D8.1 – Hygienic Design workshop and hygienic system requirements

Fraunhofer
3/26/2012

Flexible robotic systems for automated adaptive packaging of fresh and processed food products

The research leading to these results has received funding from the European Union Seventh Framework Programme under grant agreement no 311987.

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1 Introduction

Hygienic design of equipment and facilities is one of the main tools that have food manufacturers to achieve their legal responsibility for ensuring product safety. Unsafe foodstuffs may not be placed on the market. Both food manufacturers and food equipment manufacturers should be aware of the importance of considering hygienic aspects in their operations.

2 Aim

The course gives knowledge and insight into the hygienic design of machinery, equipment and processes for the food industry in order to fulfill present legislation and standards with respect to hygienic food production and to satisfy the needs of purchaser and retailers. These includes minimal down time, cleaning costs, environmental impact and efficient cleaning, optimal product safety and constant product quality.

3 Methodology

The course is given from a practical point of view by different trainers. The fundamentals of the different subjects are given in a short and concise manner, continuously relating to practice by means of good/bad examples. The course gives tools to design equipment and machinery for the PicknPack-production line in a hygienic way. The participants will get handouts of the presentations.

The content of the course is based on EHEDG (European Hygienic Engineering and Design Group) guidelines and their training and education material.

4 Program

The workshop will be held on 26th April 2013 during the 2nd PicknPack Project meeting at AZTI-Tecnalia, Astondo bidea, 609 eraikina - 48160 Derio, Spain.

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<th>End</th>
<th>Topic</th>
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<td>Welcome, introduction, program</td>
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<td>13:30</td>
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<td>Materials of construction</td>
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<td>15:00</td>
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</tr>
<tr>
<td>17:00</td>
<td>17:15</td>
<td>Summary</td>
</tr>
</tbody>
</table>
5 System Requirements

The hygienic system requirements have also been reported to the Deliverables D 5.1.

5.1 Hygienic Requirements from present Legislation and Standards

Figure 1: European food safety regulations

5.2 Hygienic Requirements – general

Definition: product contact surface
- Surfaces that intentionally or unintentionally come in contact with the product
- Surfaces from which product or condensate may drain, drop or be drawn back into the main product or product container

All articles, fittings and equipment with which food comes into contact are to:
- be effectively cleaned and, where necessary disinfected,
- be so constructed, of such materials, in good order, repair and condition, as to minimize any risk of food contamination.

Materials and equipment shall be selected so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:
- endanger human health,
- bring about an unacceptable change in the composition of the food,
- bring about a deterioration in the organoleptic characteristics thereof.
5.3 Hygienic Design Criteria - 8 Keys to hygienic Design

To fulfill the general hygienic requirements and to reduce / avoid product contaminations from:

- Foreign bodies (stones, leaves, equipment & replacement parts, packaging, personnel)
- Chemical substances (lubricants, additives, cleaning & disinfection residues, incorrect process management),
- Microorganisms, pests (birds, insects, rodents),
- Allergens (yeasts and moulds, algae; bacteria; viruses)

the following equipment design criteria have to be followed:

- Smooth surfaces – hygienic welding
- No crevices (metal to metal contact)
- No protrusions
- No sharp corners
- No dead areas
- Accessible for cleaning and inspection
- Drainability
- Food grade of ancillary liquids

5.4 Packaging technology

Based on the product properties, the distribution and storage conditions and the shelf life of the product a hygienic or aseptic packaging process has to be developed.

Hygienic equipment

- Equipment that is easily cleanable

Aseptic equipment

- Hygienically designed equipment that is sterilizable and is impermeable to microorganisms to maintain its aseptic status.

Aseptic process

- A process using equipment and packaging material sterilized before use, and which, in running conditions, is protected against recontamination by microorganisms.
- Adequate decontamination of internal environment and/or packaging material has to be provided

Depending on the food product to be processed and the selected packaging technology the need of a hygienic zoning concept for the packaging line has to be discussed (Fig. 2).
Figure 2: Generic layout of hygiene zones in food factories and food processing machines
Legal Requirements
Content

• Codex Alimentarius

• Legal Requirements
  • European Legislation
  • EU Hygienic-Regulation
  • Directive 2006/42/EC on machinery
  • US-Legislation
Codex Alimentarius - Food Hygiene

„Food safety”

Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the joint FAO/WHO Food Standards Programme.

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<tr>
<th>Basic Texts</th>
<th>Codex Alimentarius</th>
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<tr>
<td>RECOMMENDED INTERNATIONAL CODE OF PRACTICE</td>
<td></td>
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<tr>
<td>GENERAL PRINCIPLES OF FOOD HYGIENE</td>
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</table>
Food Safety

**Equipment / Hardware**
- Hygienic Design Criteria

**Process**
- Hygiene Food Processing Criteria

**EU-regulations:**
- RE (EC) 178/2002
- RE (EC) 852/2004
- RE (EC) 2073/2005

- Regulation (EC) 1935/2004 - on materials and articles intended to come into contact with food
- Regulation (EU) 10/2011 - on plastic materials in food contact
- Regulation (EC) 2023/2006 - on good manufacturing practice for materials and articles intended to come into contact with food
Regulation (EC) 178/2002 laying down the general Principles and Requirements of Food Law

- Basic hygiene principles
- Food & feed business operator: legal responsibility for ensuring product safety
- Unsafe foodstuffs may not be placed on the market
- Traceability
- Consideration of long-term, cumulative effects
Regulation (EC) 852/2004 on the Hygiene of Foodstuffs

- Primary production (Farm Level, Annex I) and further steps (Annex II)
- Analysis of potential food safety risks and determination of Critical Control Points (Hazard Analysis and Critical Control Points - HACCP)
- HACCP based on principles of Codex Alimentarius
- Control and documentation requirement during the whole production process
- Registration is mandatory for all food manufacturing establishments
Regulation (EC) 852/2004 on the Hygiene of Foodstuffs

Risk assessment - HACCP

• Conduct hazard analysis
• Determine critical control points (CCP’s)
• Establish critical limit(s)
• Establish system to monitor CCP’s
• Establish corrective action
• Establish verification procedure
• Establish documentation
Regulation (EC) 852/2004 on the Hygiene of Foodstuffs

Annex II (food business operators)

Surfaces (including surfaces of equipment) … will require the use of smooth, washable, 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 of the equipment and the surrounding area
Regulation (EC) 2073/2005 on microbiological Criteria for Foodstuffs

• Determining limits for safe food
• Process hygiene criteria during manufacturing
• Annex I: Food safety criteria for best before date for different food categories
Directive (EC) 2006/42 Annex I 2.1. Food processing Machinery and Machinery for pharmaceutical and cosmetic Products

Principles

Machinery intended to come into contact with

- Food, Cosmetics, Pharmaceuticals

must be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion.

Machine parts / materials in contact with food can be cleaned before each use.

Where this is not possible disposable parts must be used!
Requirements on Machine Conditions

All surfaces including their joining with product contact (exception: disposable parts) must

- Be smooth, without ridges or crevices
- Reduce projections, edges and recesses to a minimum
- Be easily cleaned and disinfected
- Inside surfaces must have curves of a radius sufficient to allow sufficient cleaning
Design Requirements

It must be possible for liquids, gases and aerosols deriving from products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged from the machinery.

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.

Machinery must be designed and constructed in such a way that no ancillary substances, including the lubricants used, that are hazardous to health can come into contact with products.
EU-Legislation

Summary

All regulations and directives, except the machinery directive, arise from consumer protection and therefore from food law.

The basic principle is that everyone is self-responsible and has to perform risk assessment to assure food safety.

The framework of the legislation does not provide design details, but is supported and expanded by non-normative standards and EHEDG-guidelines.

Consider allergens
Legal Requirements

USA
Legal texts USA

Food and Drug Administration (FDA):
Food code

United States Department of Agriculture (USDA):
Legislation on machines processing agricultural products

FDA

USDA

Work jointly together with other local, federal and national organizations
Food and Drug Administration (FDA)

- Monitors and regulates manufacturing and trading of pharmaceuticals, cosmetics and food
- Monitors by regular inspection (incl. NON-USA)
- No accreditation of machine components and equipment
- Demand for FDA-compliant materials according to 21CFR 174-178
Title 21--Food and Drugs

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 110--CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

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Hazards in Hygienic Processing
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• Introduction
• Foreign bodies - Potential sources of contaminations
• Chemical contamination
• (Micro)biological contamination
  • Potentially pathogenic microorganisms (MO)
• Size of MO
• Growth of MO
• What MO need in order to multiply?
• What you should know about MO?
• Contamination routes
Introduction

What could happen to your business?

2008 Canadian listeriosis outbreak linked to a Maple Leaf Foods plant in Toronto (August 2008 to December 2008)

- 22 people died and 57 injured
- recall cost $20 million
- 4 separate class-action lawsuits in Ontario, Quebec, Saskatchewan and British Columbia (one claiming damages of $350 million)
- Loss of image „Tragically, our products have been linked to illness and loss of life“ - Maple Leaf Foods CEO M. McCain

Introduction

Contamination

• Introduction or occurrence of any biological or chemical agent foreign matter or other substance not intentionally added to product which may compromise product safety or suitability

Types of contamination

• Foreign bodies

• Chemical

• (Micro)biological

• Allergenic
Foreign Bodies - Potential Sources of Contamination

Raw Materials / Contaminated goods

- stones, sand, leaves…
- equipment & replacement parts (washers, seals, screws…)
- packaging (film, containers, board, trimmings from packaging film)
Foreign Bodies - Potential Sources of Contamination

Processing machines

• e.g. screws, gaskets, metals, plastics, glass
Foreign Bodies - Potential Sources of Contamination

Environment

• e.g. ceiling plaster, dust, fibres, broken glass…

Source: Soro, Ainia

Source: Barnickel, LfL

Dirt in aerodynamic death space

Air
Foreign Bodies - Potential Sources of Contamination

Personnel

• e.g. ties, rings, gloves, tools and mobile phones…

Source: Fraunhofer AVV

Mobile Phone

Source: Barnickel, LfL
Chemical Contamination

• additives and lubricants
• cleaning and disinfection residues
• due to incorrect process management
(Micro)biological Contamination

Pests

• bug tightness: max. tolerable pin hole size of 100 µm
• birds, insect, rodents, etc.
(Micro)biological Contamination

Microorganisms

- yeasts and moulds, algae; bacteria; viruses

**Saccharomyces cerevisiae**
- red: *E. coli*, green: *Ent. faecalis*
- orange: *Salmonella typhimurium*

**Hepatitis A Virus**

[Source: Eschenhagen, TU Dresden]

[Source: Eschenhagen, TU Dresden]

[Source: Eschenhagen, TU Dresden]

http://pathmicro.med.sc.edu/virol/hep-a5.jpg
Useful Microorganisms

- act on foods to produce desirable characteristics (odours, flavours, textures, microbiological stability…)

![Images of cheese, bread, wine, and beer]
Spoilage Microorganisms

- alter food
- produce undesirable characteristics

Pathogenic Microorganisms

- affect individuals that have taken them causing food borne illness.
- They do not necessarily change the organoleptic characteristics of the food.
Pathogenic Microorganisms

Microorganisms are one of the most important biological foodborne hazards, and are reported in more cases of foodborne illness than any other hazard.

Examples:

- *Listeria monocytogenes*
- *Campylobacter*
- *Salmonella*
- *Clostridium botulinum*
- *Escherichia coli*
- *Vibrio cholerae*

Source: Barnickel, LfL
Pathogenic Microorganisms (MO)

Microbial toxins

- even when you kill them, some leave behind toxins (Endotoxins)
- heat-stable toxins (*Staphylococcus aureus*)
- other toxins, esp. moulds
Size of MO

<table>
<thead>
<tr>
<th>Bacteria</th>
<th>Spores – Ø [µm]</th>
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<tbody>
<tr>
<td>Clostridium botulinum</td>
<td>3-8 0,5 - 0,8</td>
</tr>
<tr>
<td>Clostridium perfringens</td>
<td>4-8 1 - 1,5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mould</th>
<th>Length [µm]</th>
<th>Thickness - Ø [µm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspergillus</td>
<td></td>
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</tbody>
</table>

If you can’t see and reach it, you can remove or sample it!

Typical representation of a stainless steel surface profile of Ra =0,6 µm roughness achieved by 240 grit mechanical polish. No surface defects or damage.

Source: Fraunhofer AVV, Leibniz – Institut für Polymerforschung Dresden
Growth of MO

- bacteria multiply by dividing and producing two identical new cells
- when conditions are just right, they can multiply very rapidly
- growth at: pH 0 to 13, most bacteria prefer a neutral environment (pH = 5-7)
- growth at salinity: 0 to saturated and hydrostatic pressure 0 to 1000 bar

Source: Timmerman, Diversey Inc.
Growth of MO after Sterilisation without Recontamination after Heat Treatment
Growth of MO after Pasteurisation
What MO need in order to multiply?
What MO need in order to multiply?

Influence of temperature on growth rate

- Bacillus, Spores
- Listeria monocytogenes
- Salmonella
- Legionella

Source: Barnickel, LfL
What MO need in order to multiply?

**Food and water**

Need food and water in order to grow and multiply. Each type of bacterium is specific in its needs.

Most bacteria of concern prefer foods high in proteins and carbohydrates.

**Dried foods**: do not contain enough water (free water, $a_w$-value, water activity) to allow bacteria to grow, but are not necessarily free of bacteria or spores.
What MO need in order to multiply?

Effects of the water activity ($a_W$-value) on growth of MO

$$a_W$$-value | MO growth inhibited at lowest value (partial) | Examples
---|---|---
1 - 0,95 | spores of bacteria, some yeasts, gram-negative bacteria | ![Eggs](https://via.placeholder.com/150), ![Apple](https://via.placeholder.com/150)
0,91 – 0,87 | most yeasts | ![Salami](https://via.placeholder.com/150), ![Cheese](https://via.placeholder.com/150)
0,87 – 0,80 | most moulds, *Staphylococcus aureus* | ![Condensed Milk](https://via.placeholder.com/150), ![Spaghetti](https://via.placeholder.com/150)
< 0,5 | no growth of microorganisms | www.carnation.co.uk

Source: Buchner: Verpackung von Lebensmitteln. Springer-Verlag, 1999
What MO need in order to multiply?

Oxygen and acidity

Aerobic bacteria: must have oxygen in order to grow $\rightarrow$ mainly of concern

Anaerobic bacteria: can not survive when oxygen is present

Facultative anaerobic: can grow with or without free oxygen

Microorganisms

- yeasts
- moulds
- pathogene bacteria

Food

- alkaline
- weak acid
- acid
- strong acid

$pH$ - value

meat, fresh slaughtered, egg white

meat, fish, poultry, vegetables

tomatos, pears, apples, yogurt

sauerkraut, many fruits, lemons
What you should know about MO?

Microorganisms…

- can swim in fluids or films (chemotaxis - they swim towards the food, up to 160mm/h)

Source: http://www.youtube.com/watch?v=PZfsIGT5NIs
What you should know about MO?

Microorganisms…

• form slime (biofilm) for protection & adhesion
• grow at interfaces, liquid or solid residues (fungi)
• are working together

Source: Bechtluft, KHS AG
What you should know about MO?

Microorganisms...

- surfaces are favored substrates to settle and to develop - resist flushing
- can penetrate plastic and can induce corrosion
What you should know about MO?

You can kill, reduce or inhibit growth by:

- sanitizers (e.g. citric acid, silver ions)
- physical treatments (e.g. heat, UV, drying)
- chemicals (e.g. chlorine, peracetic acid)
- but some have:
  - high tolerance against UV light and radioactive radiation
  - high resistance against biocides, especially in biofilms
- an important method is: keep environment as dry as possible
Contamination Routes

Wet floor – „Product contact“ surfaces?

Source: Roland Cocker, Cocker Consulting
Contamination Routes

Water-borne

- condensate / wet films
- stagnant water or liquid, drops
  - poor installations allowing backflow
  - non potable water

Drain opened
Contamination Routes

Water-borne

- Fresh water hose: residual water in tube, app. 2 month stagnant: 87 cfu/ml
- after 2 min. steaming: < 1 cfu/ml

Source: Barnickel, LfL
Contamination Routes

Ancillary liquids

- lubricants, coolants, signal transfer liquids

- example of contaminated food grade grease

Source: EHEDG Guideline 23
Source: Bowmer, Bel-Ray Company Inc.
Contamination Routes

- product (meat) in a pipe connection after cleaning

Source: Soro, Ainia
Contamination Routes

Protection of Microorganisms by Soil

- Thermal Kill
- D-values** (min) for Spores of Bacillus subtilis (** D-value is the time taken to reduce numbers tenfold, or by 90%)

<table>
<thead>
<tr>
<th>Product</th>
<th>a_w</th>
<th>t (min)</th>
<th>Time Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physiological Saline</td>
<td>1.00</td>
<td>0.23</td>
<td>1</td>
</tr>
<tr>
<td>Fat &amp; Protein</td>
<td>0.49</td>
<td>28.4</td>
<td>X 128</td>
</tr>
<tr>
<td>Fat</td>
<td>0.50</td>
<td>25.0</td>
<td>X 109</td>
</tr>
<tr>
<td>Molasses</td>
<td>0.59</td>
<td>12.8</td>
<td>X 56</td>
</tr>
<tr>
<td>Protein</td>
<td>0.61</td>
<td>27.1</td>
<td>X 118</td>
</tr>
</tbody>
</table>
Contamination Routes

Airborne

- Microorganisms fly as passengers on dust particles/ aerosols
  (High pressure sprays!)
- passive transport on hairs, skin flakes, dust, etc.
Contamination Routes

Airborne - Problem high pressure cleaning
Contamination Routes

Airborne – Aerosol as transport vehicle

- e.g. steam

Source: Diversey Inc
Contamination Routes

Human error - Contamination source No.1

- Scalp – approx. 1 million / cm²
- Saliva – approx. 10 million / gm
- Armpit – 1-10 million / cm²
- Feet – 1 million / cm²
- Faeces – greater than 100 million / gm

- Forehead – 100-1000 / cm²
- Nasal fluid – app. 10 million / gm
- Hands – 10,000-100,000 cm²
- Groin – 1-20 million / cm²

Air: Grade A: <1 cfu/m³; Grade E: <500 cfu/m³ (EC Guide to GMP, Revision Annex 1, 2003)
Potable water (22°C): 100 cfu/ml
Contamination Routes

Human error

Before Hand washing  After washing  After desinfection

Source: Barnickel, LfL
Hygienic Practices to avoid MO Input

• Training of personnel to use equipment as designed and to follow hygiene rules is essential

• No contact to hair
• No contact to mobile phone
• Don’t put anything from the floor on the working place
• Minimize draft or aerosol
• Appropriate sanitary practice
Bacteria on a Spider

Source: Salker, Barnickel LVFZ 2010
Contact Plate Test Results

Door handle

Desktop next to filler without cleaning

Contamination of floor water

Source: Barnickel, LfL
Detection of MO on Surfaces: Contact Plate Test

- Sterile agar plate with nutrient medium
- Collection of MO on test surface
- Incubation
- Counting of colonies

Source: Barnickel, LfL / Soro, AINIA
Content

• Hygienic design criteria for open equipment
  • Introduction
  • Welds,
  • Dismountable joints
  • Drainability,
  • Belts, Frameworks….

• Hygienic design criteria for closed equipment
  • Introduction
  • Seals, Welds, Pipe connections
  • Drainability
  • T-pieces
Definition

Open processes

• Product and product contact surfaces are exposed to the environment around the equipment.

Closed processes

• Product and product contact surfaces are NOT exposed to the environment around the equipment during normal processing.

Hygienic equipment class I

• Equipment that can be cleaned in-place and be freed from relevant microorganisms without dismantling.

Hygienic equipment class II

• Equipment that is cleanable after dismantling and can be freed from relevant microorganisms after reassembly.
Open process (GL: 8, 10, 13, 22)

- product in (limited) contact with environment / surroundings
- often large product contact surfaces with complex geometries
- design of equipment plus environment must prevent any increase in soil and microbial concentration
Definition of machine areas

Product contact surfaces

The machinery surface which are exposed to the product (direct) and from which the product or other materials can drain, drip, diffuse or be drawn into (self returned) the product or product container (indirect).
Indirect product contact area

If possible: Keep it dry, high pressure cleaner?

Stagnant water
General recommendations

- Correct choice of materials of construction
- Smooth surfaces – hygienic welding
- No crevices (metal to metal contact)
- No sharp edges and corners ($r > 3\text{mm}$)
- No dead areas
- Accessible for cleaning and inspection
- Equipment must be fully self drainable
- Cabinets slope away from product

- make it close if possible
- keep it covered
Color code for EHEDG diagrams

- **Product or product area**: Dark Blue
- **Water**: Light Blue
- **Bacterial film or soil**: Orange
- **Hygienic risk, poor hygienic design**:
- **Correct, easy cleanable design**
Welds

(a) product area, (b) step, (c) sloped edge, (d) intermittent welding, (e) continuous welding, (f) crevice due to metal-to-metal contact
Welds

Internal angles and corners must be effectively cleanable

- Sharp corners (≤90°) must be avoided
- Corners with angles smaller than 135° must be smooth and have a minimum radius of 3 mm. (preferably equal or larger than 6mm)

(a) product area, (b) sharp internal angle
Dismountable joints

- fully drainable
- fully sealed, avoid metal to metal contact (b)
- fixed compression
- fasteners on non-product-contact side

(a) product area, b) metal-to-metal contact, c) dead area, crevice
Dismountable joints

(a) product area, (b) domed head, (c) elastomer, (d) metal, (e) circular collar
(f) sloped, (g) domed, (h) hexagon, (i) stud
Drainability

- the exterior and interior of all equipment and pipework must be
  - self-draining or drainable
  - easily cleanable
- horizontal surfaces (upwards or downward facing) must be avoided
- surfaces should always slope away from product
- in case of external surfaces: slope away from the main product area
- Drainage of condensates should be considered when appropriate
Drainability of condensates

Source: Rafa Soro, AINIA
Drainability

(a) product area, (b) residual soil

Tank for special purposes (e.g. brewery)
Self-drainable designs

(a) product area, (b) hinge
Arrangement of ancillary equipment

(a) product area,
(b) contamination,
(c) motor with fins,
(d) thrower ring,
(e) selfdraining protection sheet with “upstand” [dismountable]
Arrangement of ancillary equipment

Physical hazards: e.g. Paint flakes
Arrangement of ancillary equipment
Reinforcement of belts

(a) open edge, (b) reinforcement, (c) rounded rim, (d) covered edge
Sides of conveyor belts

- (a) product area
- (b) pivoted cover
- (c) hinge
- (d) belt
- (e) frame
- (f) dead area
- (g) detachable cover
Special belt design

(a) framework, (b) overhanging belt sides, (c) cladding, (d) stainless steel table, (e) roller, (f) belt, (g) released tension, (h) support roller, (i) swivel-mounted roller
Conveyor drive arrangements

(a) product, (b) cover for motor and gear, (c) belt, (d) roller, (e) open framework, (f) sealed window, (g) sensor, (h) gear, (i) motor, (j) covered and sealed housing
Design of rollers

(a) pressed-in roller end, (b) residues of soil and product, (c) crevice, (d) welds, (e) shaft
Framework
Framework

Source: Soro, AINIA
Framework - Example
Horizontal surfaces

- avoid product or liquid collection

(a) residues of soil, (b) small clearance, (c) clearance, (d) slope, (e) radius, (f) sealing
Horizontal surfaces

- Source: EHEDG Guideline No. 29

Inclined plane, out of one piece

Source: Bellin consulting
Installations

(a) product area, (b) rounded pedestal, (c) clearance, (d) sealed to the floor

Source: Jon J. Kold, Stålcentrum
Installations

Source: Bellin consulting

Source: Diversey

© 2010 EHEDG / Manuel Helbig
Closed process

Source: Lorenzen, Tuchenhagen GmbH
Seals

Static seals

- no crevice on product side, surfaces must be precisely positioned
- O-rings in rectangular grooves have too much range of movement during strong temperature changes!

(a) product area, (b) elastomeric seal, (c) heating, (d) cooling, (e) micro-organisms (f) gap
Seals

Static seals

Source: Rafa Soro, AINIA
Seals

Static seal

- axial stop for controlled compression of the seal
- appropriate groove shape to avoid displacement and pinching
- shrink or expand with changes in temperature

(a) product area, (b) elastomeric seal, (c) crevice, (d) sealing at the product area
Seals

Dynamic seal

- seals that slide into and out of the product
- springs in product (mechanical seals)
- annular crevices

(a) product area, (b) dynamic seal, (c) reciprocating or rotating shaft, (d) gap
Seals

Dynamic seal

- membrane seals
- aseptic process: double seal and flushing of the barrier area

(a) product area,
(b) dynamic seal,
(c) reciprocating or rotating shaft,
(d) flushing chamber

- verification of flushing
Pipe connection

Requirements

- centering
- defined sealing pressure
- no crevice before sealing
- sealed by metal-polymer combination, avoid metal to metal contact

(a) product area, (b) metal coupling, (c) metal to metal contact area, (d) annular crevice
Pipe connection

DIN 11851

Clamp ISO 2852

Crevice

Undefined closure, crevice

Source: Jürgen Hofmann
Pipe connection

DIN 11864-2 Form A, DIN 11853-2

Source: Jürgen Hofmann

Centered sealing with defined compression
Pipe connection

Flexible Connections

Source: Soro, AINIA
Pipe expansion

- cleaning requires mechanical energy input
- design has to be customized accordingly! – less flow disturbance

Water, 23 °C
Flow velocity: \( v=1,5 \text{ m/s} \)
Extent from \( \varnothing \) 26mm to 38mm

Drainability

(a) product area, (b) concentric reducer,
(c) eccentric reducer, long version,

(a) product area, (b) inlet, (c) outlet,
(d) undrainable volume
Drainability

Sump area in a valve
Not drainable in this position!

Source: Matthias Schäfer, GEA Tuchenhagen GmbH
Drainability

(a) product area, (b) sensor, (c) dead end
**T-pieces in CIP-cleaning**

- avoid dead legs
- The configuration in pic. i) can be acceptable if the death leg is short (l/d < 1)

![Diagram](image)

(b) dead leg with residual soil

*Source: Fraunhofer AVV*

*Quelle: EHEDG GL. 10*
T-pieces in CIP-cleaning

1.5 m/s  D=50mm; L/D=1.0

1.5 m/s  D=50mm; L/D=1.5
Materials of Construction for Equipment in Contact with Food
Content

• Introduction

• Regulations for the use of food contact materials

• Material of Construction - Austenitic stainless steels
  • Surface characterization - Roughness
  • Surface treatment
  • Influence of roughness on cleanability
  • Corrosion of stainless steel

• Material of Construction - Elastomers

• Material of Construction – Plastics

• Other materials
Product contact surfaces

Closed surfaces

Source: Lorenzen, Tuchenhagen GmbH
Product contact surfaces

Open surfaces

Source: Fraunhofer AVV

Source: Diversey
Regulations for the use of food contact materials

Directive 2006/42/EC

All surfaces in contact with foodstuffs, cosmetics or pharmaceutical products must:

• be smooth and have neither ridges nor crevices
• be easily cleaned and disinfected

The machinery must be so designed and constructed in such a way that these materials can be cleaned before each use.

Where this is not possible disposable parts must be used.
Regulations of specific materials

- Directive 2002/72 plastic materials and articles intended to come into contact with foodstuffs
- Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food

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<tr>
<th>Member States</th>
<th>OTHER</th>
<th>Adhesives</th>
<th>Ceramics</th>
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SUMMARY OF THE NATIONAL LEGISLATION

SANCO E6/MS(30/04/2010)

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Metals

Product contact surfaces

Stainless steel (austenitic)

- EN 1.4301  AISI 304  X5CrNi18-10
- EN 1.4305  AISI 303  X8CrNiS18-9
- EN 1.4401  AISI 316  X5CrNiMo17-12-2
- EN 1.4404  AISI 316L X2CrNiMo17-12-2
- EN 1.4435  AISI 316L X2CrNiMo18-14-3
- EN 1.4541  AISI 321  X6CrNiTi18-10
- EN 1.4571  AISI 316Ti X6CrNiMoTi17-12-2

- Currently there is no regulation regarding the use of different grades of stainless steel at European level.
Metals

Non-product contact surfaces

Stainless steel

Aluminium
- e.g.: Hardcoat anodization, Anodization

Mild steel – surface coated
- e.g.: Active primer and metallic top coat
- e.g.: Nickel plating
Austenitic stainless steels

Alloying components

- alloy of iron, carbon, chrome and nickel, at least 18% chrome and 8% nickel

Properties

- malleable and weldable
- non magnetic
- high resistance to corrosion

Operating range (food, drug, biotechnology)

- construction of apparatus and container
- piping and components
General operating ranges

Products with low chloride content

• AISI 304 or EN 1.4301 (Caution: Pitting)

Products with chlorides, moderate temperature (<60°C)

• AISI 316 or EN 1.4401 (Caution: Stress cracking corrosion)
• AISI 316L or EN 1.4404

Products with chlorides, high temperature (60-150°C)

• AISI 410 or EN 1.4006 (no stress cracking corrosion)
Surface characterization

Arithmetic average of roughness Ra, Average distance Rz

Source: Alfredo Calvimontes, Topographic characterization of polymer materials at different length scales and the mechanistic understanding of wetting phenomena, PhD Thesis, TU Dresden
Surface treatment - Electropolishing

Definition

removing material from a metallic work piece (minimum 15 µm) by using DC and acid (mixture of phosphoric and sulphuric acid)

Results

• Surface profile is smoothened in micrometre range
• Low surface roughness, inhomogeneous layers / structure will be removed
• Results a nonporous surface, which is free of cracks
• Excellent conditions for passivation and resistance to corrosion
Surface treatment - Pickling

Definition

• Acid is used to remove the surface impurities, such as scale, oxides, rust…

Aim

• Preparation of stainless steel surface to achieve a tight passive layer

Process

• Dipping into a pickle bath (nitric acid and hydrofluoric acid), using pickling paste
  • Rinsing with water to remove acid completely

Result

• Resulting surface roughness is coarser than from electropolishing
Surface treatment - Passivation

Definition

Formation of an oxide layer (passive layer), usually chromium oxide.

Process

Treatment with an oxidizing acid (e.g. nitric acid, high concentration).

Passivation should be repeated at larger intervals.
Surface treatment - Grinding

Ra = 1µm, K 150

Ra = 0,6µm

ground  electropolished

Source: IPF Dresden
Surface treatment - Bead blasting

Ra = 0,9µm

Ra = 0,4µm

bead-blasted

Source: IPF Dresden
Influence of roughness on cleanability

Closed cleaning – EHEDG in-place cleanability test

Influence of roughness tending to be low

Source: Bobe, AiF ZN210
Effects of crevices

Growth of MO in welds - Penetration behaviour of liquids

- Water 72 mN/m
- Milk 52 mN/m
- Beer 43 mN/m
- Quats 24-34 mN/m
- Soil, Microorganisms
Protection of MO by soil and geometry

Test unit for testing protection of microorganism by soil in crevices

Tests done in artificial crevice with a width of 0.5 mm and a depth of 50 mm

GEA Tuchenhagen VARINLINE®
Process Connection with artificial crevice

Internal part of test unit
Protection of MO by soil and geometry: Against thermal disinfection

Source: Roy Curiel, Unilever
Protection of MO by soil and geometry: Against chemical disinfection

- Inactivation of *B. Subtilis* by Peracetic Acid in the presence of soil in crevices.
- In water a PAA concentration of 264 mg/kg will give 8 log reduction in 10 minutes

<table>
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<tr>
<th>Contact time (min)</th>
<th>Log reduction</th>
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<tr>
<td>10</td>
<td>0.7 0.9 1.0</td>
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<tr>
<td>30</td>
<td>0.6 0.7 0.9</td>
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<tr>
<td>30</td>
<td>0.4 0.6 0.8</td>
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<tr>
<td>0 - 10</td>
<td>0.4 0.7 0.8</td>
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<td>30 - 40</td>
<td>0.4 0.7 0.8</td>
</tr>
<tr>
<td>40 - 50</td>
<td>0.5 0.7 0.9</td>
</tr>
</tbody>
</table>

Source: Roy Curiel, Unilever
Corrosion

Localised corrosion (pitting) is most frequently encountered corrosion of stainless steel esp. in the presence of halides (chlorides).

Sources of chlorides in food industry:

**Supply Waters:** e.g. heating, cooling, or process fluids

**Detergents and Sanitising Formulations:** Some are based on sodium hypochlorite or organic chlorine donors

**Brines:** widely used in food processing, mainly as refrigerants, but are sometimes essential to the preparation of foods (cheeses, meats or dry products)

**Products:** Many foods contain sodium chloride.
Corrosion Resistance

Source: Eric Partington, Nickel Institute, Brussels
Types of corrosion

Pitting corrosion

Source: Eric Partington, Nickel Institute, Brussels
Types of corrosion

Pitting corrosion

Source: Diversey
Types of corrosion

Crevice corrosion

• requires presence of crevices
• may be constructive or operational (e.g. deposits)
• same mechanisms like pitting
Types of corrosion

Crevice corrosion

Source: Eric Partington, Nickel Institute, Brussels
Types of corrosion

Crevice corrosion

Source: Eric Partington, Nickel Institute, Brussels
Types of corrosion

Stress corrosion cracking

• requires simultaneous presence of 3 conditions:

I. Surface is under tensile stress,
II. Influence of a special medium (mostly chloride ions),
III. Disposition of the material to stress corrosion cracking

• austenitic CrNi- and CrNiMo-steel is more sensitive to stress corrosion cracking than (austenitic-) ferritic steels
Types of corrosion

Stress corrosion cracking

Source: Diversey
Types of corrosion

Galvanic corrosion

Source: Diversey
Elastomers

Properties

• highly elastic → preferred material for seals, gaskets and hoses
• is composed of a number of ingredients including polymers, fillers and plasticisers → can be optimised by giving the desired physical properties

Swelling and shrinkage

• may absorb process fluids and swell
• may shrink as ingredients in the compound are degraded, dissolved or leached out
• also shrink or expand with changes in temperature
• EPDM can absorb oil, grease and swell
EPDM / NBR exposed to gearbox oil (GL 8)

Change of EDPM

• Test parameters: gearbox oil, 70°C, 75h
  • Increase in mass:
    • 0h: ~1,5g
    • 75h: 2,67g
    \(\rightarrow\) >1,1g oil absorbed
  • Increase in diameter
    • 0h: ~45mm
    • 75h: ~58mm
    \(\rightarrow\) Factor ~1,3

• Olive oil: increase in mass and diameter is less compared to gear box oil
## Elastomers

<table>
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<tr>
<th>Elastomer type</th>
<th>Nominal range °C</th>
<th>Hot water (150°C)</th>
<th>Steam</th>
<th>Ozone</th>
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<td><strong>Excellent</strong></td>
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</table>

Source: Eric Partington, Nickel Institute, Brussels

Just examples, ask seal manufacturers for specified applications.
Elastomers

Properties

Compression Set

- a measure of the inability of a material to recover to its original dimensions after deformation to a specified strain

Adhesion

- high temperatures also cause seal materials to adhere to the surfaces of their housing

Source: Eric Partington, Nickel Institute, Brussels
Unused sealings

PTFE

Source: Barnickel, LVFZ Kempten

EPDM

Source: Barnickel, LVFZ Kempten
Used EPDM sealings

- Damage due to high compression
- Sealing area was not in contact with product or cleaning fluid, influenced only by compression and heating
- Brittle, cracked and porous EPDM-sealing, less softener on product contact areas

Source: Barnickel, LVFZ Kempten
Used EPDM sealings

Blue EPDM-sealing, aged 6 month at 20 °C with a 2-% solution of sodium hydroxide, wear of material due to softener migration

Source: Barnickel, LVFZ Kempten
Used EPDM sealings

Source: Barnickel, LVFZ Kempten
Plastics

PE (Polyethylene) e.g. container
PP (Polypropylene) e.g. components (potable water)
PVDF (Polyviniliden) e.g. components (ultra pure water)
PTFE (Polytetrafluorethylene) e.g. components (coatings)
  1. generation of PTFE is porous
PMMA (Polymethylmethacrylat) e.g. perspex

• no general guidance on which plastic to use without consideration of the application
Plastics

Behaviour

Ultraviolet light and ozone

• Exposure to ultra-violet radiation (such as from UV sterilising equipment or strong sunlight) or to ozone can result in embrittlement

Hydrolysis

• many suffer from hydrolytic attack at elevated temperatures over extended periods of time (can lead to e.g. cracking, embrittlement or mechanical failure)

Acidity

Many are pH-sensitive

• Polyvinylidenefluoride performs well in strongly acid environments
• Polyetheretherketone in strongly alkali environments - but not the other way round

Source: Eric Partington, Nickel Institute, Brüssel
Plastics

Behaviour

Electrostatic charges

• many can collect an electrostatic charge when rubbed and this attracts dust and bacteria which will then adhere tenaciously

• anti-static agents must be food-approved

Phase changes

• many undergo phase changes at specific temperatures

Creep

• many polymers will behave in a plastic manner at low stresses → result in slow dimensional changes

Source: Eric Partington, Nickel Institute, Brüssel
Plastics

Behaviour

Brittleness

• Plastic components may shatter under tensile, bending forces or under impact → represent a hazard similar to glass

Abrasion

• Polymers whose surfaces become abraded by solids or pastes may suffer from an increase in the accumulation of soils and biofilms and a reduction in cleanability

Source: Eric Partington, Nickel Institute, Brüssel
Surface coatings

• Layer of a different material applied to a metal substrate

Applications

• Anti-adhesive coatings (rollers, containers, screws, knives, guide rails)

• Potential for food contamination by flakes which have detached from the substrate

• Coating should be of contrasting color

• Colorant must be of food compatible material

• Consider sufficient adhesion to the substrate and durability over lifetime

Materials used in Hygienic Design

• e.g. PTFE, FEP, PFA
Ceramic materials

Legislation

• Directive 84/500/EEC (some amendments, i.e. Directive 2005/31)

Applications

• Bearings, mechanical seals, sensors, coatings etc.
• Excellent chemical, wear and high temperature resistance
• Brittleness may represent a hazard in some applications

Materials used in Hygienic Design

• silicon carbide, aluminium oxide
• zirconia oxide, chrome oxide
Glass

- Chemically stable
- Brittleness. Avoid in food contact surfaces that could suffer some impact.
- When used in the food industry in non food contact surfaces, impact resistance should be considered (i.e. as defined in NSF/ANSI 51 Food Equipment Materials).
- Recommendation for the food industry: have an internal written policy and documented controls in place for glass devices
Content

- Introduction
- Welding technology
- Definition of an “ideal” hygienic weld
- Bad examples
- EHEDG welding guideline
- Practical tips to achieve better welds
Introduction
Introduction

Weld defects (e.g. cracks, porosities or oxidation) will cause

• increased adhesion of product
• potential for bacterial growth
• negative effects on cleanability
• potential for corrosion

A minimum microbial level in the process reduces the need for cleaning cycles → enhancing efficiency of plants

The ideal “hygienic” weld is as easy to clean as the adjacent pipework
Introduction

Application area of welding

• if no detachable connections are necessary
• if geometry / material allows welding

• Results:
  • better cleanability
  • maintenance free in comparison with joints
Welding technology

Source: Kopitzke, Arc Machines GmbH, Much

Source: Barnickel, LfL
Definition of an “ideal” hygienic weld

Although manual welding can achieve equally good individual results, but the required repeatability and consistency of the welds cannot be guaranteed with manual methods.

- Full penetration
- No cracks or pores
- No misalignment
- No internal colouration
- No inclusions
- No concavity
- No convexity
- No lack of fusion
- Minimal increased surface roughness
- No associated metallurgical changes

Source: Kopitzke, Arc Machines GmbH, Much
Bad examples

Source: Barnickel, LfL
Bad examples

Source: Barnickel, LfL
Bad examples

Source: Classen, DTI
Bad examples

Source: Classen, DTI
Bad examples

Sources: Barnickel, LfL
Bad and good example
EHEDG welding guideline

Document 35 defines the quantitative characteristics and geometrical values to assure hygienic acceptance of produced welds.

These parameters include:

- Gap before welding
- Misalignment
- OD concavity
- ID concavity
- Lack of penetration
- Convexity
- Weld bead width variation
- Weld bead meandering
- Cracks and cavities
- Arc strikes
- Inclusions
- Internal discolouration
- Tack welding
EHEDG welding guideline

Gap before welding

- less than 0.25 mm prior to welding is acceptable

Source: Kopitzke, Arc Machines GmbH, Much
**EHEDG welding guideline**

**OD concavity**

- should be less than 15% of the wall thickness of the thinner tube

Source: Kopitzke, Arc Machines GmbH, Much
EHEDG welding guideline

ID concavity

- should be less than 10% of the wall thickness of the thinner tube

Source: Kopitzke, Arc Machines GmbH, Much
EHEDG welding guideline

Convexity

- should not be higher than 10% of the wall thickness of the thinner tube

Source: Kopitzke, Arc Machines GmbH, Much
EHEDG welding guideline

Tube alignment

- Failure should be less than 15% of the wall thickness of the thinner tube

Source: Kopitzke, Arc Machines GmbH, Much
EHEDG welding guideline

Weld bead meandering

- the middle of the weld bead should not deviate more than 25% of the weld width from the ideal mid axis of the weld

Source: Guideline 35
EHEDG welding guideline

Internal discolouration - Oxygen level in purge gas

Source: Kopitzke, Arc Machines GmbH, Much

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No. 1 → 10 ppm    No. 3 → 50 ppm    No. 5 → 200 ppm    No. 7 → 1000 ppm    No. 9 → 12500 ppm
No. 2 → 25 ppm    No. 4 → 100 ppm    No. 6 → 500 ppm    No. 8 → 5000 ppm    No. 10 → 25000 ppm
EHEDG welding guideline

Tack welding

should only be performed with minimal heat input, adequate external and internal purging and should not fully penetrate the tube walls.

Tacks must be smaller than the weld bead and completely remelted by it, so that tacks are not visible after the welding process.

Acceptable tacks

Unacceptable tacks

Unacceptable tacks after welding

Source: Kopitzke, Arc Machines GmbH, Much
EHEDG welding guideline

Arc wandering

- Sulphur content inside the material is an important criteria for a hygienic weld

Source: Kopitzke, Arc Machines GmbH, Much
EHEDG welding guideline

Arc wandering

Weld puddle profile

Low Sulphur
0.001 - 0.008 %

Medium to high Sulphur
0.008-0.030 %

Source: Kopitzke, Arc Machines GmbH, Much
Video
Conclusions

• if possible, orbital welding is to be preferred
• welds should be inspected
• no pickling or grinding before optical inspection
• properly welded joints are preferable to gasketed couplings
• Guideline Doc. 9, 35
Factory siting, layout and building design
Introduction

Protect your product comprehensively!

• Even a hygienically designed machine is no guarantee for a safe production without an effective barrier to the environment

• A good building layout and master concept, also called master plan, for the design of a food processing facility is necessary to avoid:
  • Attraction, entry and nesting of pests
  • Accumulation of water, soil and dust
  • Microbiological and allergenic contaminations

• Building layout should facilitate cleaning and disinfection activities
Zones for factory planning

1. Environment
2. Factory site
3. Building envelope
4. Production areas

Source: Fraunhofer AVV
Environment

- Legal requirements
- Climatic conditions
- Landscape
  - Local flora and fauna
  - Higher humidity close to water
  - Breeding place for insects and pests
- Economic use
  - Infrastructure
  - Local emissions
  - Quality of groundwater
  - Adequate distance to dumps, farms, chemical plants
Zones for factory planning

2 Factory site

Source: Fraunhofer AVV
Factory site

Ground and facilities

- Checking of soil quality and soil support capability
  - Precluding chemical or biological contamination
  - Cracking due to sagging foundations

- Prevention of hiding places for animals

- Covered waste collection unit
Factory site

Perimeter fence

- Uninterrupted with a managed entrance
- Unplanted stripe inside and outside (e.g. coarse gravel)
- High enough
- Deep enough
- Smooth enough
- Distance to trees and bushes (climbing support)

Prevent entry of climbing, jumping and burrowing creatures
Factory site

Distance to buildings

Grit size ≤ 2,5 cm

≥ 10 m

≥ 1 m

≥ 15 cm

Source: Fraunhofer AVV (acc. to Hauser 2008)
Factory site

Areas for roads, walk and parking

- Stable and cleanable materials
- Minimize or eliminate joints (e.g. use concrete, tarmac or similar materials)
- Periodic maintenance (remove pest plants and close gaps)
Factory site

External light sources

- On poles or standards (not at buildings)
- Lamp design: Avoid possibility of accumulation, perching on lamps
- Avoid high-UV amenity lighting
Factory site

Sufficient draining of the premises

• As possible: plane surfaces
• Inclined away from buildings
• Qualified surface drainage system
• At every local minimum on the site must be a drain

→ Fast removal of water out of the premises
Factory site

Simple model of a structured site

- Location and arrangement of buildings have to be accurately projected
- Routes for employees, products, production equipment, products, disposal...
- Barrier to environment
- Prevent possibility of contamination from laboratories inside the factory
Zones for factory planning

3 Building envelope

Source: Fraunhofer AVV
Building envelope

Protection against animals, pests and microbial contamination

• Prevention of hiding places for animals
• Building envelope impenetrable to living invaders
• Self closing openings/ doors/ windows/ apertures (protected by fine screens if open) / Pest-tight openings
• No light sources above entrances
• Avoid stairs for personnel next to loading bays
• All opening screened with stainless steel mesh < 1mm x 1 mm
Source: Roland Cocker, Cocker Consulting
Building envelope

Placement of air supply systems

- Prevention of cross-contaminations
Building envelope

Roof

- Pest-tight, water proof
- Sloped (≥ 3°) and self draining
- As possible: Consist of a single membrane
- Avoid internal roof drains
- No Ventilation devices that discharge food particles onto the roof (Birds and pests could feel attracted!)
- Spaces between roof and upper side of suspended ceilings should be accessible

Source: Fraunhofer AVV (acc. to Hauser 2008)
Building envelope

Wall exteriors

- Smooth surfaces
- All gaps sealed
- No horizontal surfaces (gradients $\geq 45^\circ$)
- No windows next to product area
- As few as possible entrances
Zones for factory planning

4 | Production rooms

Source: Fraunhofer AVV
Main Flows

Layout

Others: packaging, traffic

Services: gases, utility water, air

Personnel flow

Waste and Residues flow

Product flow
Product flow

- Segregation of zones with different hygienic standards
- Routes as short and straight as possible,
- Minimise product traffic
- Product flowing from basic to high hygiene
- Prevent cross contamination between product and
  - Raw material
  - Secondary packaging material
  - Residues
  - Cleaning chemicals / non-food chemicals
Zoning

What’s the meaning of zoning?

• Set of procedures, practices and physical barriers aiming to prevent product (cross) contamination
• Part of a total hygiene concept
Zoning

Zoning may involve

• Equipment, tools and other working devices of restricted use within designated areas (e.g. Color code)

• Make provision for local storage as appropriate

• Internal hygiene policy: requirements of each area (clothing, hands cleaning and disinfection for accessing certain areas, etc.)
Production rooms

Overview production room surfaces

- 3 main classes of walls / surfaces
  - Floors
  - Vertical walls
  - Ceilings
- Openings
  - Windows, doors, stairways
- Installations
  - Light sources, pipes, wires, air boards, (HD-plants)

Source: Fraunhofer AVV (acc. to Hauser 2008)
Production rooms

Floors: Hygienic design criteria

- impermeable
- resistant to expected loads, chemicals
- without cracks;
- with cleanable joints (material + dimensions);
- self draining
- easy to clean
- the subfloor must be strong enough for the installation
- good wet grip
Production rooms

Floors: Drainage

• To avoid stagnant water:
  • Inclined floor (slope ≥ 2%)
  • Covered discharge gutters
  • Central drainage channel, lateral drainage channel, central drainage points
  • Hygienic designed sink trap
• For cleanability:
  • Floor finish
  • Connection to vertical walls (wall socket design)
Production rooms

Floors: Walkways

- Avoid walkways over exposed product stream/lines
- Covering the product line OR walkways in hygienic design
- The stair must be in accordance with local regulation about people safety

Source: EHEDG GL Doc. 11

Source: EHEDG GL Doc. 26
Production rooms

Vertical walls

- Material (hard, flat, smooth, washable)
- Covers / cladding (wall tiles, plates, panels)
- No ledges / no protrusions
- Wall socket design for easy cleanability

- Openings: windows, doors, stairways
- Sealed openings for services through the wall (pipes, …)

- Installations: equipment placed near the wall needs enough distance to the wall → accessible for cleaning (e.g. electrical cabinets, boards)
Production rooms

Vertical walls: Design

- Edge protection strips (metal or plastic)
- Impact protection at lower part of the wall
- Wall socket: rounded tiles with a suggested minimum radius of 75mm

Source: Fraunhofer AVV (acc. to Hauser 2008)
Production rooms

Vertical walls: Protection

Source: R. Soro, Ainia
Production rooms

Vertical walls: Openings

- e.g. windows / doors / wall breaktroughs
- Eliminate if not needed!
- Impermeable to pests (e.g. screened permanently closed)

Vertical walls: Installations

- e.g. electrical cabinet
- No horizontal surfaces
- Sealed to the wall or enough space for easy cleaning accessibility

Source: EHEDG GL Doc. 13
Production rooms

Ceilings

- Suspended ceiling not sealed from the room only acceptable in areas with basic or medium hygienic requirements
- Covers, cladding (glazed tiling, plates)
- Openings: stairways, elevators, conveyor belt
  → Sealing systems required!

- Installations: pipes, wires, light sources, air ventilation
  → Falling contaminants

Source: Fraunhofer AVV
Walk-on Ceilings

Walk-on composite ceiling with services above

Production

Typical walk-on ceiling

Source: Curiel, Unilever
Production rooms

Ceilings: Electrical installations

- Not acceptable
  - Open pipes for fixing
  - Horizontal surfaces
  - Clusters of electric wires
- Hygienic design
  - minimise cableing in process areas
  - Closed pipes with sealed outlet
  - Inclined stainless steel grid
  - Distanced parallel electric wires

Source: EHEDG GL Doc. 26
Production rooms

Ceilings: Installation of light sources

- Avoid soil deposition and glass fragments
- Integrate in walls/ceilings
- Relocate if possible
- Seal up

Source: EHEDG GL Doc. 26
Production rooms

Pipe mounting through a wall

- Not acceptable
  - Forces = cracks in the wall
  - Short distance to ceiling

- Hygienic design
  - Sealed protection pipe
  - One support near each wall side
  - Distanced to ceiling = accessible for easy cleaning

Source: EHEDG GL Doc. 26
Production rooms

Ventilation

• Adequate ventilation should be provided to prevent condensation or excessive dust.

• Natural ventilation should be avoided

• Best option: controlled combination of supply and extraction systems

• Air flow must go from high hygiene to basic hygiene zones

• The system must ensure the number of air changes recommended depending on the hygienic requirements of the area.
Production rooms

Ventilation

- Air must be filtered

- A moderate over pressure (25 pascal) is recommended in production areas to prevent contaminants from entering.

- Air should be kept as dry as possible to avoid microorganism growth

- Ventilation for a clean and free of contaminants air will be achieved through the combination of filtration, temperature and humidity control and pressure gradient.
**Production rooms**

**Controlled directed air circulation (one way)**

- Air supply system
- Decontamination of air

→ Prevent the transfer of air-transported particles into the H-Zone

Source: Fraunhofer AVV (acc. to Hauser 2008)
Production rooms

Movement of personnel / traffic

• Controlled movement / access control
• Protective clothing
• Routine hygiene trained personnel

• Well organized infrastructure, so that personnel can keep / follow hygienic rules
  • e.g. switch for washing basin handled with knee or by motion sensors
  • Doors opened by motion sensors
  • Changing rooms and ergonomically designed desinfection equipment
• Effective locks
Summary

Hygienic design rules for building layout

- Remote from farms, dumps, effluents, airborne particle sources
- No entry / no encouragement for vectors
- Zoning philosophy: multiple barriers = “boxes within boxes“
- Control all mass flows (necessary and unwanted)
- Export potential hazards from the high care zone
- Select qualified raw materials
- Stop accumulation of moisture / water
- Minimize / eliminate horizontal surfaces
Food Grade Lubricants in Food Production
Content

• Food grade registrations
• Storage and handling of food grade lubricants
• Lubricant hazards in the food production plant
• The importance of Best Manufacturing Practice
• Switching to food grade lubricants
• Reasons for bearing failure
• Summary
• EHEDG Guideline Document 23
Lubricant registrations

- FDA (U.S. Food and Drug Administration)
  - List of allowed ingredients
- NSF International (formerly the National Sanitation Foundation)
  - List of lubricants: www.nsfwhitebook.org
  - certifies lubricants and manufacturers of lubricants according to ISO 21469
- INS (Europe)
Food grade registrations

Food safety is ensured by:

• only using FDA listed ingredients
• only using ingredients from correct section (lubricants- CFR, Title 21, section 178.3570)
  • up to the maximum percentage stated (%v/v)
• Only using lubricants accepted for H1 registration
Food grade registrations

- H1 – Product can come into incidental contact with food
- H2 – Absolutely no contact with food
- 3H – Proprietary Substances.
  - Release agents, food processing products, potentially part of the ingredients of the food
- HT1 – Heat transfer fluids that have incidental contact
Food grade registrations conformance

- Packaging must show approval mark
- Packaging must show registration number
- Packaging must show classification
- Reference number covers formulation and labels
- All changes require re-registration
H1 Product availability

H1 Registered Products

- bearing greases, track treatment
- chain lubricants
- gearbox fluids (enclosed and open)
- assembly and anti-seize compounds
- hydraulic & compressor fluids
- airline lubricants
- penetrating fluids
- can seamer lubricants
- sugar dissolving solutions
- release agents
- general purpose sprays and lubricants
Storage and handling of food grade lubricants

Storage

• separate stores for food grade lubricants
• clean and dry warehouse
• store drums on their side

Handling

• do not use wood or dirty steel parts to dispense grease
• use clean metal scoop
• do not leave containers open after use
• use dedicated containers for storage and lubrication transfer

Source: Bowmer, Bel-Ray Company Inc.
Lubricant hazards in the food production plant

Packaging

• labels correct
• sealed, no damage

Storage

• damaged packaging leaking
• contamination
• mixing food and non food grade products
• correct labeling
Lubricant hazards in the food production plant

**In use**

- leakage from open lube points and bearings
- contact between sliding surfaces and food produce
- contamination
- spillage
- over lubrication
- non food grade lubricants mixed with food grade lubes

Source: Bel-Ray Company Inc.
The importance of Best Manufacturing Practice

Have clear procedures including:

- Lubrication Management System
- factory survey
- correct lubricant
- lubrication frequency
- monitoring
- sampling and testing
- record keeping for audit purposes
- lubrication training

Source: Bel-Ray Company Inc.
The importance of Best Manufacturing Practice

Completing lubrication tasks:

- use dedicated transfer containers
- always use clean tools
- cover areas prone to contamination
- use drip trays where possible
- use correct amount of lubricant
- clean up any spills
- identify and label critical control points to comply with HACCP regulations
- dispose of soiled wipes correctly
- complete job sheet and record actions
Lubricant cleanliness

A clean lubricant will:

- last longer in the component
- ensure longer lasting parts
- will keep components clean
- lower your costs

Source: Bel-Ray Company Inc.
Switching to food grade lubricants

Oil Products

• drain the system
• change filters
• flush with food grade product
• check / change filters
• fill with food grade product
• seek assistance from your supplier

Grease Products

• check compatibility
• clean bearing out
• 1/3 to 1/2 fill product with food grade grease
• purge any grease lines with food grade product
• seek assistance from your supplier
Switching to food grade lubricants

**Gear Oil Products**

- drain the system
- change filters
- flush with food grade product
- check / change filters
- fill with food grade product
- run the gearbox
- sample analysis
- seek assistance from your supplier
Reasons for bearing failure

- Improper lubrication: 43%
- Material fatigue: 9%
- Improper mounting: 27%
- Other reasons: 21%

Avoid high pressure cleaning

- water can enter the lubrication system
- damage of sealing → spillage of oil
Breakdown of “improper lubrication” section

- Over lubrication: 60%
- Lack of lubrication: 40%
Potential failures due to over lubrication

- Standard grease gun can develop 200 bar
- High pressure grease guns can develop >400 bar
  → RISK: OVERLUBRICATION

Potentially resulting in drag of the bearing causing:

- increased power demand
- ball/roller skid
- increased friction
- excessive heat
- excessive race wear
- degradation of the lubricant
Correct application of a lubricant

Little & often!

Precision bearings

• Typically fill 1/3 to 1/2 of vacant area in bearing.
• High speed bearings require approx. 1/3 fill.

Plain bearings

• Typically fill until clean grease shows.
Application

Deterioration of Lubricants during operation

Bad cleaning example

Major cause of food contamination
Application

Potential lubricant contamination

Bearing as high risk lubrication point

Open lubrication: Contamination risk
Summary

• use only food grade lubricant
• NSF H1 registered
• identity lubrication point
• avoid contamination
• avoid high pressure cleaning
• be alert to any spillage
EHEDG Guideline Document 23

- guideline for using food grade lubricants
- covers all items presented today
- in depth guide to potential hazards and solutions for the safe use of food grade lubricants
- available at www.ehedg.org