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WHITE PAPER

GUIDE TO HYGIENIC DESIGN OF ROBOT-BASED AUTOMATION SYSTEMS

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Vlaanderen is ondernemen

CERTIFICATION ISO 9001 BQA

BQA_QMS019_C_2017325

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Table of content

1 Introduction

Having hands, mouths and noses close to food means a risk of contamination – the hygiene offered by a machine minimises the transfer of germs and pathogens. Robots are used on the production site in lots of different industries, but in the food industry are usually deployed only for packing and palletising. The main factors that have determined a limited use of robotics in food manufacturing until now are two: the cost of robotics technology and the lack of robots designed to manipulate food - i.e., ingredients which are fragile, deformable and which are often in powder or liquid state of matter. While the cost of robots is rapidly decreasing and thanks to the huge leaps forward that have been made in gripper technology and intelligent image processing, there is now huge potential for the use of robots in the processing and production of food. But these are non-traditional robot applications, therefore not all robot manufacturers design robots for these applications, and not all integrators are equipped to handle these demands successfully.

One issue is the challenge in meeting regulations around food hygiene and easy cleaning of robots. The ability to effectively clean equipment is a prerequisite for food handling technology. Protocols set by the Machine Directive require complete sanitization of any surface that comes in direct contact with the food.

Food equipment manufacturers should always look for ways to help customers keep their places of business bacteria-free. The intent of this white paper is to provide a thorough understanding of the proper application of **hygienic practices to robotic automation solutions design.** This document addresses the robot and ancillary robotic system equipment, including the robot base, end of arm tooling and robot dressing.

2 What is Hygienic Design?

The task of the food processing industry is to take crops or farm animal products and use them to produce all kinds of foodstuffs. Speaking of food manufacturing, we have to make a distinction between primary processing, secondary processing and packaging.

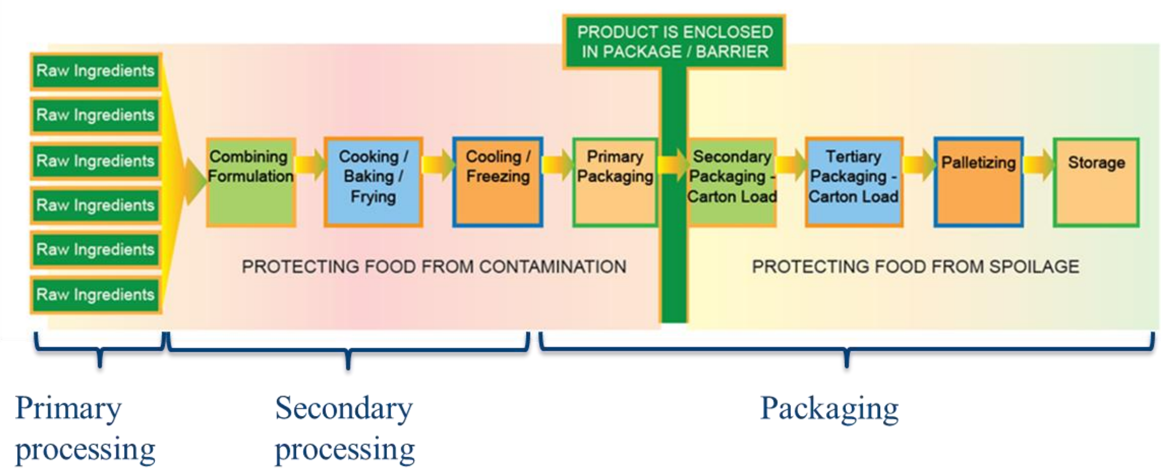


Figure 1 : primary processing, secondary processing, packaging

Primary processing includes operations on raw food - e.g., cleaning, sorting, inspecting, transporting - while secondary processing includes the operations needed to combine ingredients to produce food products - e.g., blending, cooking, chilling. Food packaging is about all the operations needed to produce a package able to provide the required protection, resistance and physical, chemical or biological properties that food needs.

As a result of the development and application of increasingly mild preservation technologies, processed foods become more sensitive to microbial (re)contamination, requiring greater control of the manufacturing process. One way to achieve this added control is to 'build in' hygiene into the equipment used in the food manufacturing facility from the start (see figures below). Especially in secondary processing, where food comes in direct contact with equipment, it's essential to have machines that are designed and constructed to ensure that, where necessary, they can be adequately cleaned, disinfected and maintained to avoid the contamination of food. It must be possible to hose down or wash these machines with water, so they have to be resistant to corrosion and damage to their working parts that water might cause.

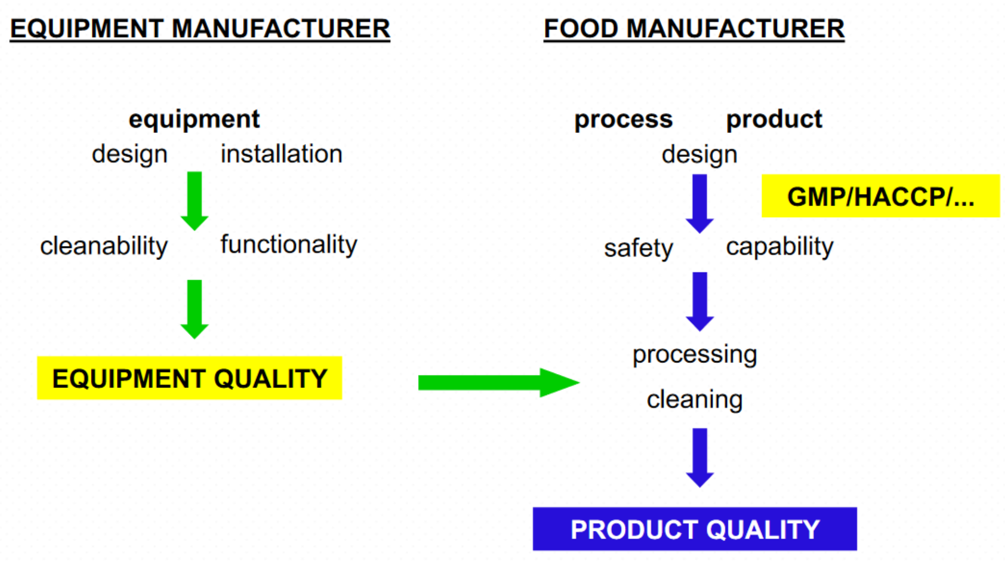


Figure 2 : relation between equipment quality and product quality

Figure 3 : Components of controlling pathogens

Hygienic design is a design process or set of design principles to manage hazards and reduce food safety risks in food processing equipment, processes and facilities. It plays an important role in controlling the pathogens and unwanted microorganisms in facilities and equipment used for food processing.

Using machinery designed with hygienic design principles in mind helps food manufacturers limit the risk of toxins or other microbiological organisms coming into contact with food supplies. The good news is that hygienic design doesn't necessarily cost more than the same equipment would cost without these principles in mind. That said, there is sometimes a higher upfront cost due to certain material choices, but the benefits of these choices reduce operating costs in the long-term. The better the clean ability, the less water, the less concentration of the cleaning agent and energy is needed to clean and therefore the cheaper the cleaning process. Cleaning is also easier, faster and more reliable.

3 Who sets the standards ?

3.1 European legislation and regulations

European legislation and regulations require that handling, preparation processing and packaging of food is done hygienically using hygienic machinery and in hygienic premises according to the machinery directive, the food hygiene directive and the food contact materials directive.

For food processing machines that do not meet the 'easy to clean' requirements of the Machinery Directive 2006/42/EC and other relevant standards, conformity to the CE mark is not valid.

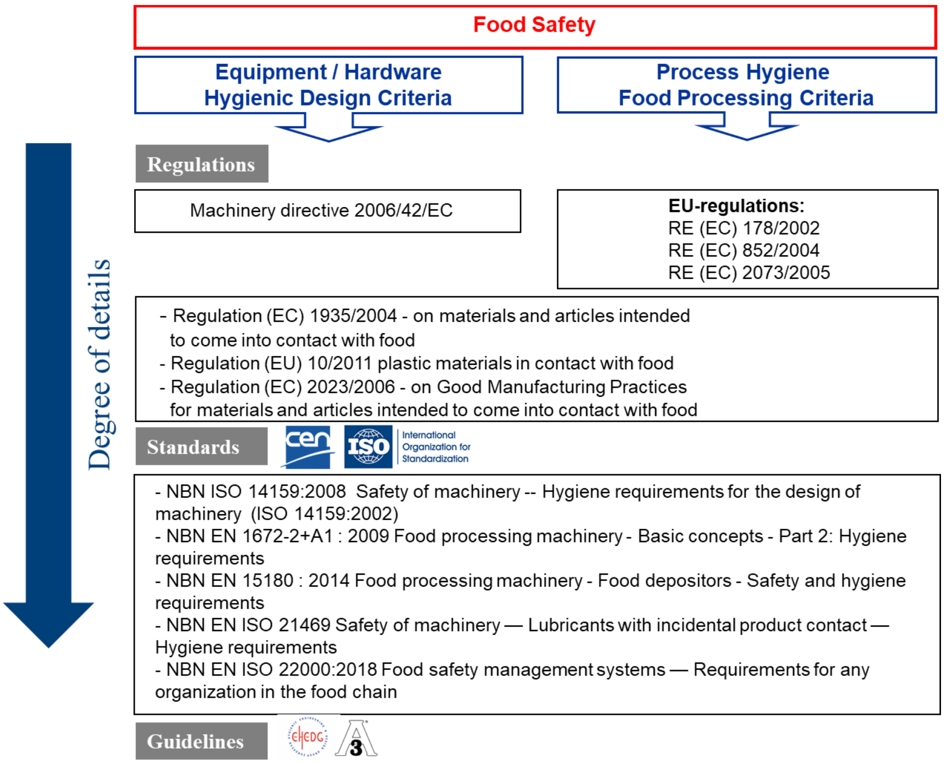


Figure 4 : overview of relevant standards for hygienic design

3.1.1 Machinery Directive

Hygienic design of food processing equipment is regulated by law in all countries of the European Union. The machinery directive for food processing equipment refers to EN 1672-1 (safety) and EN 1672-2 (hygiene). Chapter 2.1 of Annex I of the EU Machinery Directive 2006/42/EC and Annex V of Council Directive 93/43/EEC on the Hygiene of Foodstuffs require that equipment used to handle food should be hygienically designed: (a) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimize any risk of contamination of the food; (b) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept thoroughly cleaned and, where necessary, disinfected, sufficient for the purposes intended; (c) be installed in such a manner as to allow adequate cleaning of the surrounding area (d) where machine parts / materials in contact with food can't be cleaned before each use, disposable parts must be used.

Concrete requirements for the condition of equipment intended for food production are :

- all surfaces in contact with foodstuffs other than surfaces of disposable parts, must:
  - be smooth and have neither ridges nor crevices which could harbour organic materials. The same applies to their joins,
  - be designed and constructed in such a way as to reduce the projections, edges and recesses of assemblies to a minimum,
  - be easily cleaned and disinfected, where necessary after removing easily dismantled parts; the inside surfaces must have curves with a radius sufficient to allow thorough cleaning;

Design requirements are :

- it must be possible for liquids, gases and aerosols deriving from foodstuffs as well as from cleaning, disinfecting and rinsing fluids to be drained completely from/of the equipment or device part.
- machinery must be designed and constructed in such a way as to prevent any substances or living creatures, in particular insects, from entering, or any organic matter from accumulating in, areas that cannot be cleaned;
- machinery must be designed and constructed in such a way that no ancillary substances hazardous to health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmaceutical products. Where necessary, machinery must be designed and constructed in such a way that continuing compliance with this requirement can be checked.

The instructions for foodstuffs machinery and machinery must indicate recommended products and methods for cleaning, disinfecting and rinsing, not only for easily accessible areas but also for areas to which access is impossible or inadvisable.

3.1.2 Food hygiene directive

– Regulation (EC) 178/2002 lays down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. It contains a reference to working according to ISO 22000.

– Regulation (EC) 852/2004 lays down general hygiene requirements to be respected by food businesses at all stages of the food chain including primary production. Some hygienic design requirements are mentioned in annex 1 and 2.

  – Annex I (primary production)

  Articles, fittings and equipment must be able to be cleaned and, where necessary, to be disinfected.

  – Annex II (food business operators)

  Surfaces (including surfaces of equipment) will require the use of smooth, cleanable, corrosion resistant and non-toxic materials, …(Chapter II)

  Articles, fitting and equipment must ….(Chapter V)

    – be effectively cleaned and, where necessary, disinfected

    – be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination

    – be installed in such a manner as to allow adequate cleaning and - if required - disinfection of the equipment and the surrounding area

– Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs

3.1.3 Food contact materials directive

– Commission Regulation (EC) No 1935/2004

The regulation sets out the general principles of safety and inertness for all Food Contact Materials (FCMs). Food contact materials directive 1935/2004/EC applies to all food contact materials that are intended to be brought into contact with food, are already in contact with food, or can be expected to be brought into contact with food. In addition to the general legislation, certain FCMs — ceramic materials, regenerated cellulose film, plastics (including recycled plastic), as well as active and intelligent materials — are covered by specific EU measures There are also specific rules on some starting substances used to produce FCMs.

– Commission Regulation (EC) No 2023/2006

The regulation ensures that the manufacturing process is well controlled so that the specifications for FCMs remain in conformity with the legislation. Good manufacturing rules apply to all stages in the manufacturing chain of food contact materials, although the production of starting materials is covered by other legislation.

– Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food

3.2 ISO and CEN standards

In the framework of the machinery directive and the food contact materials directive many CEN and ISO technical committees (TC) are involved in the preparation of standards. Standards are non-legally binding. They represent recommendations. Relevant standards for hygienic design of machinery are listed below :

– NBN ISO 14159:2008 Safety of machinery -- Hygiene requirements for the design of machinery (ISO 14159:2002)

– NBN EN 1672-2+A1 : 2009 Food processing machinery - Basic concepts - Part 2: Hygiene requirements

  This document specifies common hygiene requirements for the machinery and provides information for the intended use to be provided by the manufacturer. It applies to all types of machinery and associated equipment used where there may be hygiene risks to the consumer of the product. The standard makes a distinction according surfaces categories, such as:

  – Food area
  – Splash area
  – Non-product area

  The document identifies the hazards which are relevant to the use of such food processing machinery and describes design methods and information for use for the elimination or reduction of these risks[...]. Examples of hygiene risks and acceptable solutions are given in the informative Annex A.

– NBN EN 15180 : 2014 : Food processing machinery - Food depositors - Safety and hygiene requirements

– Food-grade lubricant certified NSF H1 : see NBN EN ISO 21469 intended for 'incidental contact'

– NBN ISO 22000:2018 Food safety management systems — Requirements for any organization in the food chain. ISO 22000 describes the General manufacturing Principles GMP and the General Hygienic Principles GHP. The following of these principles is laid down by the producers of food in procedures according to ISO 9001 and is controlled by means of the HACCP method.

3.3 EHEDG guidelines and 3-A Sanitary Standards

Hygienic design is mandatory by law but legislation gives few details on hygienic design.

The European Hygienic Engineering and Design Group (EHEDG) has developed design criteria and guidelines on the hygienic design of equipment and hygienic processing that help fulfil European legislation requirements. These guidelines are collections of good practices drawn from experience.

Basic Hygienic Design guidelines	EHEDG
8	Hygienic design principles
9	Welding stainless steel to meet hygienic requirements
10	Hygienic design of closed equipment for the processing of liquid food
13	Hygienic design of equipment for open processing
23 P1	Use of H1 & HT1 Registered Lubricants, Part 1
23 P2	Production of H1 & HT1 Food Grade Registered Lubricants, Part 2
25	Design of mechanical seals for hygienic and aseptic applications
32	Materials of construction for equipment in contact with food
45	Cleaning Validation in the Food Industry - General Principles, Part 1
50	Hygienic Design requirements for CIP Installations

Figure 5 : EHEDG basic hygienic design guidelines

EHEDG was founded in 1989 to promote hygienic equipment and facility design within the agri-food industry. It is a consortium of equipment manufacturers, food processors, research institutes and public health authorities. It has links with the European Committee for Standardization (CEN), 3-A Sanitary Standards, NSF International and ISO. EHEDG have chosen not to issue standards. EHEDG has active working groups for improving and creating guidelines, provides training materials and sessions (in Belgium, see Agoria Academy) and has a yearbook and yearly world congress. EHEDG is offering several types of certification to the benefit of equipment suppliers and food manufacturers :

- **Equipment suppliers:**
  Their equipment can be approved by EHEDG to be in compliance with EHEDG criteria. In certain cases, approval may only be granted after testing by a laboratory accredited by a notified body, using EHEDG test methods.

- **Food manufacturers:**
  They may select hygienically designed equipment although users must still validate that such equipment is suitable for its intended use.

3-A Sanitary Standards (3-A SSI) maintains a large inventory of design criteria for equipment and processing systems developed using a modern consensus process based on ANSI requirements to promote acceptance by USDA, FDA and state regulatory authorities. 3-A SSI oversee the 3-A Symbol Authorization program and other voluntary certificates to help affirm the integrity of hygienic processing equipment and systems and provide extensive Knowledge Resources to support the training and education needs in the rapidly changing food, beverage, and pharmaceutical industries. Representatives of 3-A SSI and EHEDG cooperated to develop the EHEDG Glossary of definitions to provide uniform general interpretation of common terms, phrases and definitions.

The current list of standards/accepted practices is charting below :

Current List of Standards/Accepted Practices and Their Assigned Work Group

WG	*Name*	*Standards*
1	Vessels	01-, *05-, 22-, 24-, 25-, 29-, 32-, *78-, 84-
2	Fillers	*17-, 23-, 27-
3	Fittings & Valves	*33-, *42-, 51-, 52-, 53-, 54-, 55-, 56-, 57-, *58-, 59-, 60-, 62-, *63-, 64-, 65-, 68-, 82-, 85-, 95-
4	Pumps & Mixers	02-, 04-, 21-, 35-, 36-, 44-, 73-, 87-
5	Heat Exchangers	*11-, 12-, 19-, *31-, *61-
6	Conveyors	39-, 41-, 75-, *81-, *88-
7	Instruments	*28-, *46-, 50-, *74-
8	Concentrating	16-, *26-, 34-, 40-, *45-, 49-, 607, 608-, *610-
9	Farm & Raw Milk	10-, 13-, *30-, 606-, 611-
10	Cheese & Butter	*38-, *70-, 71-, 72-, *83-
11	Process & Cleaning	101-, 603-, 605-, 613-, 614-
12	Plant Support	*103-, 604-, 609-, 612-
13	Materials	18-, 20-
14	General Requirements	00-

* Indicates the Standard/Accepted Practice has been converted to "B Level" Format using the General Requirements Standard as the normative reference

Figure 6 : List of 3-A Sanitary Standards

The 'General Requirements 3-A-00-01' is a normative baseline document ("A Level"), which stands on its own by establishing the common fabrication criteria of hygienic design principles and definitions found throughout all 3-A SSI Standards & Accepted Practices. Only specific fabrication criteria with necessary exceptions or additions to the GR will be found in the 'B Level' Standards/Accepted Practices.

3-A SSI vs EHEDG

The main differences between the two associations are the requirements for the design of hygienic equipment. This is due to the differently defined hygiene levels of each organisation. There are also differences in the requirements for certification. While a 3-A certification requires only a theoretical review of design requirements, EHEDG certification reviews the design both theoretically and practically (using a standardised hygiene test).

The design specifications of the 3-A standards are very detailed and describe, for example, precisely the execution of radii and the required surface finish. If these specifications cannot be met, a 3-A certification of the product is not possible. The EHEDG, however, is more general in its formulations and describes the intended effect. If, for technical or functional reasons, the design, geometry and surface specifications cannot be met, the EHEDG (DOC 37 – Hygienic Design and Application of Sensors, Section 4.1.3) permits the cleanability to be compensated for in other ways. The effectiveness of the chosen design must be proven through a cleaning test. If this test is passed successfully, this measuring instrument will receive an EHEDG certificate, despite its design deviations.

Something specific for the hygienic design of robot-based automation systems ?

3-A SSI published in 2016 the 3-A Sanitary Standard for Robot-based Automation System (3-A-103-00). It addresses the robot and ancillary robotic system equipment, including the robot base, end of arm tooling, tool changers and robot dressing. Specifically, the standard includes materials and fabrication requirements as well as special requirements unique to robot systems, including zone considerations, programming requirements, controller requirements, wiring/robot dressing requirements and tooling, and installation. The standard does not apply to robots associated with milking systems or dairy farms.

This standard refers to

– 3-A Sanitory Standards 3-A-00 General requirements

– 3-A Accepted Practices 3-A604 Supplying Air Under Pressure in Contact with Product, and Product Contact Surfaces

– Other references and Standards : National Sanitation Foundation (NSF) category H1/21 CFR Part 178.3570 or other applicable CFR Section(s)

 103-00

TABLE OF CONTENTS

 103-00

Figure 7 : Table of content 3-A Sanitary Standard for Robot-based Automation System (3-A-103-00).

4 Hazards analysis when using robots/cobots in the food industry

4.1 Make a risk assessment

When specifying robotics systems for food, the first step is to complete a comprehensive risk assessment to understand the risks of contamination by the equipment. The hygiene risk assessment follows the methodology described in NBN EN ISO 1672-2. It is a team approach. Multiple skills and capabilities are required to determine what is right for specific manufacturing process and associated risks. When ensuring a machine's design is hygienic, all the risks must be taken into account, and action must be taken to prevent or reduce these risks. Each part, assembly, disassembly, adjustments, systems monitoring, sanitation and so forth needs to be considered, evaluated and included in a comprehensive written project assessment and execution manual.

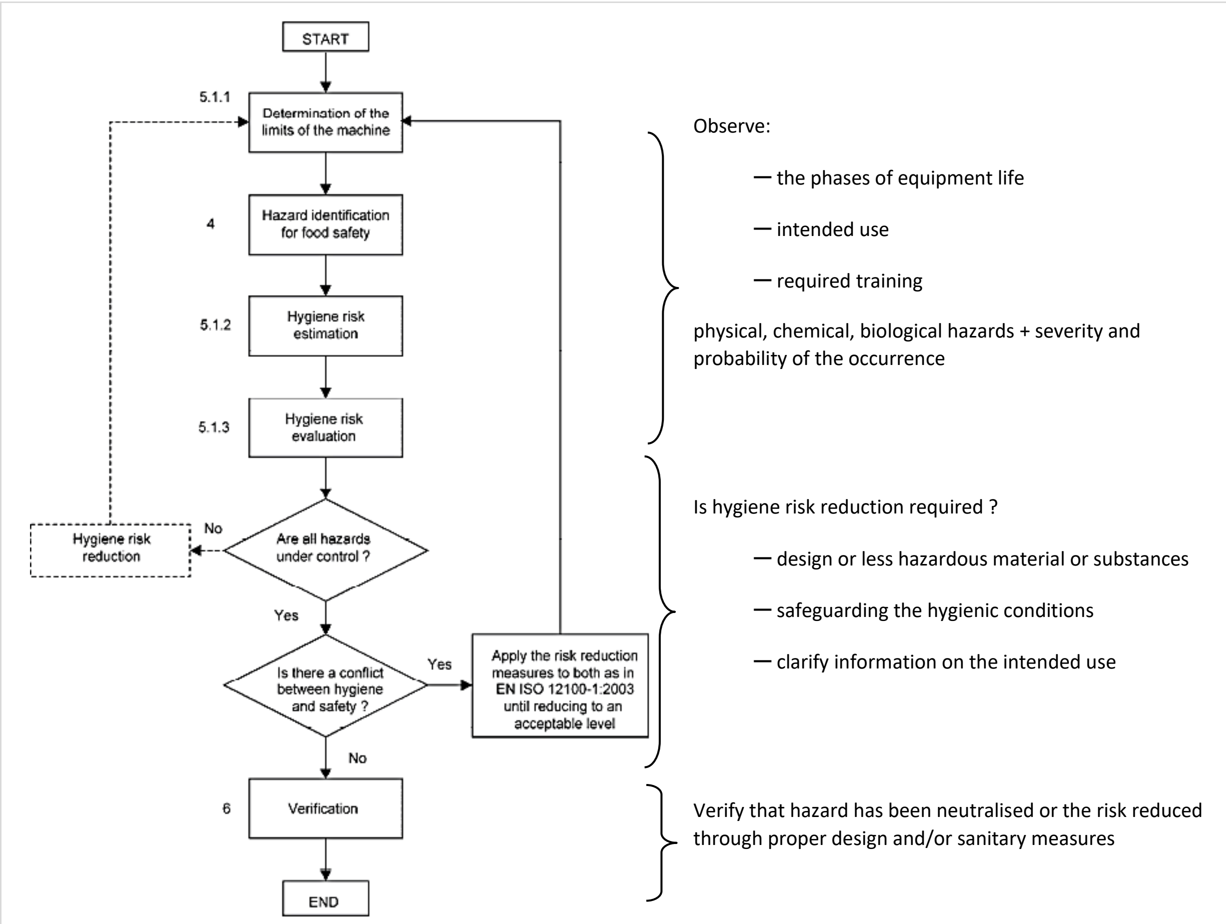


Figure 8 : hygiene risk assessment

Food contamination happens when food are corrupted with another substance. Risks can be categorized as:

- physical hazards : rust particles, paint particles, foreign bodies from the equipment such as lost nuts and bolts, plastic pieces, glass particles and pieces of worn out elastomers. If the foreign objects are bacteria, both a physical and biological contamination will occur.
- biological hazards : pathogens, viruses, mould, parasites
- chemical hazards : cross-contaminations due to lubricants, hydraulic fluids, paint particles, residues from cleaning chemicals or disinfectants

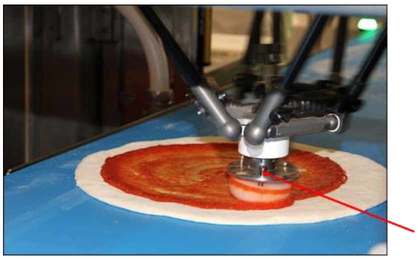
4.2 Examples of possible physical hazards

4.2.1 Loss of spring

Source : ABI Source : Autonox24

Figure 9 : Hygiene risk reduction : fasteners elimination or reduction

4.2.2 Loss of bolts



Source : Zume Pizza

Figure 10 : Hygiene risk reduction : fasteners elimination or reduction

4.2.3 Loss of suction cups

Source : Schmalz

Figure 11 : Hygiene risk reduction : Suction cups made from SI-MD silicone, a material that can be detected by a metal detector

4.3 Examples of possible biological hazards

4.3.1 End-effector/tools is "direct food contact" surface

The end-effector/tool should not introduce any risk of contamination of the product. Both materials and the end-effector/tool design play an important role.

The material used in area that come in contact with product should be non-toxic and hygienically approved. Stainless steel and any plastic materials are acceptable. The most common source of contamination is residues left on the gripper from the handling of objects. These residues will lead to the growth of bacteria if they are not removed by regular cleaning.

Source : Dewilde Engineering

Figure 12 : Hygiene risk reduction :

- End-effector/tool replacement after a certain number of cycles
- Intermediate cleaning and disinfection of end-effector/tools after several cycles (CIP or COP)

Suction grippers are vulnerable in this respect since they rely on air flowing into the gripper. Proper cleaning measures are therefore needed. Table below shows a summary of the hygienic characteristics of three types of suction grippers.

Operating principles of suction	Collection of organic residues	Risk of bacterial growth	Cleaning
Vacuum	Will collect organic residues in suction device on the suction cup surface	Large	Difficult to clean the inside of the ejector or vacuum pump. Surface cleaning by washing
Coanda	Will collect organic residues on suction cup surface but not in ejector	Moderate	Self-cleaning ejector, surface cleaning by washing
Bernouilli	No collection of residues	None	Not required except for general equipment cleaning

Figure 13 : Schmalz – Flow gripper SCG based on Coanda's principle

Figure 14 : FIPA - Bernoulli vacuum gripper made from PEEK, a material suitable for use with foodstuffs

4.3.2 Robot/cobot where pneumatic tool/end-effector operates on compressed air

Figure 15 : Materialise's automation gripper

- Hazard : leak in the gripper
- Hygiene risk reduction : food grade filtered compressed air at the point of use

Compressed air quality is frequently overlooked as a potential hazard during an internal risk assessment. Compressed air is seen as a basic operational function (utility) such as water and energy supplies in the food chain. Its provision is normally included in the pre-requisite programme rather than directly as part of the hazard analysis and critical control point (HACCP) activity. But it is still the case that a hazard analysis shall include items subject to a pre-requisite programme to establish whether there is a need to include the compressed air provision at any specific hazard analysis critical control point.

The air is invisible. It leaves no visible trace where it contacts the food, other food contact surfaces, or the packaging. Without adequate hurdles and physical barriers in place, the microbial, particulate, and (in some cases) compressor oil contamination is left behind after the air dissipates. The sources of contaminants in compressed air food processing environments could be physical, chemical, or biological hazards. Primary sources of contamination of a compressed air supply include the ambient intake air and the compressor itself. At any given time the atmospheric air feeding the compressor inlet can have contaminants such as solid particles (dirt, sand, soot, metal oxides, salt crystals), water vapor, oil vapor, and microorganisms. Careful consideration should be given to the placement of the compressor intake to avoid these contaminants as much as possible. The intake filter as a first defence should be routinely replaced according to the manufacturer's guidelines. The compressor, if oil lubricated, can also add oil in the form of liquid, aerosol, or vapor. Any compressor that is improperly maintained can be a source of contamination. Other sources of contamination include the system piping and air storage receivers. New piping should be tested to assure that it is has been properly purged of potential contaminants such as particulates and solders or glues used during installation. Older piping can have an accumulation of water, rust and oil. When connecting new piping to an older piping distribution system, the jarring of the old piping can cause particulates (such as rust, pipe scale, dirt, metal oxides, etc.) to be loosened and introduced into the new piping. Storage receivers with excess water (vapor, liquid, or a mixture of oil and water) can become a breeding ground for microorganisms.

In the United Kingdom, to help manufacturers and ultimately protect the consumer from compressed air contamination, two major bodies have jointly developed a Code of Practice for Food Grade Compressed Air. These bodies are the British Retail Consortium (BRC), which represents the retail industry, and the British Compressed Air Society (BCAS), which is the UK governing body for compressed air. The Code of Practice provides minimum purity or quality standards for compressed air and defines allowable levels for dirt, water and oil, in line with purity levels specified in ISO8573-1:2010, the international standard for compressed air quality.

Amount of contamination allowed per cubic metre of compressed air (ISO8573-1:2010)

Purity Class	Solid Particulate: Maximum number of particles per m³ compressed air: 0.1-0.5 micron	0.5-1 micron	1-5 micron	Particle size	Mass concentration mg/m³	Water: Vapour Pressure Dewpoint	Liquid g/m³	Oil: Total Oil (aerosol, liquid & vapour) mg/m³
0	As specified by the equipment user or supplier, and more stringent than Class 1							
1	≤ 20 000	≤ 400	≤ 10	-	-	≤ -70°C	-	≤0.01
2	≤ 400 000	≤ 6000	≤ 100	-	-	≤ -40°C	-	≤0.1
3	-	≤ 90 000	≤ 1000	-	-	≤ -20°C	-	≤1
4	-	-	≤ 10 000	-	-	≤ +3°C	-	≤5
5	-	-	≤ 100 000	-	-	≤ +7°C	-	-
6	-	-	-	≤ 5	≤ 5	≤ +10°C	-	-
7	-	-	-	≤ 40	5-10	-	≤ 0.5	-
8	-	-	-	-	-	-	0.5-5	-
9	-	-	-	-	-	-	5-10	-
X	-	-	-		>10	-	> 10	> 10

Source: Parker Hannifin - division domnick hunter, 2009b

Compressed Air Quality Class 1.2.1 corresponds with compressed air quality

- ≤ 20 000 particles in a range 0.1-0.5 micron per m³,
- ≤ 400 particles in a range 0.5-1 micron per m³,
- ≤ 10 particles in a range 1-5 micron per m³,
- vapour pressure dew point of ≤ -40°C
- total oil content of ≤ 0.01 mg/m³

Figure 16 : Purity levels specified in ISO8573-1:2010

BCAS FOOD AND BEVERAGE GRADE COMPRESSED AIR
BEST PRACTICE GUIDELINE 102

ISO 8573-1:2010 PURITY CLASS	PARTICLES (P): By Particle Size (maximum number of particles per m³): 0.1 µm < d ≤ 0.5 µm	0.5 µm < d ≤ 1.0 µm	1.0 µm < d ≤ 5.0 µm	WATER: Vapor Pressure Dewpoint: °C	°F	OIL: Aerosol & Vapor: mg/m³
Direct Contact 2:2:1	400,000	6,000	100	≤ -40	≤ -40	≤ 0.01
Indirect Contact 2:4:2	400,000	6,000	100	≤ +3	≤ +37	≤ 0.1
Microbial Contaminants	Hazard analysis shall establish the risk of contamination by microbiological contaminants from compressed air. The level of control identified as being required over microbiological contaminants in the compressed air shall be detected using the test method specified in ISO 8573-7.					
Footnotes	(P) Particle classes 1-5 may not be employed if particles >5 micron are present according to ISO 8573-1.					

Air & Gas Specifications referenced above may be viewed and/or purchased from: BCAS - British Compressed Air Society

Source : BCAS guide

Figure 17 : BCAS Food and beverage grade compressed air – best practice

These air quality requirements determine the extent of filtration required in any leg of the distribution system for the particular process. The goal is to keep grease or contaminants on or in the gripper from being released into the environment and contaminating the part or process. Multiple steps are needed to remove water and contaminants from compressed air from the time it leaves the compressor until it reaches the pneumatic tool or equipment it powers. Installing a filter-regulator as close as possible to the tool using compressed air ensures the correct level of particle filtration and pressure regulation.

Figure 18 : Festo-air preparation modular system

4.4 Examples of possible chemical hazards

4.4.1 Ingress of non-food grade lubricants into the product

(on courtesy of Frank Moerman)

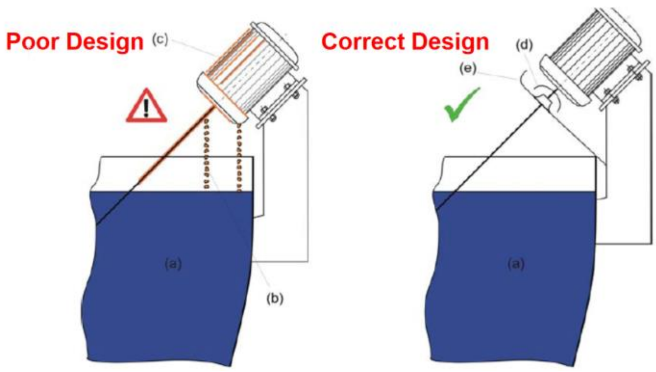


Figure 19.1 and 19.2 : Hygiene risk reduction :

– lubricated bearings/gear boxes mounted outside product zone

– drip pan to avoid that oil ends up directly in the product zone

– use of food-grade lubricant

5 How to manage the hazards by design ?

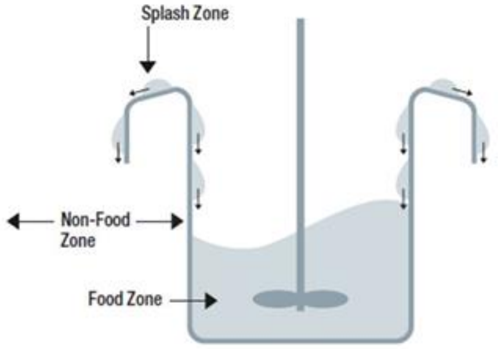
Food processors continuously look for the holy grail of increased production, reduced cleaning time, and reduction of costs. It is desirable to be able to clean the equipment fully assembled or with a minimum of disassembly, and subsequent reassembly. This is not as simple as just attaching a spray device and a solution return line to the piece of equipment. With other words, every aspect of the design has to be evaluated through the filter of CIP.

Hygienic design starts with the very first lines drawn on a blueprint. The first task of the designer is to determine what is to be considered a food contact surface and whether it is an open or closed process.

5.1 Food contact zones

The food contact zone is determined by the potential contamination that can be occur based on the production equipment's exposure to food and its by-products.

Three zones - food zone, splash zone, non-food zone - are defined by the European standard EN 1672-2, Food processing machinery – Basic concepts.



Source : automation-insight.blog

- The food zone are all surfaces which are exposed <u>intentionally (direct) or unintentionally</u> (non-direct) to the food and from which the food, condensate, liquids may drain, drop, diffuse or be drawn into (self-returned) the food or onto food contact surfaces or surfaces that come into contact with food contact surfaces of packaging materials.
- The splash zone consists of exposed surfaces from which splashed food, condensate, liquids, or other materials <u>cannot</u> drain, drop, diffuse or be drawn into or onto the food, food contact surfaces, open packages, or the food contact surfaces of package components. These area are not intended for contact with consumable food.
- The non-food zone are exposed equipment surfaces other than those specified above. They do not come into direct contact with food of any kind, including food debris, during expected conditions.

Depending of the application, these definitions may take the following form for a robotic system :

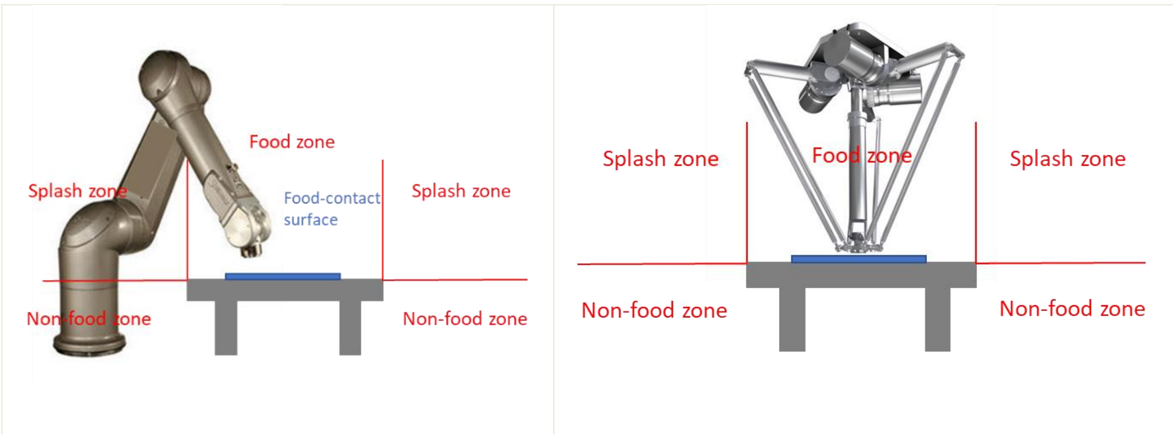
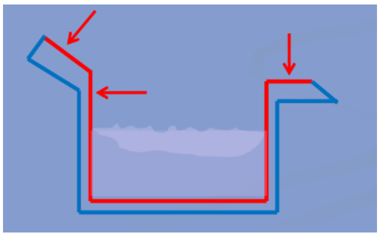


Figure 20 : food zone, splash zone and non-food zone

The surfaces belonging to these three zones are grouped into two categories:

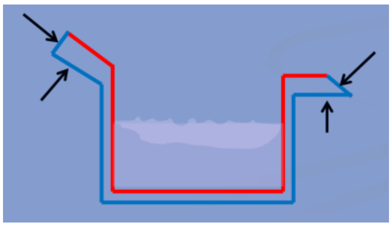
– **Food contact surfaces** – any surface that has direct and indirect contact with food or ingredients during normal operations

These are the surfaces exposed in the Food Zone.



Because these surfaces, if contaminated, can directly result in food contamination, rigid hygienic design criteria must be met. These surfaces must therefore be included in the hazard analysis.

– **Non-food contact surfaces –t**hese are the surfaces exposed in the splash zone and the non-food zone.



5.2 Open and Closed Production

In the food and beverage industry, it is also important to discuss whether the manufacturing process is open or closed. The distinction between the two plays a significant role in determining machine cleaning requirements.

– Closed Process: A manufacturing operation in which the food product never comes in contact with the environment. All food contact zones are sealed such as the inner surfaces of tanks, pipelines, valves, pumps and sensors.

– Open Process: A manufacturing operation in which food does have contact with the environment outside of the machine. This requires a hygienic design of the process environment, as well as the surfaces of the apparatus and components.

A robot-based automation system is an open process.

6 Basics design requirements

6.1 Contact Surfaces design principles

6.1.1 Materials Used

Construction materials used for equipment must be completely compatible with the product, environment, cleaning and sanitizing chemicals and the methods of cleaning and sanitation.

All materials having product contact surfaces shall be of such composition as to retain their surface conformational characteristics :

– corrosion resistant

– chemically resistant

– non absorbent

– temperature resistant

They shall not impart any toxic substance into the product under normal use and when exposed to the conditions encountered in the environment of their intended use, including cleaning, sanitizing treatment, and/or sterilization.

They shall not transfer undesirable odours and colours to the food

They shall not contribute either to contamination of food or have any adverse influence on the food

Different materials meet different requirements depending on the type of food processing machinery. Some manufacturers incorporate antimicrobial coatings into their designs to improve safety. Any materials or surface coatings used should conform to the standard needed by that particular industry.

Metals:

Stainless Steel – The preferred metal of choice due to its resistance to corrosion and the durability it brings to various machine designs. High-alloy stainless steel is usually the logical choice of material for the construction of a production system in the food industry. Typical materials include AISI-304, AISI-316 and AISI-316L (DIN material no. 1.4301/1.4401/1.4404), commonly known as V2A, V4A or INOX. But it can presents challenges for machining and drilling, as well as being trickier to assemble. Tests were made with robots designed from stainless steel, but they were not successful and the conclusion was that stainless steel is not suitable material for a dynamic robot.

Aluminum – Often used for food processing machinery designed with a lighter weight in mind. It's extremely susceptible to corrosion and becomes warped and cracked after a long period of use. Oxidizing cleaning products accelerate the decline of the metal. Most aluminium products designed for food contact must be coated with some sort of plastic coating or through the application of an anodised oxide layer to protect against this. Typical aluminium grades include AlMg2Mn0.8, AlMgSi1 and AlMgSi0.5.

Titanium – The cost prohibits the more wide-spread use of this metal. It's also corrosion-resistant and long-lasting. You'll often find it in stainless steel alloys used to build machines handling foods with a high level of acidity.

Platinum – Similar to titanium in providing higher quality but prohibited from more extensive industry-wide usage due to its cost.

Copper – Used primarily for equipment in the brewing and cheese industries. Should not be used with high-acid food as the acid residues tend to leach into the metal.

Carbonized metal and cast iron – Only used for cooking surfaces and frying equipment.

Non-Metals:

Rubber and Plastic – Plastic components permitted to come into direct contact with food must comply with Regulation 1935/2004/EC and the Plastics Directive 10/2011 (replaces Regulation 2002/72/EU) or the approvals of the FDA (CFR 21, Sections 170-199). In addition to resistance to strain, ease of cleaning is also an important factor in the selection of suitable plastic materials. They must not give off or absorb any hazardous substances.

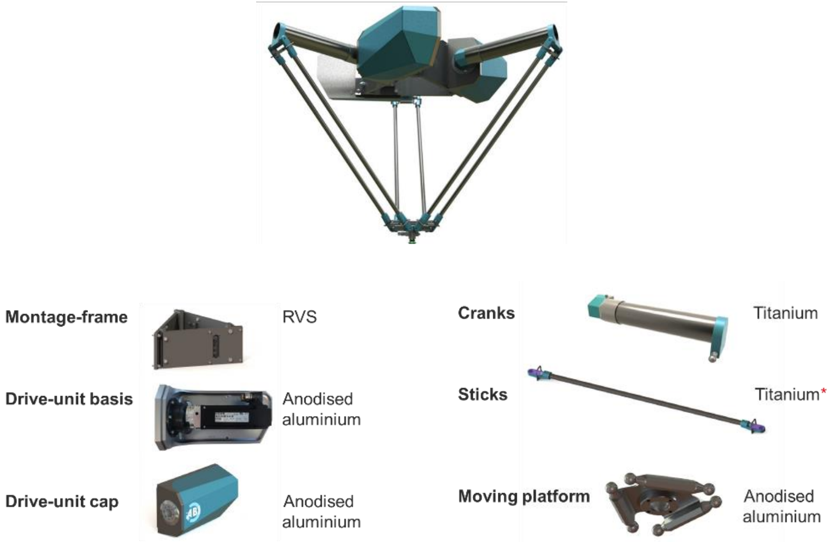
Ceramics – You'll mostly see this material used in membrane filtration systems. Certain other products requiring wear resistance might also incorporate its use to some capacity. Ceramic components must comply with the Ceramics Directive 84/500/EEC

Glass – Limited in use for food contact surfaces due to fears of breakage. Any glass products used must past tests ensuring its durability, resistance to shattering, and heat resistance. You'll also see glass used as a way to provide a line of sight inside machinery or glass piping applications. The European Commission is currently reviewing the existing regulatory framework on food contact materials, in particular Directive 84/500/EEC for ceramic articles. Among the discussed features of a possible legislative revision is the potential extension of the Directive's scope to glass materials and articles.

Paper – Typically used for gaskets in piping constructs designed to be taken apart on a daily basis. They're often intended to be used only once.

Wood – Its porous nature makes it a very poor choice as a food contact surface. Most regulators restrict the use of wood in food service outside of cutting boards or butcher blocks.

Non-metals must meet the same cleanability and sanitary design standards required of metal.



Source : ABIflexx Delta robot

Figure 21 : robot and used material

Material compatibility should be considered during the conception of a new equipment as well as any design change to avoid this kind of troubles :

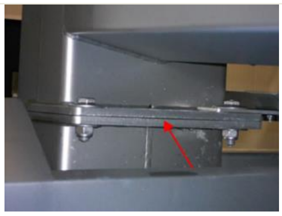
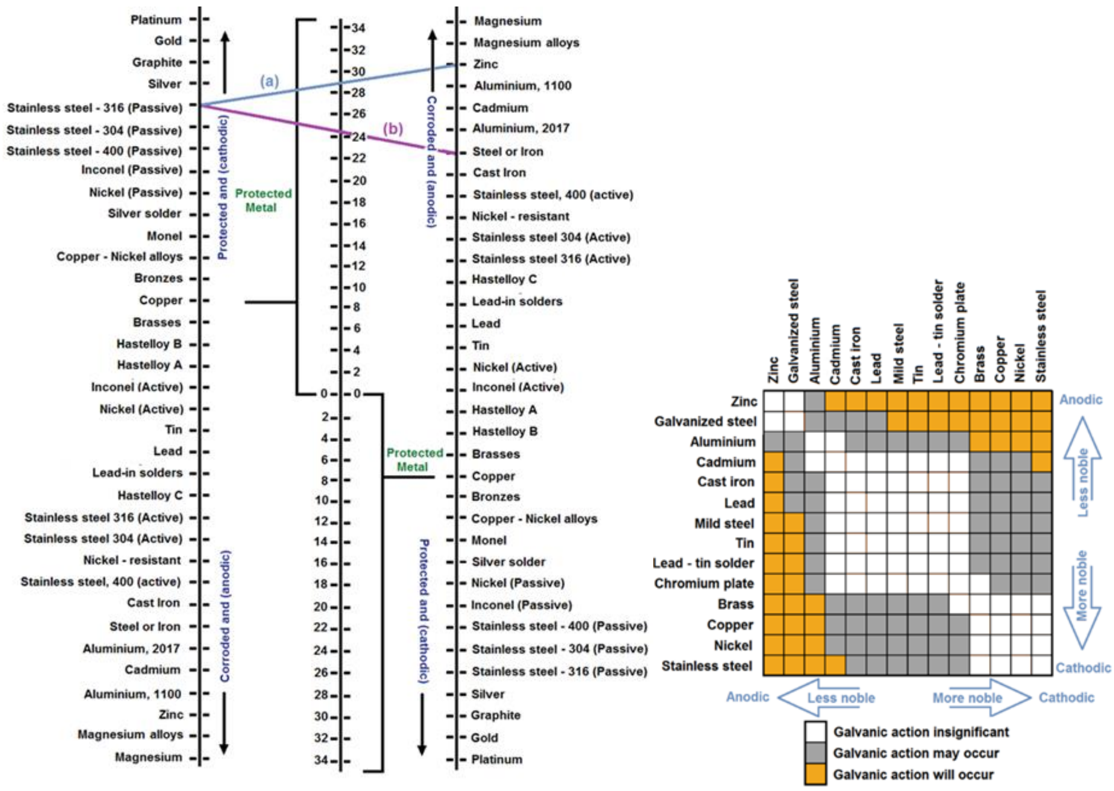
 Plate in carbon steel combined with stainless steel bolts, resulting in galvanic corrosion between stainless steel and carbon steel	 Stainless steel bolts screwed into anodized aluminum	 Avoid metal-on-metal (risk of corrosion) and horizontal surfaces (not self-draining surface)

Figure 22 : examples of galvanic corrosion



Galvanic corrosion metal compatibility diagram. Use a rule to line up the two metals, steels or alloys which are being combined. The closer to zero, the lower the risk of galvanic corrosion.

(a) Combining stainless steel 316 with zinc (e.g., zinc coating of galvanized steel) will result in severe corrosion of zinc.
(b) Combining stainless steel 316 with mild steel (also called carbon steel or black steel) will result in the fast corrosion of mild steel.

Figure 23 : galvanic corrosion metal compatibility diagram

Figure 24. Protected robot against electrical exchanges by physical separation between stainless steel screws and aluminum based structure

6.1.2 Surface finishing

The efficiency of the cleaning process depends on the characteristics of the surface being treated, in particular in terms of the roughness, topography and the surface energy and therefore its suitability for getting rid of dirt, i.e. its cleanability.

The EHEDG recommends surface roughness of less 0.8 µm in the product zone , or preferably even a *Ra* of max 0.5 micron, so that corrosion resistance is also assured. The lower the surface roughness, the better, since corrosive material and bacteria are less likely to stick to a very smooth surface. According to the EHEDG, rougher surfaces can be acceptable (<3,2 µm in the splash zone) if tests have shown that the required cleanability is achieved. Porous surfaces usually are unacceptable. As noted in EHEDG Doc. 8, cleanability strongly depends on the surface finishing technology because it can affect the surface topography

Surfaces must not only be smooth but also free from holes, gaps, crevices, folds. You should never see flaking, bubbling, chipping or any type of distortion regardless of factory environment conditions. Any modifications used during fabrication – like welding or soldering – should use appropriate materials and produce a surface meeting sanitary and hygienic design principles. This applies not only when equipment is new, but during its entire functional lifetime

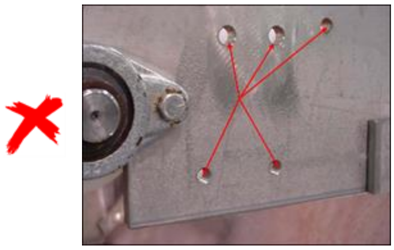


Figure 25: useless holes (on courtesy of Frank Moerman)

6.1.3 Machine Construction

It has been demonstrated that the cleanability of a material surface cannot be assessed by the Ra value alone. The geometric design of operating utilities significantly affects their suitability for use in clean manufacturing environments. Food equipment should be designed and fabricated in such a way that stagnant zones and inaccessible areas have been reduced to a minimum.

Some relevant recommendations are listed here.

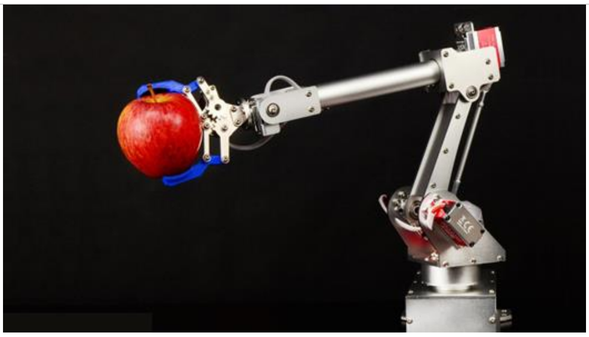
The fewer pieces of production equipment attached to the robot means less structures in which bacteria potentially can harbour or may prove difficult to clean.

Source : Wittenstein

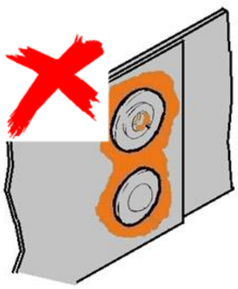
Figure 26 : less pieces, less retention surface thanks to the Hygienic Design motor-gearbox unit. Housing for the drives are not mandatory anymore. The drive is directly integrated in the process.

All coupling surfaces must be continuous and flat (e.g., substantially flush).

Welding should be preferred over fixing with rivets or screw threads and bolts.



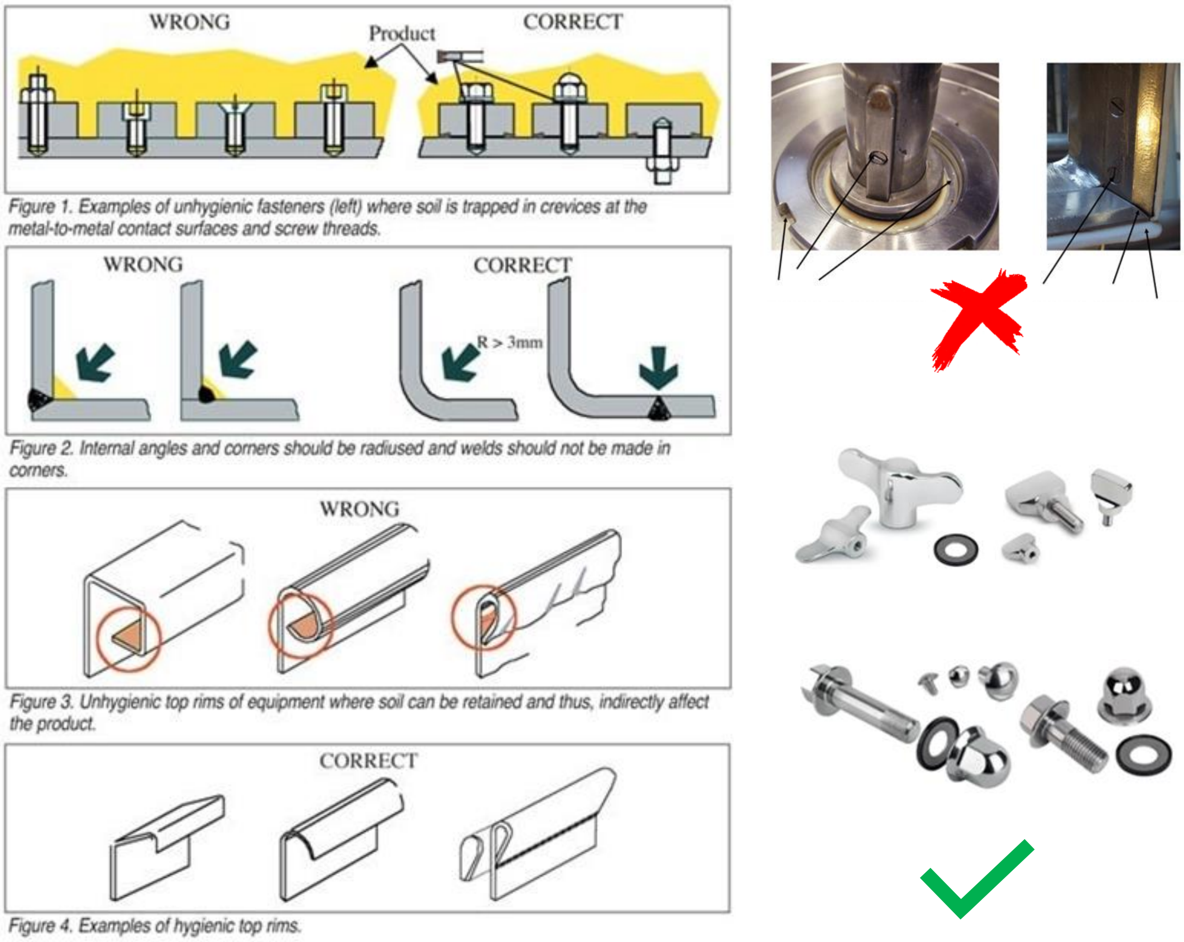
Source : 7bot



Source :CFPRA, 1983

Figure 27 : Avoid rivets & overlapping metal sections

The use of screw threads and bolts in the product area should be avoided. Where unavoidable, dead spaces can be avoided by using hex-head screws with rounded heads (cap screws) and thread seals (Figure 26.1).



Source: [Food Safety Magazine February-March 2003]

Figure 28 : hygienic design examples

Sharp corners in the product area should be avoided. Welds should not be made in corners, but on the flat surfaces, and must be smooth. Equipment standards generally require that welded joints on stainless steel surfaces be continuous, butt-type joints and ground smooth. (Figure 26.2).

The design of the top rims of product-containing equipment must avoid ledges, where product can lodge and that are difficult to clean (Figure 26.3). Open-top rim design must be rounded and sloped for draining. If the top rim is welded to the wall, the weld must be flush and polished to provide a smooth surface. In this case, the rim must be totally closed. The weld must be continuous and any holes must be sealed by welding, gaskets or plastic caps (Figure 26.4).

The exterior and interior of all equipment should be self-draining, This means that no horizontal surfaces should be present and all surfaces require a minimum 3% slope to enable liquids to run off and prevent contamination from accumulating.

Care should be taken when connecting equipment to food contact surfaces. It is necessary to ensure the connection does not create a dead end or an area where food product can accumulate and is not accessible to cleaning solutions.

Any opening or cover should be designed, fabricated, and constructed in such a manner as to adequately protect food products from contamination and to divert potential contamination away from the food product zone.

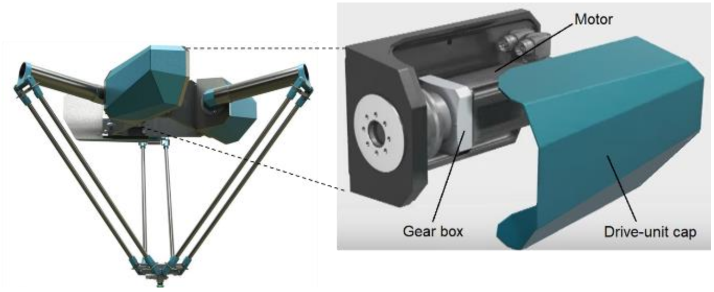
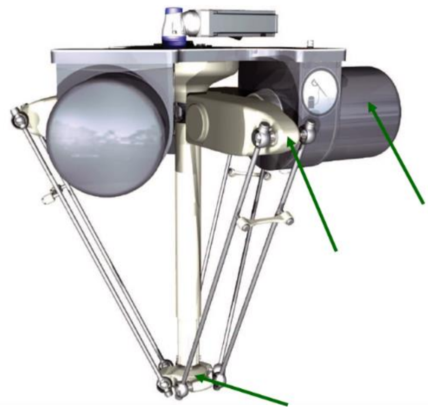


Figure 29 : ABIflexx - the motors are well isolated in enclosures and gets an optima wash down design – but what if bearings are lubricated with non-food grade lubricant?

Construction of all food handling or processing equipment should allow for easy disassembly for cleaning and inspection.

Enough space and clearance should be provided so that all equipment parts and components are readily and easily accessible for inspection, maintenance and troubleshooting.

Following example of robots illustrate some design features regarding hygienic design principles.



Autonox24
Figure 30 : - Nicely rounded corners/seams and drained surfaces

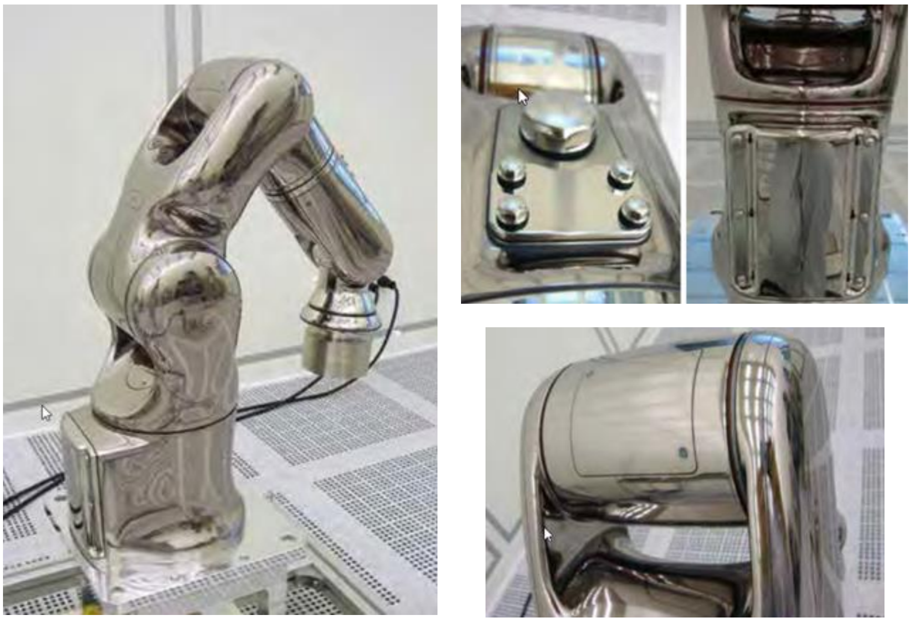


Figure 31 : EHEDG yearbook 2017/2018 - overall hygienic design : screws have been used only at the level of the robot arm to allow pneumatic hoses to be optionally connected for the grippers and on the electronics cover located at the foot of the robot ; cap screws with sealing rings; the joins and lids on the various robot components all have sealed covers to prevent the entry and accumulation of microorganisms and contamination into areas that are difficult to clean

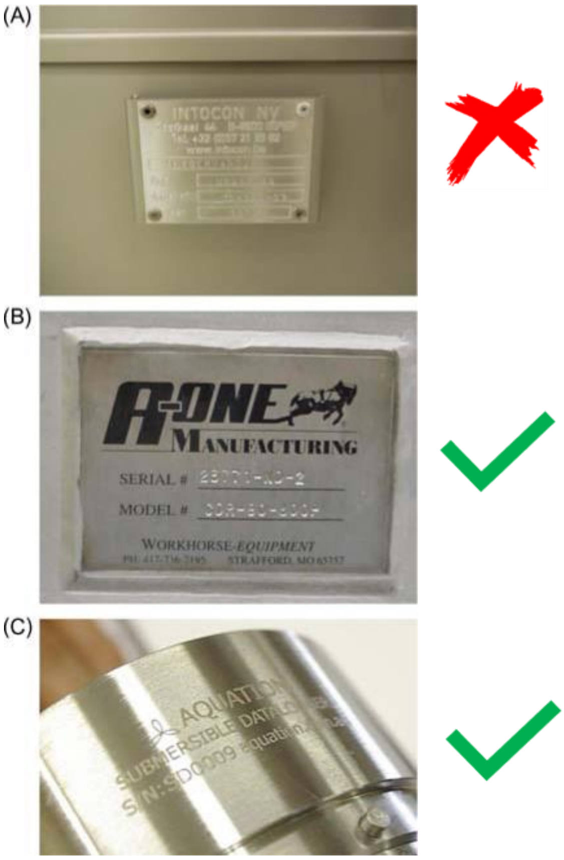
6.2 Design principles of non-food contact surfaces

Non-food contact surfaces of food equipment are a well-documented source for environmental contamination of a food facility with pathogens (especially Listeria monocytogenes). These areas can also be harbourage areas for insects and rodents. Therefore, care should be used in evaluating these surfaces of equipment with regard to hygienic construction and design. In this zone, the technical design criteria may be less stringent than in the food area, provided the surfaces are still cleanable and, where required, capable of being disinfected : higher roughness, smaller radius for internal angles and corners, use of non-food grade lubricants are tolerated.

However all nonproduct contact surfaces shall be of corrosion-resistant material or material that is rendered corrosion resistant. If the surfaces are coated, including painted surfaces, the coating shall adhere. All nonproduct contact surfaces shall be relatively non-absorbent, durable and easy to clean and disinfect, as sources of infection can develop over time. Exposed surfaces shall be relatively free of pockets and crevices where soil or liquid can collect. Tubular framing shall be totally closed or effectively sealed.

Remark : Parts that are removable for cleaning having both product contact and nonproduct contact surfaces shall not be painted.

Figure 32: painted equipment on vibrating conveyor belt - cleaning of painted equipment is risky (on courtesy of Frank Moerman)



Source : https://m.ebrary.net/49780/health/basic_hygienic_design_requirements

Figure 33 : (A) Nameplates are often fastened to the surface of process equipment by means of rivets. (B) Continuous welding of nameplates onto the equipment surface is possible, but (C) direct application of graphics on equipment components by laser engraving is preferable.

7 What are the additional and specific principles for robotic automation solution design ?

As stated in chapter 4.3, only 3-A SSI has published recommendations for an hygienic design of robot-based automation system. To conform to 3-A-103-00, the robot system shall conform to the following criteria

7.1 Materials

See basic requirements already specified above.

7.2 Machinery fluids

Components using machinery fluids shall be effectively shielded to prevent ingress of fluids into the product or onto product contact surfaces, but should one occur, the use of food-grade machinery fluids can mitigate potential contamination.

NSF classifications distinguish different types of food-grade lubricants by what they may/may not contain and how they may be used :

- H1 lubricants may be used in applications where incidental food contact may potentially occur. Such incidental contact is limited to a trace amount: It must not exceed 10 parts per million (i.e., 0.001 percent), or else the food is deemed unsafe for consumption. H1 lubricant formulations may only contain certain base stocks, additives and thickeners as specified by FDA regulations (21 CFR 178.3750). Usually, when people refer to “food-grade” lubricants, they mean H1 lubricants.
- H2 lubricants can be used in food-processing facilities, but only where there is absolutely no possibility of contact with food. Most substances used in lubricant formulations in general are acceptable in H2 lubricants, but there are restrictions pertaining to toxicology and other considerations. For example, H2 lubricants cannot contain carcinogens, mutagens, teratogens, mineral acids or intentionally heavy metals such as antimony, arsenic, cadmium, lead, mercury or selenium.
- H3 lubricants may only contain edible oils that satisfy FDA 21 CFR 172.860 (such as corn, soybean or cottonseed oils), certain mineral oils that meet FDA 21 CFR 172.878, and oils generally recognized as safe (GRAS) under either FDA 21 CFR 182 or FDA 21 CFR 184. H3 lubricants are typically used to clean and prevent rust on hooks, trolleys and other such equipment.

In contrast to robots which the use of class NSF1 lubricants adversely affects performance, some of them can continue to operate without any impairment. For example :

Collaborative robot

Yaskawa Motoman HC10DTF

Delta robot

Motoman MPP3

5 axis-robot

FANUC M-430iA/2F

Collaborative robot

Mitsubishi Melfa Assista with option NSF H1

Collaborative robot

Yaskawa Motoman HC20XP

4 axis-robot

Staubli Fast Picker TP80

Figure 34 : robot with NSF-H1 certified food-grade lubricant for enclosed gear-boxes in robot joint axes

7.3 Fabrication of product, solution and air contact surfaces

7.3.1 Cleaning and inspectability

When handling unpackaged food, the entire robot and its system must be cleanable.

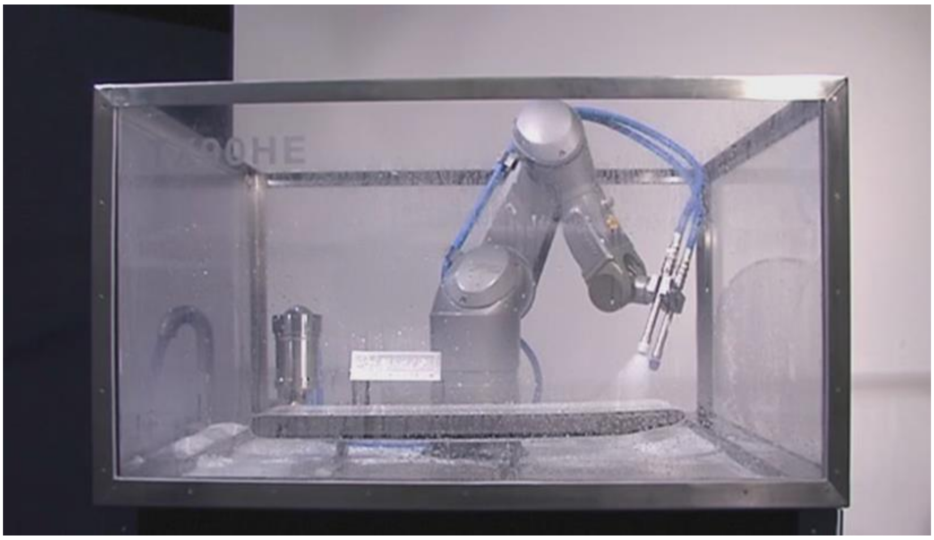
Prime locations that accumulate contamination in some robot designs include the shadow areas in the robot's castings between joints, and anything external to the robot arm like springs, moving mechanisms, pneumatic tubing, tube bundles, valves, cables, cable standoffs, hangers and the interconnect cables from the robot to the controller.

During cleaning, robot motion may be used as a means to provide accessibility to surfaces for manual cleaning, CIP (clean in place), COP (clean out-of-place) or surface inspection processes or draining (see CIP examples below). Of course, this needs to be performed and controlled in a safe manner.

The external items require dismantling or special cleaning procedures.

CIP example 1 :

Robots can actually clean themselves. The robots can wash and sterilize their tools as often as necessary, then clean their workstation and the area within their reach



Source https://www.staubli.com/en/robotics/solution-application/food-robots/

CIP example 2

The need for consistency and efficacy in cleaning and the minimizing of production downtime led JMP Engineering's automation group to take a novel approach in designing a robotic pick-and-place cell that is also capable of a completely automated washdown after two shifts of sorting and handling meat products.

The robotic cell consists of four pick-and-place robots stationed over a conveyor belt.

While it would be possible for people to wash down the entire cell in a clean-out-of-place (COP) scenario, the engineers thought it would be far too time-consuming to move the entire cell off line for manual cleaning. Then, there was the issue of how to assure people would clean all the equipment consistently and effectively every time.

Since the meat product is picked up with a vacuum system, it made perfect sense to use the existing lines in reverse to force cleaning fluids through them and flush them out. In the cell each robot is close enough to the neighbouring one so that it's possible to park robots two and four and have robots one and three clean them. Then, switching them so they're all clean." (To see this cell in action, visit http://youtu.be/eQZQ-R62Q9g.)

CIP Example 3

Video : https://youtu.be/27G_A3Atceg?t=35

End effector shall be

- CIP-able, or
- removable for COP (cleaning out of place), or
- manual cleaning by the use of simple hand tools or by use of tool changer

Figure 35 : CIP-able *m*Grip from Soft Robotic -self-draining

When end effector assemblies are too large or heavy for manual handling, appropriate mechanical means for handling or the use of a tool changer shall be provided by the fabricator or end user.

A crucial part of any cleaning protocol is inspection. All the surfaces of the end effector shall be inspectable. In a fashion similar to the ease of cleaning a fully enclosed, sealed design with smooth sides vastly eases the inspection process.

7.3.2 Draining

Surfaces shall be self-draining except for typical clingage or adherence

Robot motion may be utilize to provide effective drainage so all remnants of cleaning solutions are drained away from exposure to the sensitive product.

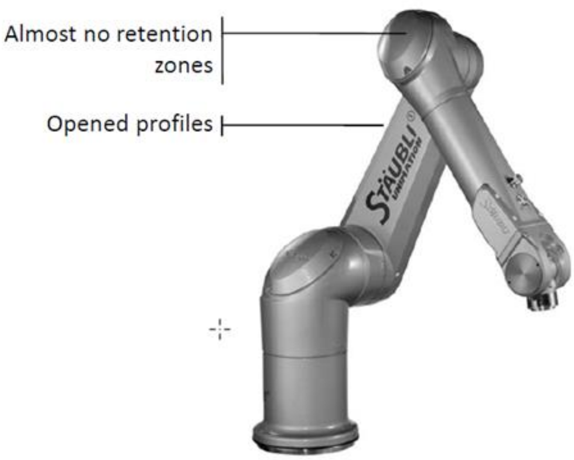


Figure 36 : Staubli robot

7.3.3 Radii

Smaller radii may be used when 6.35 mm is not possible for dimensional or functional reasons for end of effector. In no case shall such radii be less than 0.794 mm.

When radii or included angle may be changed by articulating the end of effector for cleaning, the largest radius or angle possible by articulation may be used to meet this requirement.

When radii smaller than 6.35 mm are used, the method and effectiveness of cleaning such components shall be validated and documented by the fabricator.

7.3.4 Other considerations

The sanitary design associated with the robot and the end of effector shall take motion into consideration. The motion associated with the robot, robot system or end of effector shall not defeat the robot system's sanitary design.

When drip trays are used for drip containment, the robot system motion shall be limited using safety-related means to only those areas where the drip trays are effective. (Refer to EN ISO 10218-1 and -2 for additional information regarding limiting robot motion)

The methods used to limit motions shall be verified and documented.

7.4 Fabrication of non-product contact surfaces

7.4.1 Moveable joints

Definition : A Junction between two portions of the robotic arm allowing movement in an industrial robot

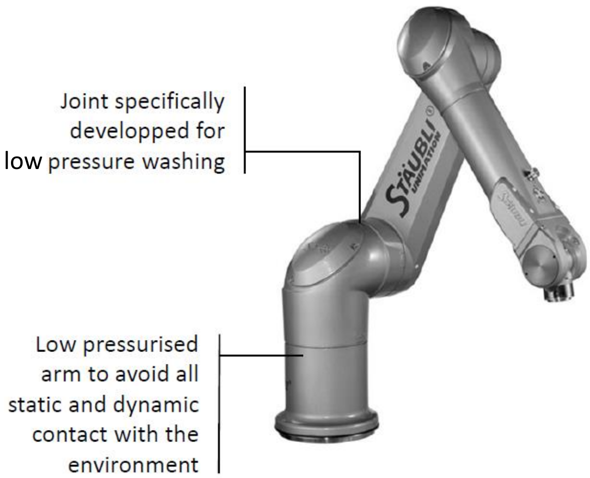


Figure 37 : Staubli robot

- Joint specifically developed for low pressure washing

An area with two moving components is always hygienically critical. Designing robot axes from the point of view of hygiene is difficult because seals cannot impair axis manoeuvrability. This problem can be solved effectively by using shaft seals. The gap between the axes should be wide enough to allow cleaning and disinfection agents to work effectively. The shaft seals should fit tightly enough to prevent the entry of microorganisms and contamination. The moveable joints shall be cleaned by CIP or shall be easily removable for manual cleaning.

- Low internal air-pressurisation of the arm

As the robot operates, it heats up to 60 to 70°C. When reducing its speed, or when static, it cools down quickly, producing condensation, and drawing the environment (air, humidity and bacteria) into the robot.

The ideal conditions for bacterial growth inside a robot are in place : medium temperatures between 15°C and 40°C; water presence and activity; vapour condensation drawn from the environment directly inside the robot; neutral pH; and most significantly, lack of access for cleaning the inner parts of the equipment.

With uncontrolled air pressurisation, bacteria and corrosion can develop within a few weeks. A low internal air-pressurisation of the arm is the best solution during and after production periods to prevent ingress of contaminants.

When purge air is used, it shall not come in contact with products or product contact surfaces. If used, product contact surfaces shall be protected from potential purge air leakage by an air flow sensor and shielding or other effective means.

7.4.2 Casters

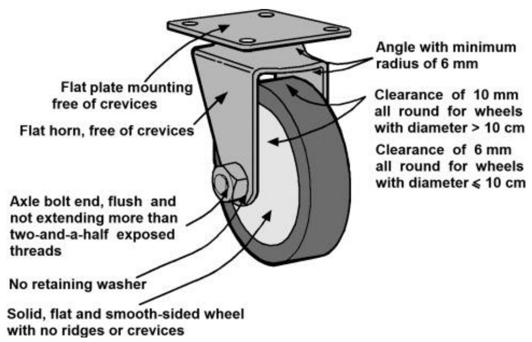


Figure 38 : Hygiene design requirements that castors in the food industry must meet (APV Baker, 2001)

Casters, if provided, shall be of sufficient size to provide a clearance between the lowest part of the base of the equipment and the floor of at least 102 mm. Casters shall be cleanable and durable under normal use and when exposed to the conditions encountered in the environment of intended use, including cleaning, sanitizing treatment, and/or sterilization, and be of a size that will permit easy movement of the equipment.

7.4.3 Mounting

Slabs, islands, or floors

If equipment is to be mounted on a slab, island, or floor, the base of the equipment shall be designed for sealing to the slab, island, or floor surface. Also, information shall be provided to the user about construction requirements for the slab, island, or floor.

Sealing the robot base to its mounting surface closes any gaps and eliminates a potential product or liquid collection space to prevent the possibility of water infiltration between these two surfaces and corrosion.

Walls and columns

If the equipment is designed to be mounted directly on a wall or column, the area of attachment of the equipment to its mounting surface shall be designed for sealing to the wall or column. If the equipment is designed to be mounted offset from a wall or column, there shall be at least a 102 mm clearance between the outside of the equipment and the wall or column

Robot dressing

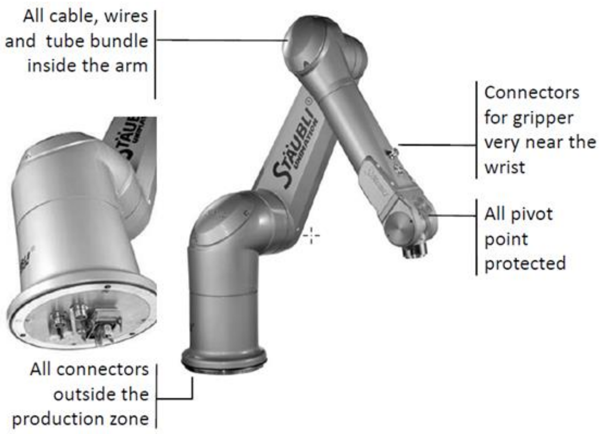


Figure 39 : Staubli robot

Robot dressing concerns cabling, tubing and other fitments affixed to the robot and required to power and control the end of effector. This includes the cabling, tubing and other fitments from the internal ports to the end of effector termination and any that must be run on the exterior of the robot itself. Dressing includes tool changer connections.

These external items accumulate contamination and require dismantling or special cleaning procedures.

Robot external arm dressing shall be installed in a manner that promotes effective cleaning

Robot tool changer connections shall be installed in a manner that promotes effective cleaning

Exhaust air from pneumatic equipment shall be piped away from product contact surfaces

If the robot dressing is in product contact, it shall conform to all applicable requirements.

7.5 Special considerations

7.5.1 Robot wiring/dressing consideration for product contact surfaces

– Robot protective jacket shall not be used

Figure 40 : robot cover

Flexible robot covers shall not be used. Some robot manufacturers recommend the use of traditional robot covers to protect the robot, but these typically employ folds to allow freedom of motion, or elastic bands to provide a seal, therefore these covers actually introduce liquid collection areas. Another concern with covers is that the operator removes the cover for cleaning and reinstalls it. If this cover is not re-installed properly, the robot is not properly covered and can expose your product to the unprotected robot, and can also expose the robot to the environment.

– Internal wiring and pneumatic lines

Robot wiring and pneumatic lines should be located inside the robot mechanism, except that when robot wiring and dressing are required external to the robot mechanism they shall be designed and constructed to meet the requirements for product contact surfaces.

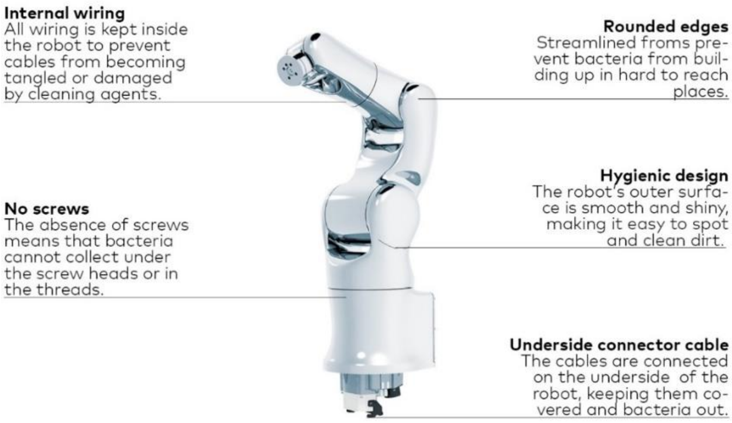


Figure 41 : DENSO Robotics

7.5.2 Robot programming considerations

The robot shall have the ability to be programmed in order to allow for specific positions that ensure safe food handling.

Home, wait , maintenance, or other positions or robotic tasks not directly involved with food handling should be conducted with the entirety of the robot and end effector in a non-product contact position. If there is not accessibility for cleaning, inspection, maintenance or other support activities while in a non-product contact position, those tasks may be performed with the equipment in a product contact position provided that no food is present and the activity is followed by appropriate cleaning.

Robots should be programmed to prohibit exhausting of pneumatic air or liquid (except food dispensed as part of operations) in the product zone.

During programming, the robot should be postured to minimize the potential for liquid or condensate draining onto the product zone.

7.5.3 Robot controller considerations

The robot controller or robot controller components should not be located in the product contact zone except where they meet all of the accepted product contact criteria. This location should be away from a location where it could be affected by moisture or condensation.

7.5.4 Tooling considerations for product contact surfaces

The robot EOAT shall be easily removable from the robot.

7.5.5 Cleaning considerations

Figure 41 : low pressure vs high pressure cleaning

Manufacturers shall provide cleaning recommendations.

Best solution for open plant cleaning in the food and beverage industry is low-pressure cleaning with boosted water. High pressure cleaning does indeed cause aerosols, which allows bacteria to be transported to other areas of the environment.

Checking chemical compatibility between cleaning solutions and the robot’s exterior will prevent any reactants from accumulating in the environment or from being exposed to the product. Robot manufacturers shall provide a list of compatible cleaners or shall offer a laboratory evaluation to detail any reaction between cleaners and coatings for any that are not on their acceptable lists.

7.5.6 Ingress Protection value (IP rating) considerations

The IP Code, International Protection Marking, standard IEC EN 60529, sometimes interpreted as Ingress Protection Marking, classifies and rates the degree of protection provided against intrusion (body parts such as hands and fingers), dust, accidental contact, and water by mechanical casings and electrical enclosures.

The first number refers to the amount of protection a scale or indicator enclosure has against solid matter (such as dust particles), while the second number defines the level of protection against liquids. The larger each digit is, the greater the protection.

The required "Ingress Protection" value (IP rating) is determined by environmental factors, such as:

- physical properties of the product to be treated: dry, wet, particle size
- humidity
- risk of condensation (determined by humidity and temperature)
- amount of dust (much/little)
- method of cleaning (manual versus automatic cleaning (CIP))
- ambient temperature in which the robot operates (<0°C, 0-5°C, 5-15°C, 15-30°C, >30°C)
  - high temperature may cause expansion of densities (influence on IP value)
  - low temperature can cause contraction of densities (influence on IP value)
  - often alternating between low and high temperatures (low t° during production, high t° during cleaning/disinfection with hot water or even steam)

⚠ IP rating refers to the robot's level of protection from the environment. This does not indicate cleanability. Fully sealed, enclosed and smooth sides are cleanable regardless of the IP rating.

8 Examples of hygienic design robots (non-exhaustive)

Hygienic robot essentials are :

- Sealed by design with smooth finish for drainage
- The construction reduces the potential above-product retention zone
- Corrosion resistant material/coating
- Surfaces chemically compatible with the cleaning products used in the industry
- Solid-body screws (vs hollow body screws)
- Pressurization of the arms to prevent water entry and damage
- Cabling protect from water ; connectors integrated into the body
- Motors and electronics protected from water with sealed covers
- NSF H1 food-grade grease
- Higher IP rating is more protection, but isn't necessary enough to be 'clean'

FANUC M-430iA/2F

- certified by the U.S. Department of Agriculture (USDA) for meat and poultry processing in 2008
- exceeds NSF/ANSI/3-A 14159-1-2002 specifications
- designed to be watertight, streamlined, easy to clean, and impervious to caustic industrial detergents
- dual seals
- small windows built into the robot body to detect moisture.
- all hoses, cables, and wires are housed inside the robot's body
- the robot's housing is pressurized
- NSF H1 food-grade grease

FANUC M20iB/25C

- 25 kg payload capacity, 1.8 meter reach
- ISO Class 5 standards
- Cables and motors are enclosed in the body of the robot
- Epoxy paint finish that meets FDA standard 21CFR 175.300
- Axes that use food-grade lubricant, such as NSF H1

Kuka KR Agilus-variant Hygienic Machine (KR 6 R700 HM-SC)

- Corrosion-resistant surfaces, food-compatible lubricants and stainless steel parts
- IP67
- electrical interface is not located in the primary contact area but rather underneath the robot.

STAUBLI FAST picker TP80 robot

Staubli's Scara robot TS2 HE

- Fully enclosed and pressurized structure to prevent microorganism penetration and avoid condensation.
- Hygienic design features smooth, rounded and tilted surfaces to eliminate liquid retention.
- Easy integration enabled by a small footprint and a variety of mounting options.
- Fully compatible with NSF H1 food-grade lubricant.
- Protected against low pressure jets of water (IP65) and immersion (IP67)
- Designed specifically for use in wet environments and full wash-down applications.
- Features stainless steel crucial components and specific coating to ensure durability in extreme conditions.
- No external cables — all connections going through the base.
- Unique, cylindrical envelope and small footprint.

Fanuc DR-3IB/8L (2020)

Fanuc food-grade DR-3iB/8L delta robot for picking and packing primary and secondary food products. IP69K, corrosion-resistant materials, an unpainted finish, and a fully enclosed body allowing it to tolerate high pressure/temperature and sanitizer wash down environments

https://dr-3ib.fanuc.eu/en/

Figure : Viewing window for grease detection

Autonox 24 - https://youtu.be/mCoELwKuYNM

— Exclusive use of materials that are permitted in the food industry.

— IP69K

— No material coatings

— No springs

— Use of special seals

— Cavity free construction, rounded corners and smooth surfaces allow quick and efficient cleaning.

— Equipped with fixed joints

— The fourth axis has a special throughput for cables, hoses for pneumatic and additional media

— Geared to the current machine directives, standards and guidelines of the “EHEDG” foundation

video : ***https://youtu.be/27G_A3Atceg***

ABB's IRB 360 FlexPicker – option stainless

- all metal parts made of stainless steel : delta plate, theta axis, arm system parts and spring unit
- IP69K
- smooth and easy to rinse-off surfaces
- lubricant free joints that are resistant to most corrosives
- cable entrance from the side

9 Additional readings on Hygienic Design for Food Equipment Manufacturers

1. Guide to application of the Machinery Directive 2006/42/EC - 2nd Edition - June 2010 – see Hygiene requirements for machinery intended for use with foodstuffs or with cosmetics or pharmaceutical products p249 (chapter 2.1)
2. NBN ISO 14159:2008 Safety of machinery -- Hygiene requirements for the design of machinery (ISO 14159:2002)

   ISO 14159 was prepared by Technical Committee ISO/TC 199, Safety of machinery.

   This International Standard is one of a series of standards relating to the safety of machinery (ISO 12100 series). It differs from other safety standards, however, in that it is concerned with the associated hygiene risks of the machinery to the consumer of the product being processed, not to the operator of the machine. Hygiene risks are very different from other safety risks. They are more associated with the ability of machines to be freed from product debris and micro-organisms, and thus preventing product contamination, rather than from the dangers of moving parts or electrical hazards to the operator. For this reason, and whilst this International Standard considers machines and their associated equipment, it can be used to provide guidance to the manufacturers of all equipment types where hygiene risks to the consumer of products to be processed by such equipment could occur. This International Standard is a Type B standard (see ISO 12100) and as such is very general. It is applicable to all machines and associated equipment in applications where hygiene risks to the consumer of the product can occur (e.g., food, pharmaceuticals, biotechnology, cosmetics). Other standards, such as for example machinery specific Type C standards may be required to provide guidance for specific types of equipment and/or for specific industry sectors. Historically, there have been cases where safety criteria have been addressed in machinery design without taking into account the implications linked to hygienic risks (and vice versa). In almost all cases, at least one of the different methods of design, safeguarding or residual safeguards can be chosen which will meet both safety and hygiene essential requirements and adequately control both risks. The option chosen shall satisfy both hygiene and safety risks, even if it may not be the most obvious option to have been adopted had the risk only been to safety or to hygiene. *When no design or safeguarding options are within the state of the art to adequately control both hygiene and safety risks, then one of the risks, or both, would have to be dealt with by residual safeguards, including instructions to the user. The assessment of the respective safety and hygiene risks shall indicate their relative significance, and the highest level of protection (i.e. safeguarding) shall be implemented to deal with the severest risk, and residual safeguards shall be used for the lesser risk.* The technical solutions given in this International Standard permit both objectives to be met for those significant and common risks identified as justifying common requirements specified in this International Standard.

3. NBN EN 1672-2+A1 : 2009 Food processing machinery - Basic concepts - Part 2: Hygiene requirements

This document has been prepared by Technical Committee CEN/TC 153 “Machinery intended for use with foodstuffs and feed”, the secretariat of which is held by DIN.

This document is a type C standard as stated in EN ISO 12100-1

This document specifies common hygiene requirements for machinery used in preparing and processing food for human and, where relevant, animal consumption to eliminate or minimise the risk of contagion, infection, illness or injury arising from this food. It identifies the hazards which are relevant to the use of such food processing machinery and describes design methods and information for use for the elimination or reduction of these risks. This document does not deal with the hygiene related risks to personnel arising from the use of the machine. This document applies to food processing machines. Examples of such groups of food processing machinery are given in the informative Annex B. NOTE Separate hygiene requirements are contained in other EU Directives (see Bibliography). In addition, the principles contained in this document can be applied to other machinery and equipment used to process food where similar risks apply. Examples of hygiene risks and acceptable solutions are given in the informative Annex A. This document is not applicable to machines manufactured before the date of publication of this document by CEN.

4. NBN EN 15180 : 2014 : Food processing machinery - Food depositors - Safety and hygiene requirements

This European Standard deals with all significant hazards, hazardous situations and events relevant to food depositors as defined in 1.2.2 to 1.2.6 and the equipment typically integrated into them, i.e. product pumps, product elevators, conveyors and indexing mechanisms, when they are used as intended and under conditions of misuse which are reasonably foreseeable by the manufacturer (see Clause 4). This European Standard deals with the significant hazards, hazardous situations and events during transport, assembly and installation, commissioning, use and decommissioning as defined in EN ISO 12100.

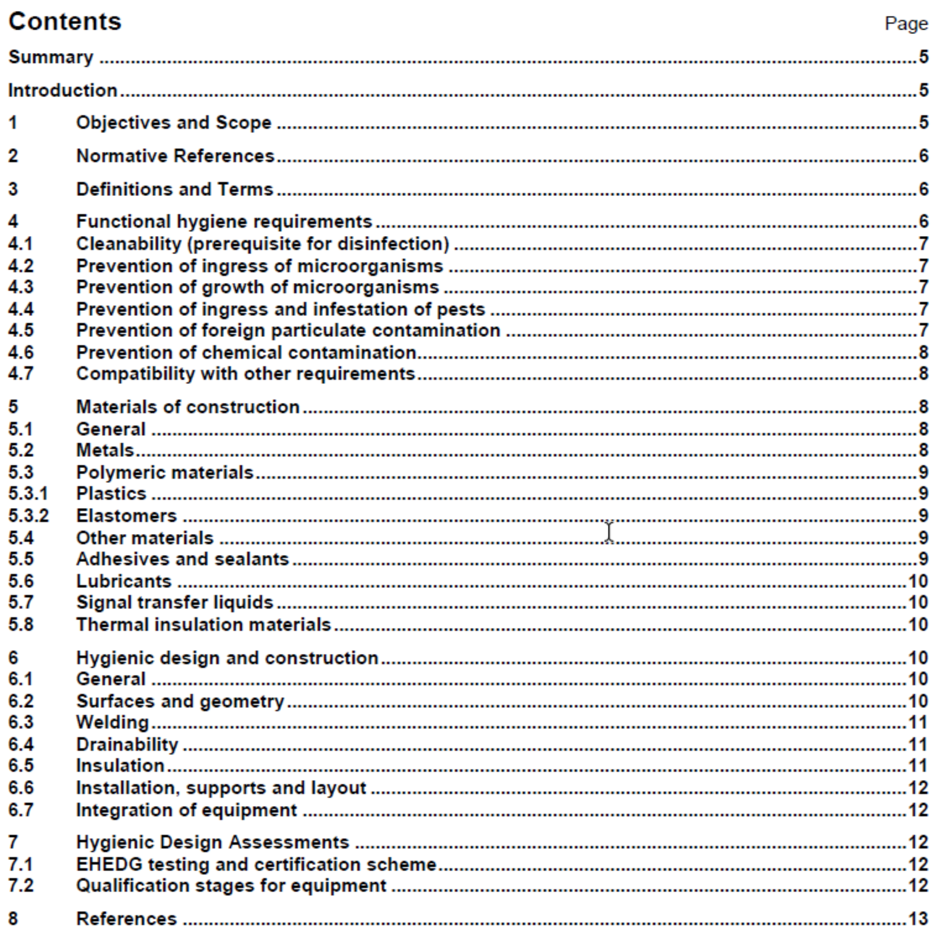
5. EHEDG Doc. 8 – Hygienic Design Principles - Third edition, March 2018 (13 pages)

This document describes the principles for hygienic design of equipment and factories intended for food manufacturing. The fundamental reason for applying hygienic design principles is to prevent contamination of food products. Equipment and factories of poor hygienic design are difficult to clean. The document details the hygienic design principles that shall be followed when designing and constructing equipment and factories for manufacturing of foods. It gives guidance on design, construction and installation so that it does not adversely affect food safety and quality. These principles apply to open and closed manufacturing operations, surrounding facilities, all being cleaned either wet or dry.

This document, first published in 1993, describes in more detail the hygienic requirements of the Machinery Directive (98/37/EC ref. 1). Parts of it have subsequently been incorporated in the standards EN1672-2 and EN ISO 14159.

Doc. 8 is used as a basis for hygienic design evaluation within the EHEDG equipment certification program.

The content of this document covers functional requirements, intended use, materials of construction, hygienic design and construction and assessment methods.


Contents

Page

6. EHEDG Doc. 13 – Hygienic design of equipment for open processing

It is important that the plant design takes into account factors affecting the hygienic operation and cleanability of the plant. The risk of contamination of food products during open processing increases with the concentration of micro-organisms in the environment and their opportunity to grow in poorly designed equipment. This means that in open plants, environmental conditions, in addition to appropriate equipment design, have an important influence on hygienic operation. The type of product and the stage of the manufacturing process must also be taken into consideration. This paper deals with the principal hygienic requirements for equipment for open processing and applies to many different types, including machines for the preparation of dairy products, alcoholic and non-alcoholic drinks, sweet oils, coffee products, cereals, vegetables, fruit, bakery products, meat and fish. It describes methods of construction and fabrication, giving examples as to how the principal criteria can be met. See also guidelines on hygienic design criteria (Doc 8), hygienic welding (Doc 9), and the hygienic design of equipment for closed processing (Doc 10). Extended summary (pdf)

7. 3-A Sanitary Standard for Robot-based Automation System (3-A-103-00)
8. 3-A SSI's on-demand E-learning Modules.

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