Y	P

10.	Nickel-containing coatings ¹	X	Y	P
11.	Tin-containing coatings ¹	X	Y	P
12.	Zinc-containing coatings ¹	X	Y	P
13.	Rock (granite rollers, porphyry)	P	–	–
14.	Mineral cotton, enclosed	X	P	P
15.	Ceramics (e.g. aluminum oxide, corundum)	Y	Y	Y
16.	Porcelain ²	Y	Y	Y
17.	Wood	X	X	X
18.	Cadmium	X	X	X
19.	Antimony	X	X	X
20.	Lead	X	X	X
21.	Enamel	X	X	Y
22.	Color coating ⁴	X	Y	P
23.	Powder coating ⁴	Y	P	P
24.	Silicate glass	X	X	X
25.	Shatterproof glass	Y	Y	Y
26.	Plastics ³	Y	P	P
27.	Compound material, adhesives	X	X	Y
28.	Sealings ⁵	P	P	P

X = not permitted

Y = permitted in certain cases (clarify directly with manufacturer)

P = permitted

¹ Risk of migration of material particles, in particular platelike particles, into the product has to be excluded.

² Take relevant food law regulations or national limitations, e.g. FDA approval, into consideration.

³ The following plastic materials are allowed. However, always have manufacturer document harmlessness in particular referring to additives such as color pigments, extenders and binding agents:

Polyamide 6-E	PA6-E
Polyamide 6-6	PA6-6
Polyacetal (homopoly)	POM
Polyacetal (copoly)	POM
Material "S"	UHMW-PE
Polyethylene, high-molecular	HMW-PE
ND-polyethylene	ND-PE
Polypropylene	PP
Polytetrafluoroethylene	PTFE
Polycarbonate	PC

⁴ Paintings and powder coatings have to be physiologically harmless, have to adhere properly and form a solid surface.

⁵ The material for the sealings must be physiologically harmless and resistant against food components. It must be non-corrosive, non-absorbing and non-porous.

4.0 Principles of Construction and Layout

4.1 General

4.1.1 Safety

Besides the optimum hygiene conditions in and on machinery and equipment, the relevant legal regulations have to be complied with.

In no case moveable machine parts shall be arranged without protective measures just for the purpose of better cleaning. This jeopardizes the safety of the operating personnel.

4.1.2 Accessibility

The accessibility has to be designed depending on the frequency of cleaning and maintenance. Thus for all surfaces and spaces within the product zone, easy accessibility is an absolute must.

4.1.3 Cleaning

It must be ensured that frequent cleaning of all parts in the product and splash zone can be done easily.

For manual cleaning without any problems, the machine parts must be spaced with sufficient distance. Product transport belts must be in food-grade quality and designed for easy cleaning. Covers must be easily removable for cleaning.

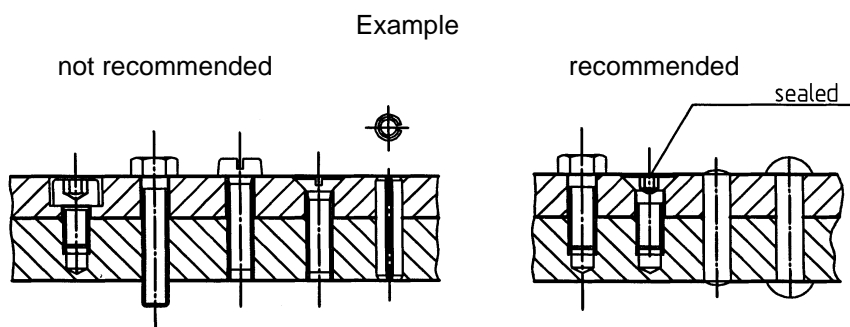
In case of wet cleaning, make sure the cleaning zone is sufficiently tight to avoid contamination of other zones with the cleaning liquid. Make sure the cleaning and flushing liquids are completely removed after the cleaning work.

4.1.4 Contamination

Use properly selected and permitted materials, which are non-toxic, non-absorbent and resistant against corrosion, to avoid contamination. Preventive constructive measures for sealings, lids, and closures are required, too. Exclude contamination risks through foreign materials and microorganisms from areas outside the product zone.

4.2 Machine zone

Group	Requirements	Product zone	Splash zone	Non-product zone
4.2.1	<u>Construction</u>			
	<u>General construction features</u>			
4.2.1.1	All machine parts must be easily accessible or removable	A	A	B
4.2.1.2	No slots, hexagon sockets or hollow spaces allowed for screw, rivet or pin joints	A	A	B

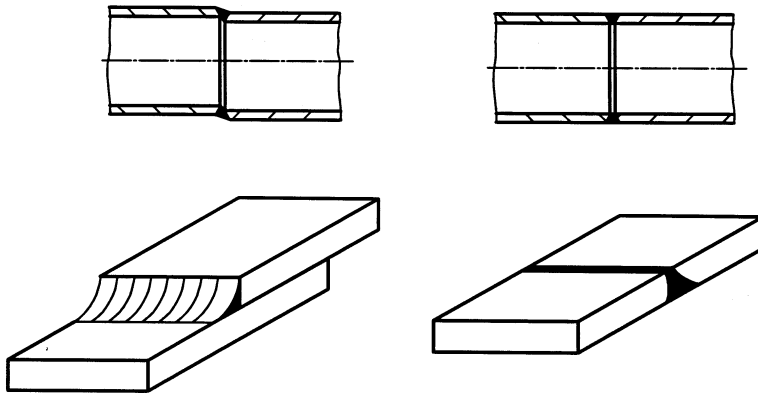


Group	Requirements	Product zone	Splash zone	Non-product zone
4.2.1.3	Permanently joined material surfaces have to be manufactured jump jointed and without gaps by welding or another methods producing the same results	A	B	B

Example

not recommended

recommended

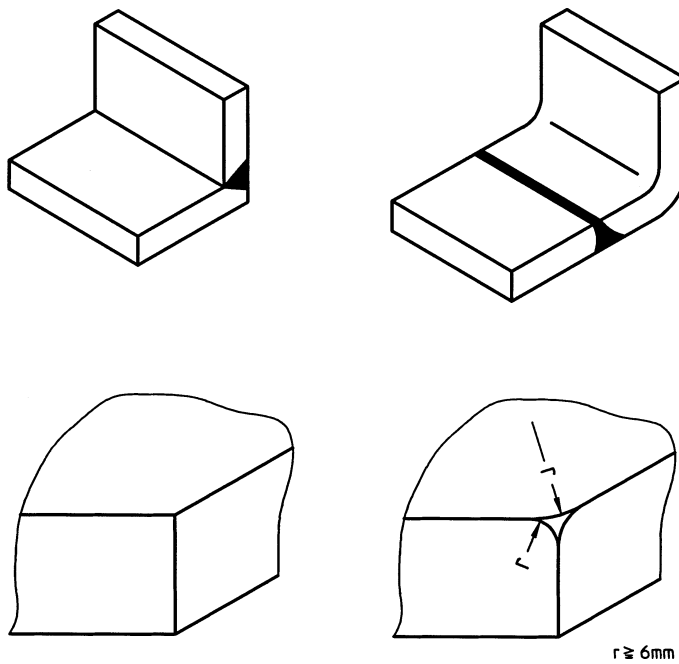


4.2.1.4	Edge joints formed by 2 or 3 surfaces with an angle $< 135^\circ$ have to have an radius of at least 6 mm tangentially to the adjoining surfaces.	A	B	B
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Example

not recommended

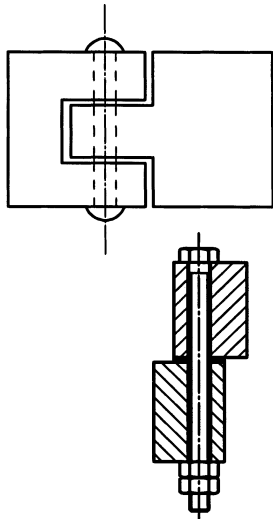
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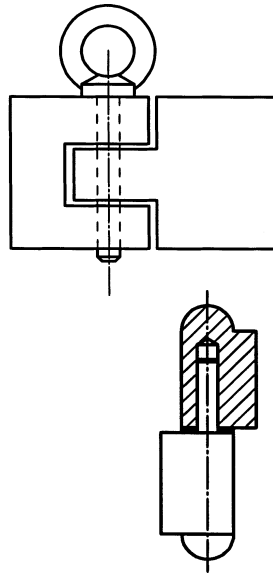
Group	Requirements	Product zone	Splash zone	Non-product zone
4.2.1.5	Hinges and bolts must be easy to disassemble and clean.	A	A	B

Example

not recommended



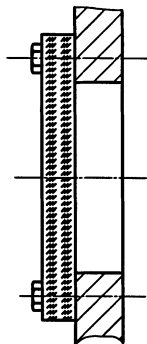
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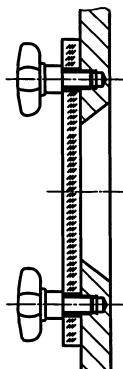
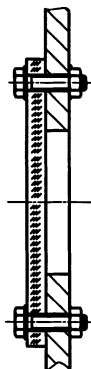
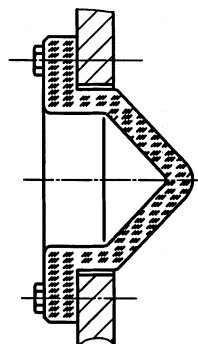
4.2.1.6	Inspection glasses and light openings must be of shatterproof material. They must be sealable or easy to remove.	A	A	B
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Example

not recommended



recommended

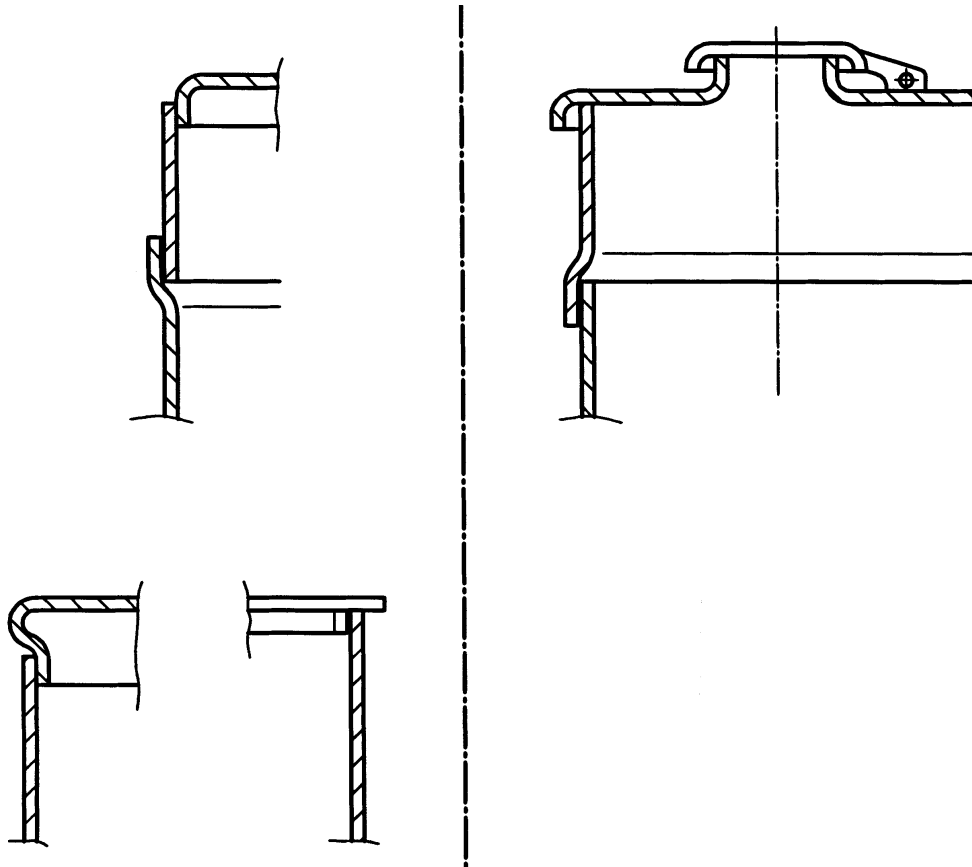


Group	Requirements	Product zone	Splash zone	Non-product zone
4.2.1.7	Covers must be overlapping and must be equipped with protection against dripping liquids. Hinged covers must open to the outside.	A	A	B

Example

not recommended

recommended

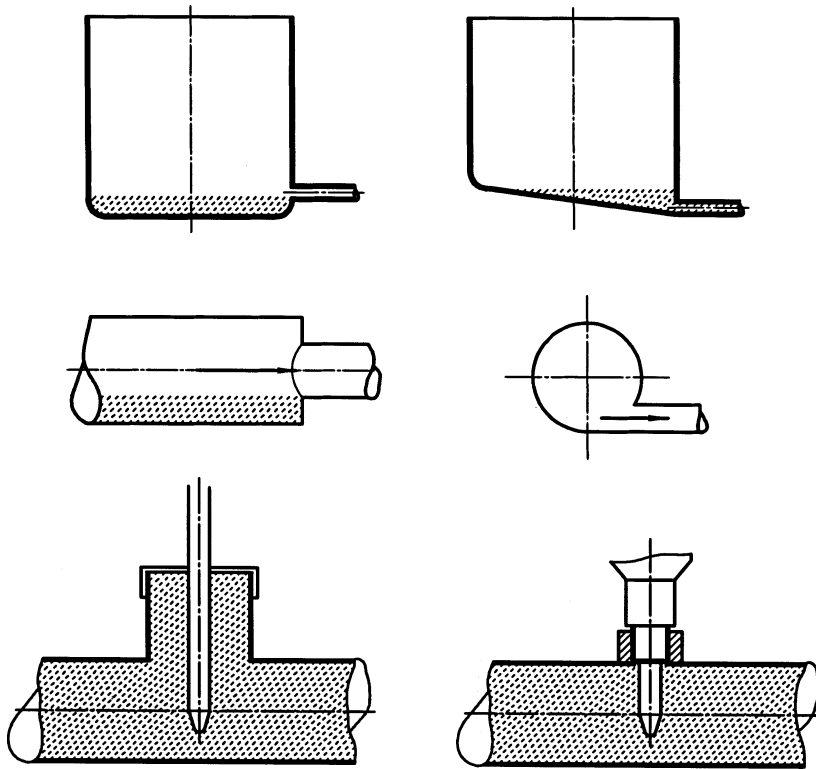


Group	Requirements	Product zone	Splash zone	Non-product zone
4.2.1.8	Dead corners and dead ends as well as spaces which can not be emptied completely are not allowed.	A	A	B

Example

not recommended

recommended



4.2.1.9	Rails and guidances for doors and covers have to be constructed in a way to minimize any type of deposit and condensate.	A	A	A
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Example

not recommended

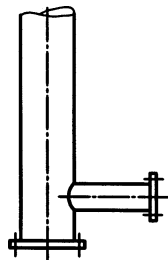
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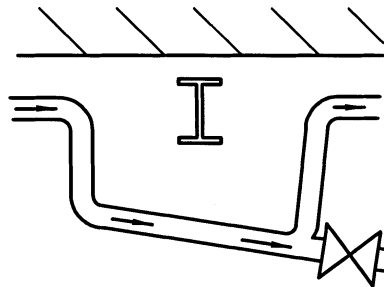
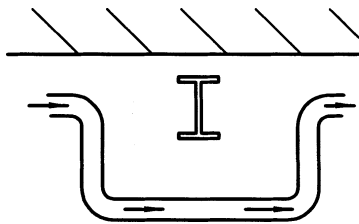
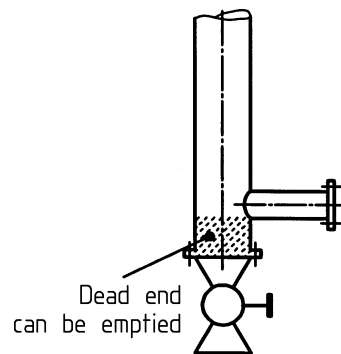
Group	Requirements	Product zone	Splash zone	Non-product zone
4.2.1.10	The lower guidance of sliding doors must have an opening sufficient for cleaning and discharge. The lower guidance cannellures must be open-ended.	A	A	A
4.2.1.11	Hollow spaces must be self-discharging and easy to clean or closed in a way that no foreign matters can enter.	A	A	B

Example

not recommended



recommended



4.2.1.12 Avoid horizontal surfaces.

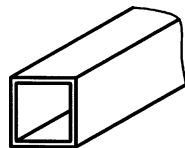
B

B

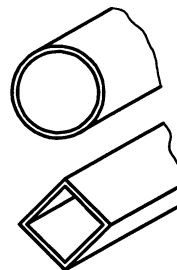
B

Example

not recommended

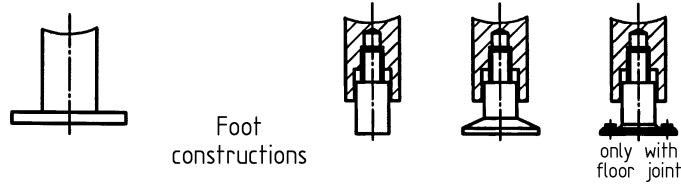
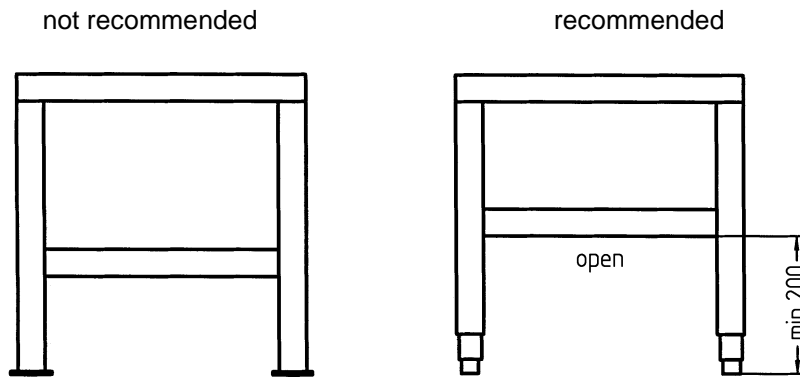


recommended



Group	Requirements	Product zone	Splash zone	Non-product zone
4.2.1.13	Machines should have a ground clearance of at least 200 mm. Seal machine foundations and machine feet in the ground.	B	B	B

Example

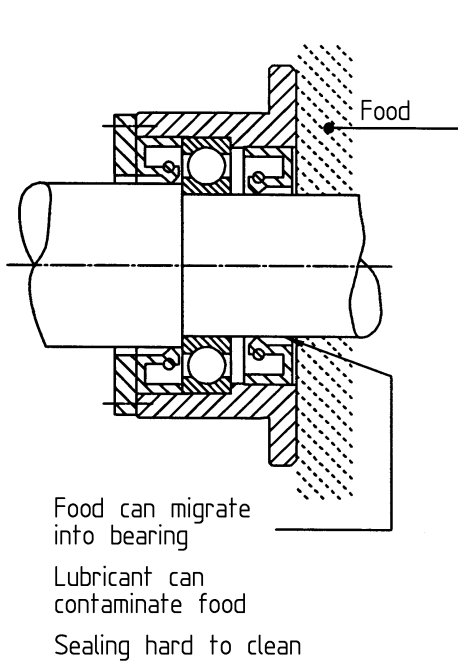


4.2.1.14	Attach drives and other units on mounting frames which are open to the bottom. Do not use motor slides.	A	A	A
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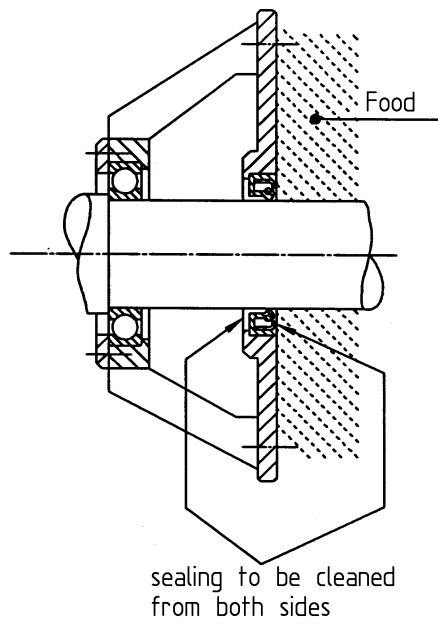
Group	Requirements	Product zone	Splash zone	Non-product zone
4.2.1.15	Bearings must be sealed and permanently greased. In case of bearings which have to be regreased, use food-grade grease only. These bearings must be constructed and designed in a way that no grease is discharged.	A	A	C

Example

not recommended



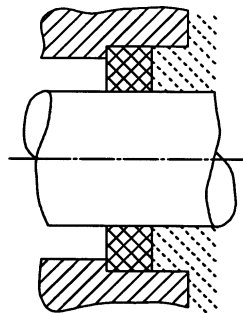
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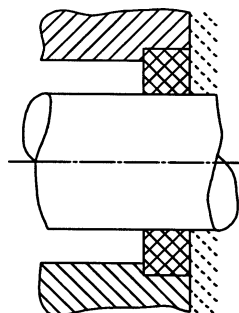
4.2.1.16	Construct and integrate sealings in a way that no protuberant edges, surfaces or dead spaces exist.	A	B	C
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Example

not recommended



recommended

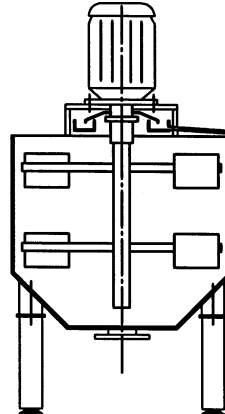
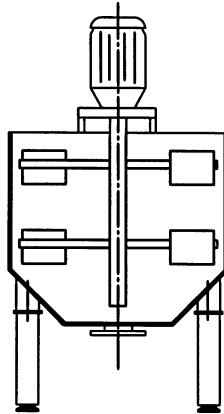


Group	Requirements	Product zone	Splash zone	Non-product zone
4.2.1.17	Collect lost grease in suitable containers and make visible.	A	B	B

Example

not recommended

recommended



4.2.1.18	Insulation against cold and hot temperatures and sound must not allow foreign matters (e.g. moisture) to enter or discharge of insulation components.	A	A	B
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4.2.2 Materials

4.2.2.1	Materials must be non-toxic.	A	A	A
4.2.2.2	Materials must be non-absorbent.	A	A	A
4.2.2.3	Materials should be non-corrosive, as long as no constructive or technical reasons contradict this requirement.	A	A	B
4.2.2.4	Avoid material combinations which might lead to electrolytic corrosion.	A	A	A
4.2.2.5	Avoid use of certain natural substances such as wood, leather, felt, textiles.	A	B	B
4.2.2.6	Materials must be odorless.	A	A	A
4.2.2.7	Materials must be non-splintering.	A	A	A
4.2.2.8	Insulation material must be non-digestible.	A	A	A

4.2.3 Surface

4.2.3.1	Surfaces should be smooth as long as no technical reasons contradict this requirement.	A	B	C
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Group	Requirements	Product zone	Splash zone	Non-product zone
4.2.3.2	Surfaces should be non-corrosive as long as no constructive or technical reasons contradict this requirement.	A	B	B
4.2.3.3	Surfaces must be non-toxic.	A	A	A
4.2.3.4	Surfaces must be abrasion-proof.	A	B	C
4.2.3.5	Surfaces must be chemically and physically resistant against the food to be processed.	A	B	C
4.2.3.6	Surfaces must be odorless.	A	A	A
4.2.3.7	Surfaces must be harmless from the nutritional point of view.	A	B	C
4.2.3.8	Surfaces must be non-absorbent.	A	A	A
4.2.4	<u>Auxiliaries and supplies</u>			
4.2.4.1	Technical gases must be free from contamination.	A	B	C
4.2.4.2	Compressed air must be free from oil, dirt and germs. Provide for respective filtering devices. Depending on type of application, a certain moisture can be tolerated. Provide for respective water traps. Arrange filter devices and water trap so that they are easy to clean and to replace.	A	A	B
4.2.4.3	Steam must be free from additives and contamination.	A	A	B
4.2.4.4	Water for cleaning must comply with the relevant regulation on potable water.	A	A	B
4.2.4.5	Oils and fat for greasing must be in proper physiological condition.	A	A	C
4.2.4.6	Liquids for the hydraulic parts must be in proper physiological condition and must not evaporate or decompose under the required operating conditions.	A	B	C
4.2.4.7	Liquid heat transfer media must be food grade and must not evaporate or decompose under the required operating conditions.	B	C	C
4.2.4.8	Refrigerants must comply with the relevant legal regulations.	A	A	A
4.2.5	<u>Electrical installation</u>			
4.2.5.1	All operating panels and displays must be outside the product and splash zone.	-	-	A

Group	Requirements	Product zone	Splash zone	Non-product zone
4.2.5.2	Control boxes, cabinets and motor as well as display panels should be made at least according to protective system IP 54, preferably IP 65. The protective system has to be clarified depending on the case.	-	-	A
4.2.5.3	Control boxes and control cabinets as well as components must be sealed against the mounting surfaces or mounted with a distance of at least 50 mm.	-	A	A
4.2.5.4	Existing hollow spaces in machine parts (e.g. pipe frames) through which cables are running, must be sealed at the ends. The cable must not be inserted from the top.	A	A	B
4.2.5.5	Preferably run cables from the bottom or the side into equipment, supply and control boxes and seal with cable joints.	-	A	A
4.2.5.6	Use insulating plastic tube with smooth surface only and run water-tight from control cabinet to the consumer unit.	A	A	B
4.2.5.7	Cable ducts inside the machine must be closed on all sides and splash-proof.	-	A	B
4.2.5.8	Mount all operating and display components either flush or with sufficient cleaning distance to each other on front panels. The surfaces must be smooth and easy to clean.	-	-	A
4.2.5.9	Lightning fixtures with light bulbs and fluorescent tubes must be in shatterproof material or otherwise protected against breakage.	A	A	A
4.2.5.10	The material for the electrical installation must be resistant against product components.	A	A	B
4.2.5.11	Electrical devices such as motor, valves, etc. should have smooth surfaces.	-	A	B
4.2.5.12	Units and installations should have a ground clearance of at least 200 mm.	-	B	B
4.2.6	<u>Measurement techniques</u>			
4.2.6.1	For measuring and display units no mercury or other toxic substances must be used as carrier medium.	A	A	A
4.2.6.2	Sensors must be designed and arranged in a way that they do dirty much and that they are easy to clean.	A	A	B
4.2.6.3	Sensors must be resistant against product components and must not cause contamination.	A	B	B

Group	Requirements	Product zone	Splash zone	Non-product zone
4.2.6.4	Sensors must be arranged easily accessible and easy to replace.	A	B	B
4.2.6.5	Front panels of measuring and display units must not break or be non-shattering, e.g. made from polycarbonate, acrylic or safety glass.	A	A	A

A = must be

B = recommended

C = not required

5.0 Recommendations for Installation and Erection

Make sure the machines and equipment fit hygienically into the total concept in the plant.

This requires a careful coordination of interfaces between the buildings as well as between production and supply facilities.

5.1 Buildings

- Floors
- Ceilings
- Walls
- Supporting constructions, scaffolds, stairs, etc.

Integrate/erect machines and equipment with sufficient distance to walls, ceilings, and to each other to make them easily accessible for operation, inspection, and cleaning.

Take in particular covers, doors, casings, collecting and dripping pans into consideration.

Seal all not accessible surfaces where equipment parts are connected to floors, ceilings, and walls.

If equipment is run through walls, along ceilings, or floors, provide for sufficient distance between the equipment and the wall, ceiling, or floor and close the opening in a way that allows proper cleaning. Otherwise seal the equipment to the adjoining surfaces.

Fixed mounted equipment based on the floor or other installations, have to be placed on stands which are sufficiently spaced to the floor. Seal them the floor or the installations.

The profiles of scaffolds, stages, and supporting constructions must be closed and have no hollow spaces.

Place equipment on hard, smooth foundations or floor which can be easily cleaned and are non-absorbent.

Mount fans, compressors, etc. to vibration absorbers.

Mount motors to the machine not to the floor.

Discharge ducts leading to outside the building must be provided with a suitable passage which allows possible extension of the duct. The passages shall stop rain from penetrating into the building.

5.2 Production equipment

- Product feeding units
- Product discharge units
- Auxiliaries, interchangeable parts and supporting functions

Tubes for liquids, powders or particulate products must be easy to disassemble and to clean, except if they are designed for cleaning or flushing in place (CIP). They have to have a slope to let the cleaning liquid run to the place where the tubes are being filled or discharged (see 4.1.3).

Position product feeding elevators in a way that they are easy to clean and have sufficient distance to floor and ceiling.

Product feeding devices (chutes, funnel) near the floor must be located at least 100 mm above the floor. They have to be equipped with overlapping covers. In case of floor passages, close and seal the gap between chute and floor.

For safety reasons and to avoid contamination with foreign matters, product feeding funnels have to have a grating compatible with the product.

Integrate interchangeable parts and auxiliaries in a way that these parts can be easily removed for cleaning. If needed, provide supporting devices for the removal and replacing (see 4.1.3).

All vats used for collecting product residues must be designed for complete emptying and easy cleaning. Fixed vats are allowed only if the complete discharge of product residues and easy cleaning is ensured.

For equipment and equipment parts to be cleaned or flushed at site provide for the separate discharge of the cleaning fluid.

Align joints and sealings with the inner edge to avoid dead spaces.

Design closing elements without any loose parts. Make sure no foreign matters will contaminate the product when using the closing elements.

5.3 Supply installations

- Tube connections for water, steam, compressed air, etc.

- Electrical connections

- Ventilation equipment

All outer surfaces of the supply lines have to be easily accessible. Make sure tubes, including insulation and adjoining surfaces are spaced sufficiently for easy cleaning.

Insulate the supply tubes if there is the risk that the temperature will fall below the dew point.

Insulation in the product and splash zone has to be splash-proof.

If water or steam are used directly for the production of food or come into contact with food, the water or steam must be of potable water quality. The tube system must be designed in a way that a flow back into the potable water or steam supply net is excluded (see 4.2.4.4).

Design, construct, and install ventilation equipment in a way to allow easy access for checking and cleaning. Provide suction openings with corresponding filters and protective gratings. Air discharge openings must also have protective gratings.

Floor drains must have to have a drain trap. Slopes must ensure the complete discharge. Drainage connections have to have drain traps. Make sure the area is well ventilated.

Mount electrical control cabinets and drives with sufficient cleaning distances to the adjoining surfaces or seal them at the surface (see 4.2.5.3).

Run cables in a way which makes them easily accessible from all sides.

Aspiration and pneumatic lines must be easy to disassemble for maintenance and cleaning purposes. Ground the cables to avoid electrostatic charging and dust collection.

6.0 Liability Exclusion

No liability is assumed for the correctness and completeness of these recommendations.

Any liability arising from the application of these recommendations, in particular damage compensation claims of any kind, are excluded, no matter on which legal basis they might be made.

7.0 References and Regulations

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