Hygienic Design & EHEDG
Principles, Practice and Benefits

Patrick Wouters and Adwy van den Berg (EHEDG)

Dairy Excellence Summit - June 2025

Mars & Interfood

Agenda

Introduction into EHEDG

HD Application in Food Manufacturing Building Design

HD Application in Food Manufacturing Equipment Design

Benefits of HD in Food Manufacturing

Presenters

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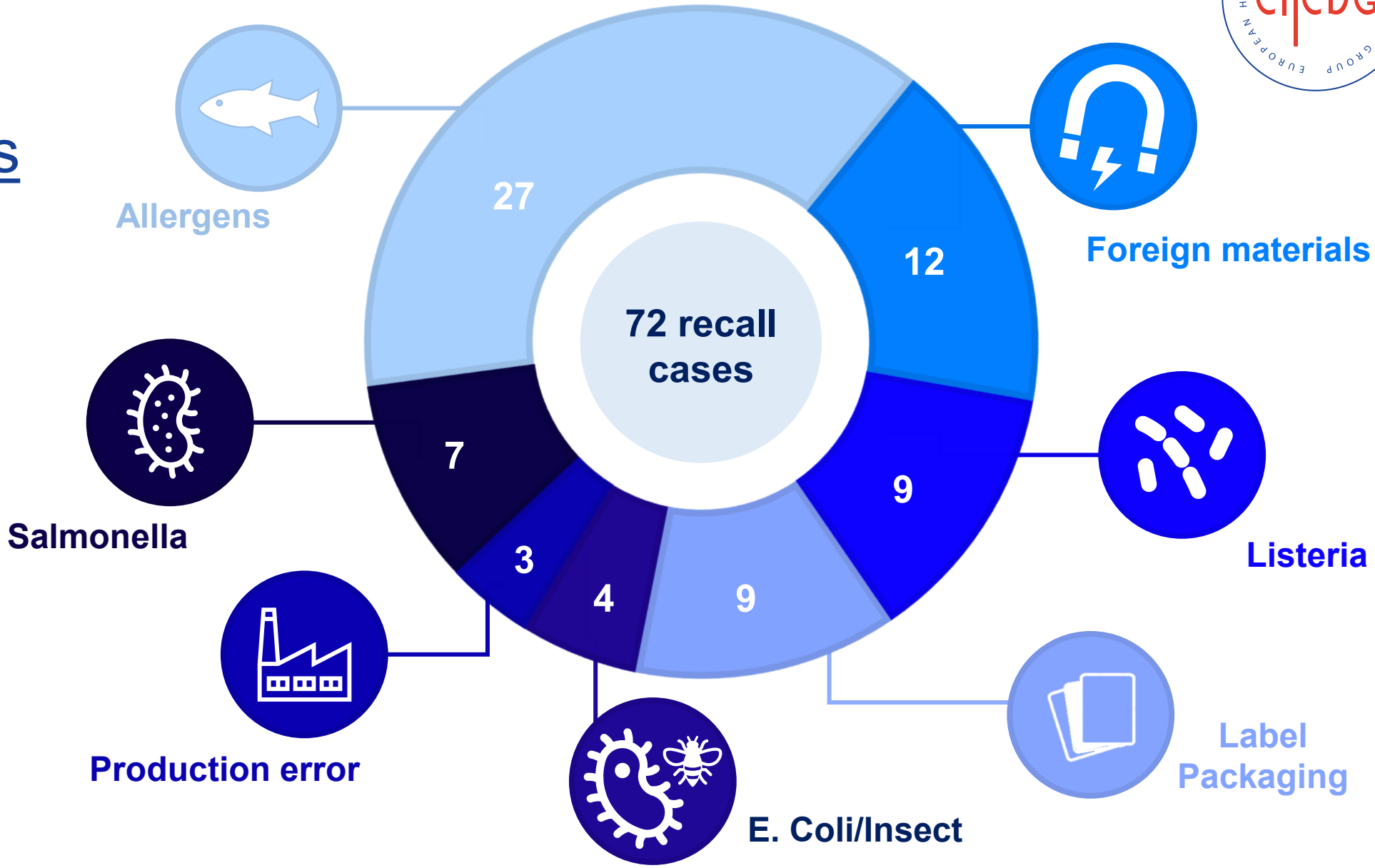
Why are we here?

In order to avoid recalls like these



Recalls, source VMT 2019

And to avoid cases like these…

Recent E.coli Cases and Outbreaks

- UK: Contaminated Salad Causes Another Outbreak
- US: Lettuce Causes Outbreak With Seriously Sick People
- France: Another Outbreak Due to Unpasteurized Dairy
- France: Many Sick Due to Buitoni / Nestlé Frozen Pizzas
- Denmark: Spring Onions Cause Outbreak
- Japan: Seaweed Salad Could Be a Contamination Lurking
- UK: Lettuce Likely Cause of STEC Outbreak
- US: Contaminated Baking Mix Causes Outbreak
- Germany: E. coli in Flour
- US: Organic Yogurt Possible Cause of Outbreak
- Belgium: STEC Fecal Bacteria Found in Handmade Goat Cheeses

Source: VMT Sept 2024

Johma salads recall

Cupper threads

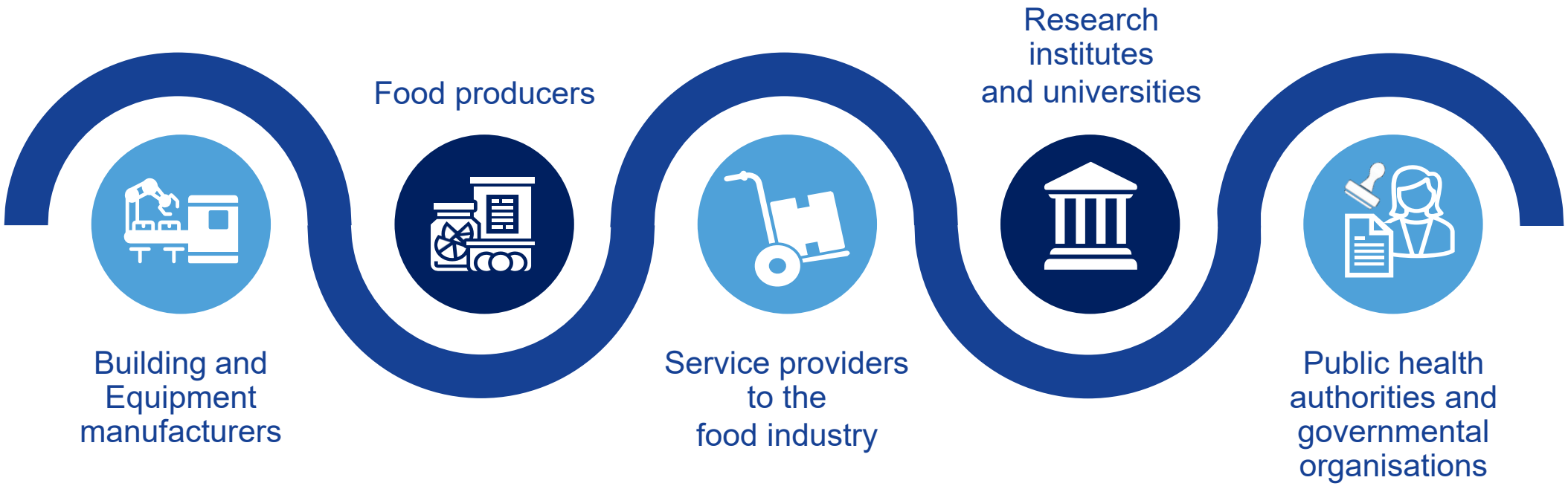
Diameter 0.16-millimetre length up to 2 centimetre

Producer advise: **Don’t eat this!**

Send a picture

Who is EHEDG?

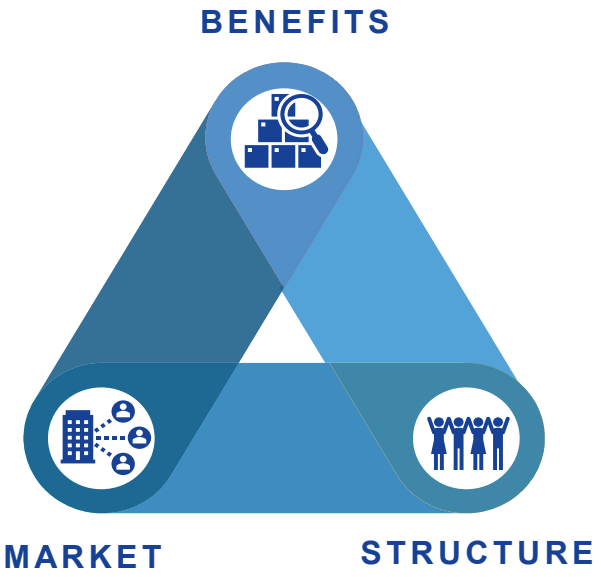
European Hygienic Engineering & Design Group (EHEDG) founded in 1989 as a non-profit consortium



Platform

The platform to discuss and define hygienic design and engineering requirements to manage food safety and quality, efficiency and sustainable operations

EHEDG organisatie



MARKET

Worldwide ‘end-to-end’ food production supply chain

BENEFITS

- Health and safety of consumers
- Prevent reputation damage
- Cost effective operations
- Sustainable operations

STRUCTURE

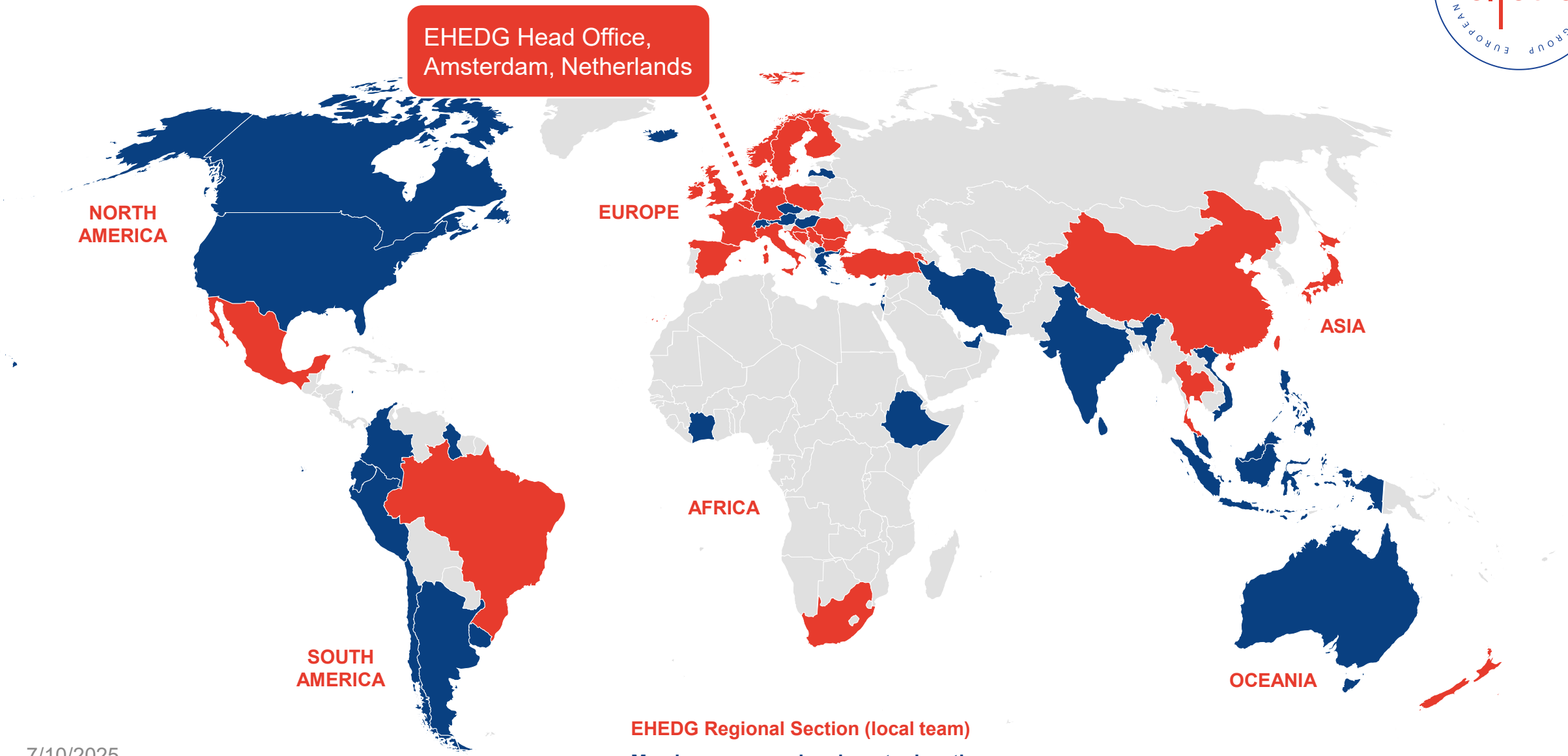
- Voluntary contribution of members
- Interesting for big, medium and small enterprises
- > 750 members and growing

Collaborations

ANUGA FOOD TEC · A3 · FOOMA JAPAN International Food Machinery & Technology Exhibition · SIIIA · Global Harmonization Initiative · Cfia · EFFoST · IFS International Featured Standards · Interclean · FSSC 22000 · Freskon HELEXPO · International Association for Food Protection

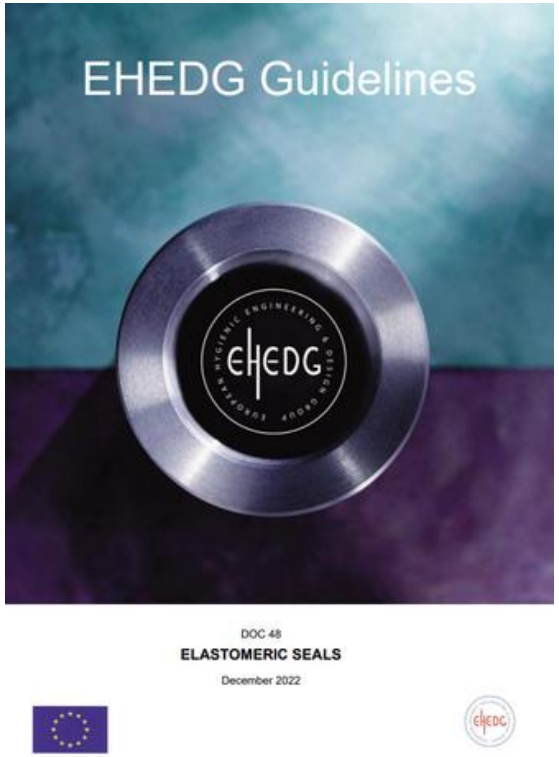
Some of our members

EHEDG – European based – global reach



EHEDG Product Portfolio

Guidelines & Working Groups



EHEDG has produced more than **55+** Guidelines

Training & Education

Certificate of Attendance

EHEDG Advanced Course on Hygienic Design

Organized by
EHEDG New Zealand Regional Section
Waikato Innovation Park, Hamilton March 8th – 10th 2022

Marc Mauermann
Chairman WG Training & Education
EHEDG

David Lowry & Shane Mason
Authorised Trainers

Certification & Testing

CERTIFICATE OF COMPLIANCE

EL Class I

Date of issue: 4 December 2023
Valid until: 31 December 2025

EHEDG hereby declares that the product

2031/2731/2103/2303/2063/3323/3363 Diaphragm Valves with order code PI01

from

Bürkert Werke GmbH & Co. KG, Christian-Bürkert-Straße 13-17 , 74653 Ingelfingen, Germany

has/have been evaluated for compliance and meets/meet the current criteria for Hygienic Equipment Design of of the EHEDG

Certificate No. EHEDG-C2300076

Signed — *President EHEDG*
Hein Timmerman

Signed — *EHEDG Certification Officer*
Karlijn Faber

EHEDG
Karspeldreef 8
1101 CJ Amsterdam
Netherlands

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59 new certificates in 2024, for a total of **298** active ones in the market

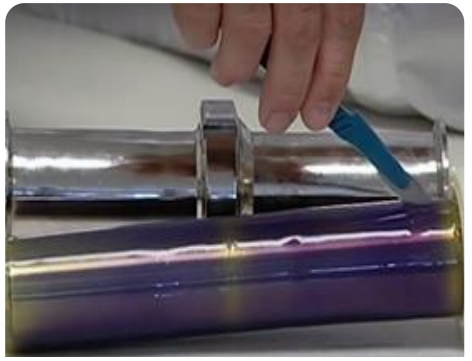
Focus areas of Working Groups

Equipment for Dry Particulate Material

Closed Equipment for Liquid Food

Packaging Machinery Incl. Filling Machinery

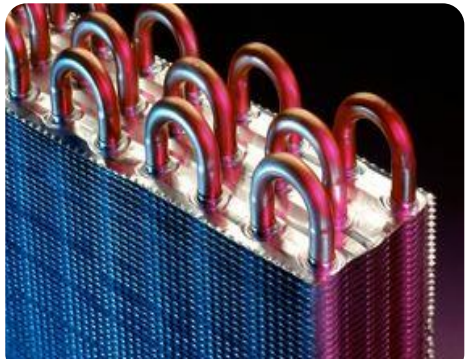
Open Equipment



Test Methods

General Principles, Materials, Surfaces

Factory Design Incl. Design of Utility Systems



Heat Treatment

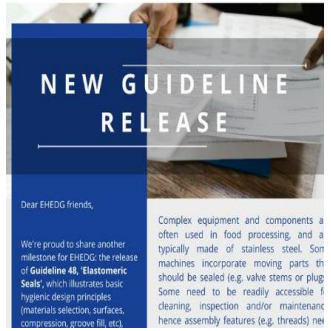
Product Line

Cleaning & Validation

EHEDG Communications

LinkedIn

Newsletter



Publications

Website

www.ehedg.org

Product Safety Management by Design

Why is important?

Requirements being incorporated in GFSI Recognized Food Safety Management Certification Programs

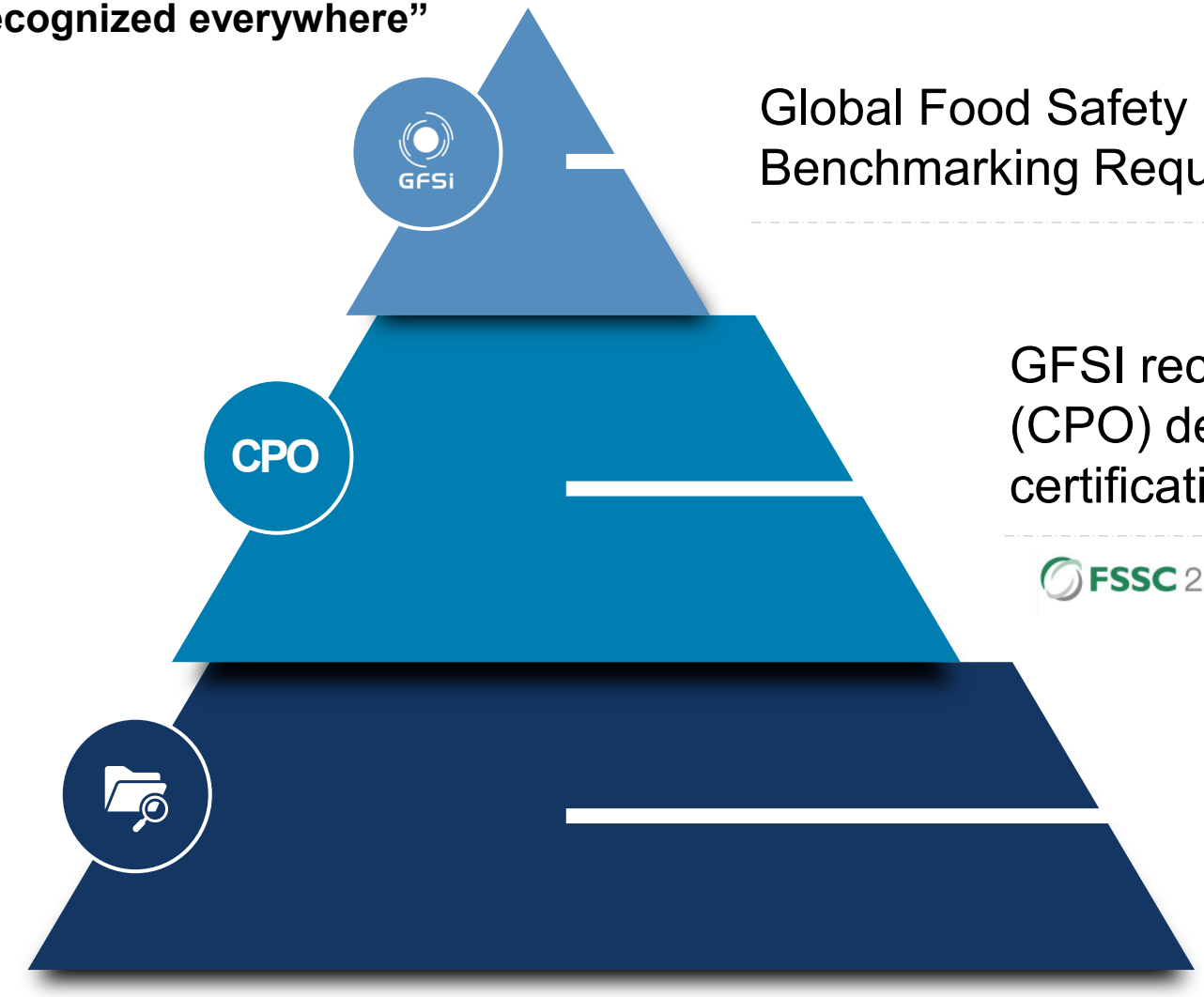
In 2024, EFSA released a scientific opinion on persistent microbiological* hazards in food and feed environments—uncovering critical risk factors such as inadequate:

- zoning and hygiene barriers
- cleaning and disinfection
- hygienic design of equipment and machines

such as Salmonella, Listeria monocytogenes, Cronobacter sakazakii

Food Safety Standards Pyramid

“once certified, recognized everywhere”



Global Food Safety Initiative (GFSI) develops Benchmarking Requirements

GFSI recognized Certification Process Owners (CPO) develop food safety standards for certification based on benchmarking requirements

FSSC 22000 · SQF · IFS Food · BRCGS

Accredited certification bodies conduct audits based on GFSI recognized standards

TÜV SÜD · DNV · TÜV NORD FSSC 22000 · dqs

GFSI Benchmarking Requirements

JI: Suppliers of Food Building and Processing Equipment incorporate HD in business processes

- HD Management System
- HD Risk Assessment when developing buildings and processing equipment
- Implement GMP practices while building and commissioning

JII: Food Producers – incorporate HD into existing GFSI scope

- HD Risk Assessment for new and existing buildings and processing equipment
- Change control on HD when modifications on equipment or building
- Procedure to ensure that HD is part of purchasing process for buildings and equipment

GFSI Benchmarking Requirements

HACCP 1.5	Hygienic Design Process	A competent multidisciplinary team shall assess the hygienic design and risk assessment of new and existing buildings/equipment, including upgrade or improvement.
HACCP 1.6	Hygienic Design Process	The hygienic design and suitability of new and existing buildings and equipment shall be assessed throughout their life cycle from the design, through construction, purchasing and during use, until the end of their intended life.
HACCP 1.9.2	Intended Use	The intended use of the building/equipment shall be described, as a specification for the intended purchase or construction of new buildings and equipment.
HACCP 1.11	Hygienic Design Principles	Buildings and equipment shall be of hygienic design, to meet all cleaning objectives.
GMP 3	Design Construction, Layout and Flow of Operations	The site, both the exterior and the interior, shall be designed, constructed and maintained to minimise food safety risks. The layout and flow of operations shall be suitable for the intended purpose and designed in line with hygienic design principles to minimise food safety risks.

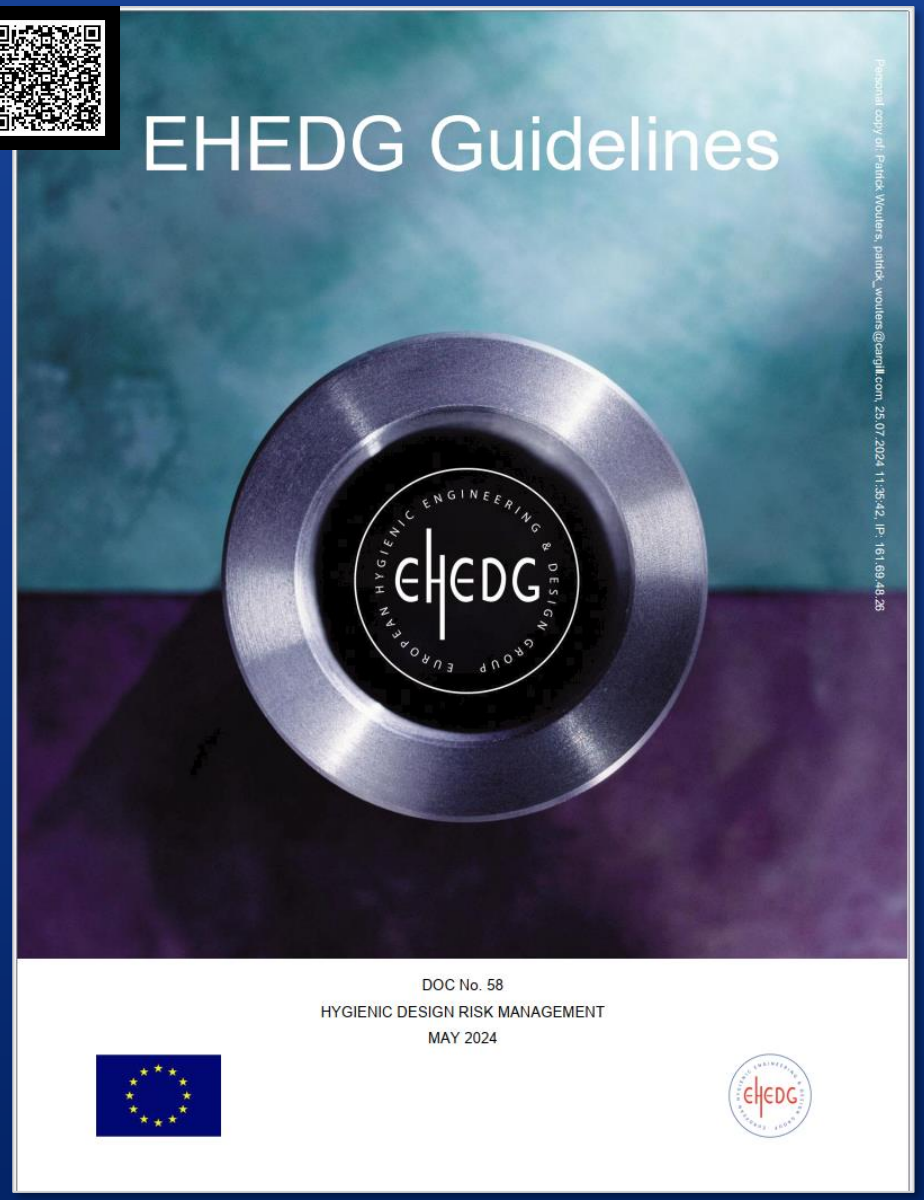
GFSI Benchmarking Requirements

GFSI BENCHMARKING REQUIREMENTS

KEY CHANGES
VERSION 2020.1 to VERSION 2024

SECTION 2: HYGIENIC DESIGN MANAGEMENT SYSTEMS

REFERENCE	ELEMENT	THE PROGRAMME SHALL REQUIRE THAT
FSM 13.1.4	Purchasing and Supplier Performance	A procedure shall be established, implemented and maintained to ensure that the newly purchased building/ equipment meets the hygienic design specification.
FSM 26	Change Management	Change control shall be undertaken and documented to evaluate the impacts of any changes/ modifications on equipment/building hygienic design and ensure that the organisation is equipped to ensure food safety during temporary, emergency and unplanned changes.
FSM 27	Change Management	A documented change management procedure shall be established, with particular emphasis on changes that could impact food safety.

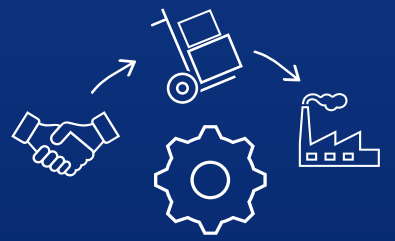


HYGIENIC DESIGN RISK MANAGEMENT (HDRM)

This guideline provides a step-by-step approach to assessing and managing food safety and hygiene risks by hygienic design of food manufacturing buildings and equipment, in accordance with existing standards and GFSI scopes JI and JII requirements.

This HDRM can be applied from:

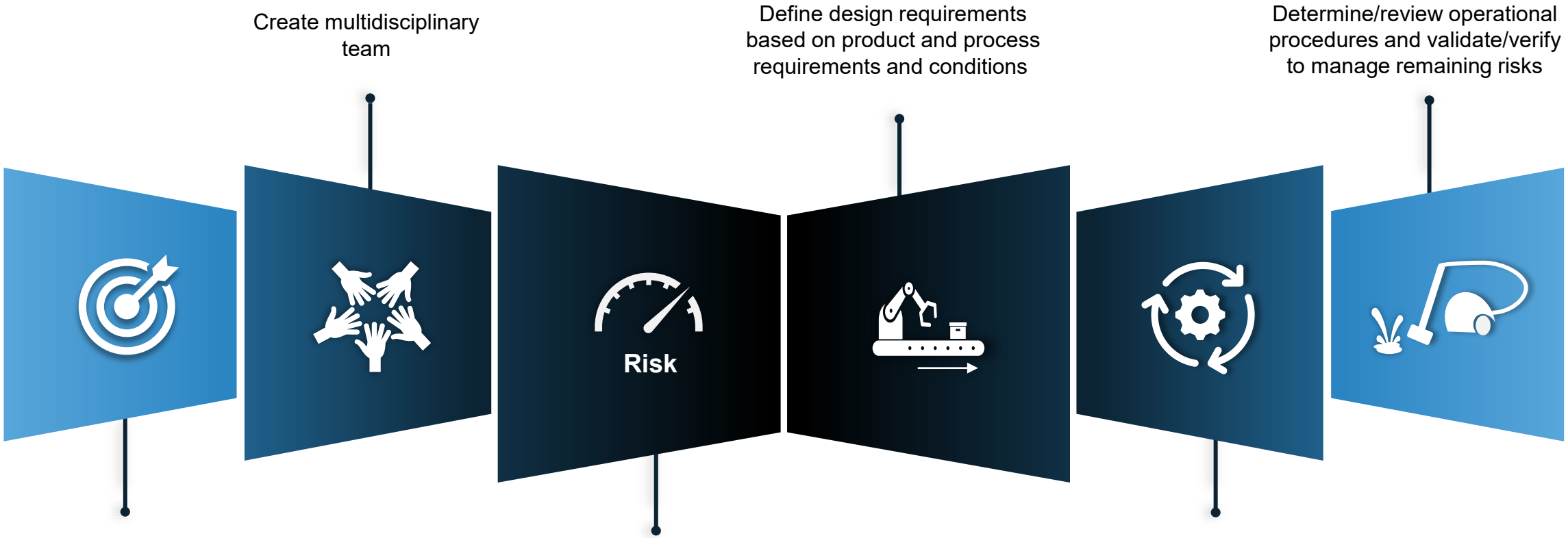
User perspective to support food safety management programs and/or design specifications.



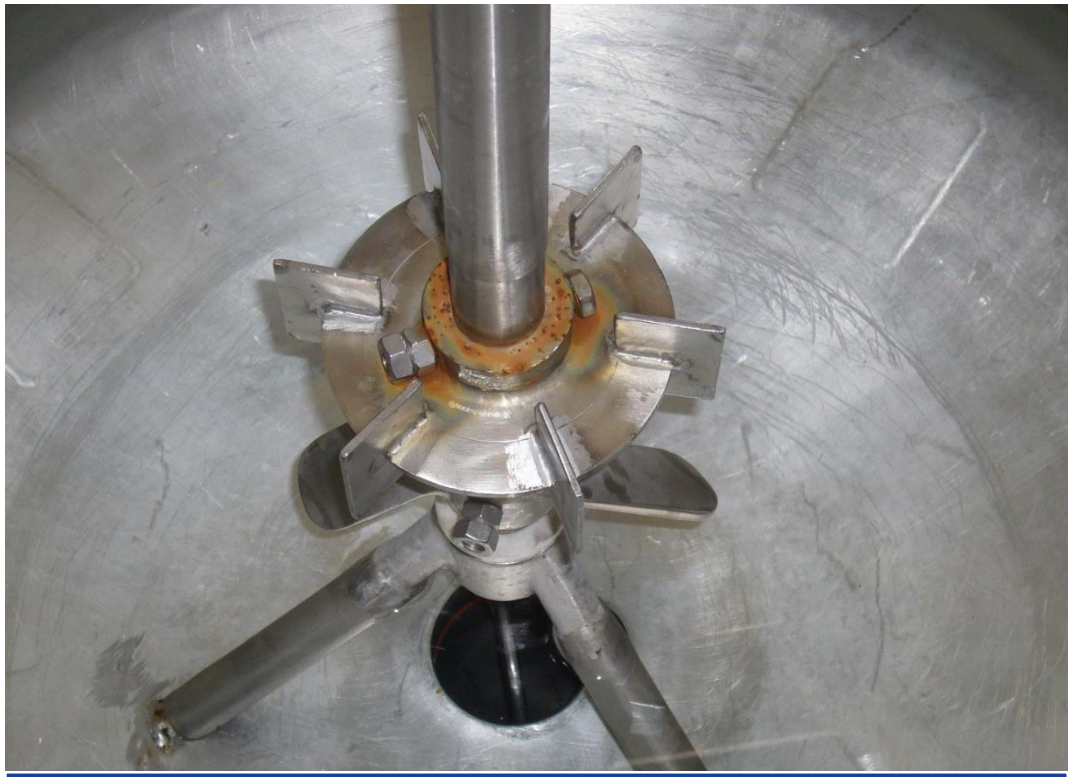
Supplier perspective when designing, fabricating and commissioning buildings or equipment.

Hygienic Design Risk Management

Approach



Hygienic Design Risk Management

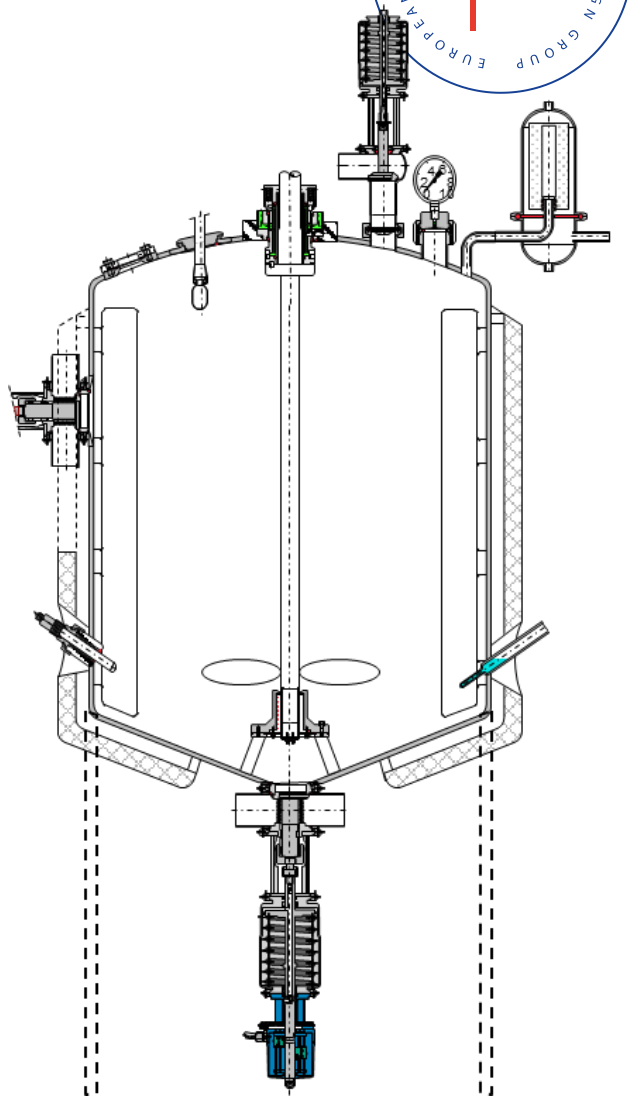


Legacy

Assessment of fitness for purpose of existing food manufacturing buildings or equipment

New

Specification and design of new equipment/building or equipment components both unassigned and bespoke that are selected/created based on user-developed requirements specifications (URS)



Dry Processing Wet Cleaning

Attention points

- Materials of construction need to withstand chemicals, water, temperature and pressure
- IP rating including non-product contact surfaces
- Contain the water inside the equipment and if not possible (open equipment), building design should be able to manage water
- Drainability design
- Drying equipment and building after cleaning

Aspects Regarding Building Design

Plant Lay-out

Air flow	Battery station
Chemical storage	Cleaning station
Control room	Corridor
Personnel facilities	Maintenance workshop
Laboratories	Material flow
People flow	Storage areas
Waste flow	Waste storage

Electrical, Instrumentation, Automation & Air Quality

Cabinet	Location of Cables
Cable trays, Conduits	Ducts
Human control interfaces	HVAC

Architecture Finishing

Transition zone	Wall penetration
Ceilings	Drains
Elevators	Internal doors
Internal floors	Internal walls
Internal windows	Junctions & Joints
Platforms & Supports	Stairs

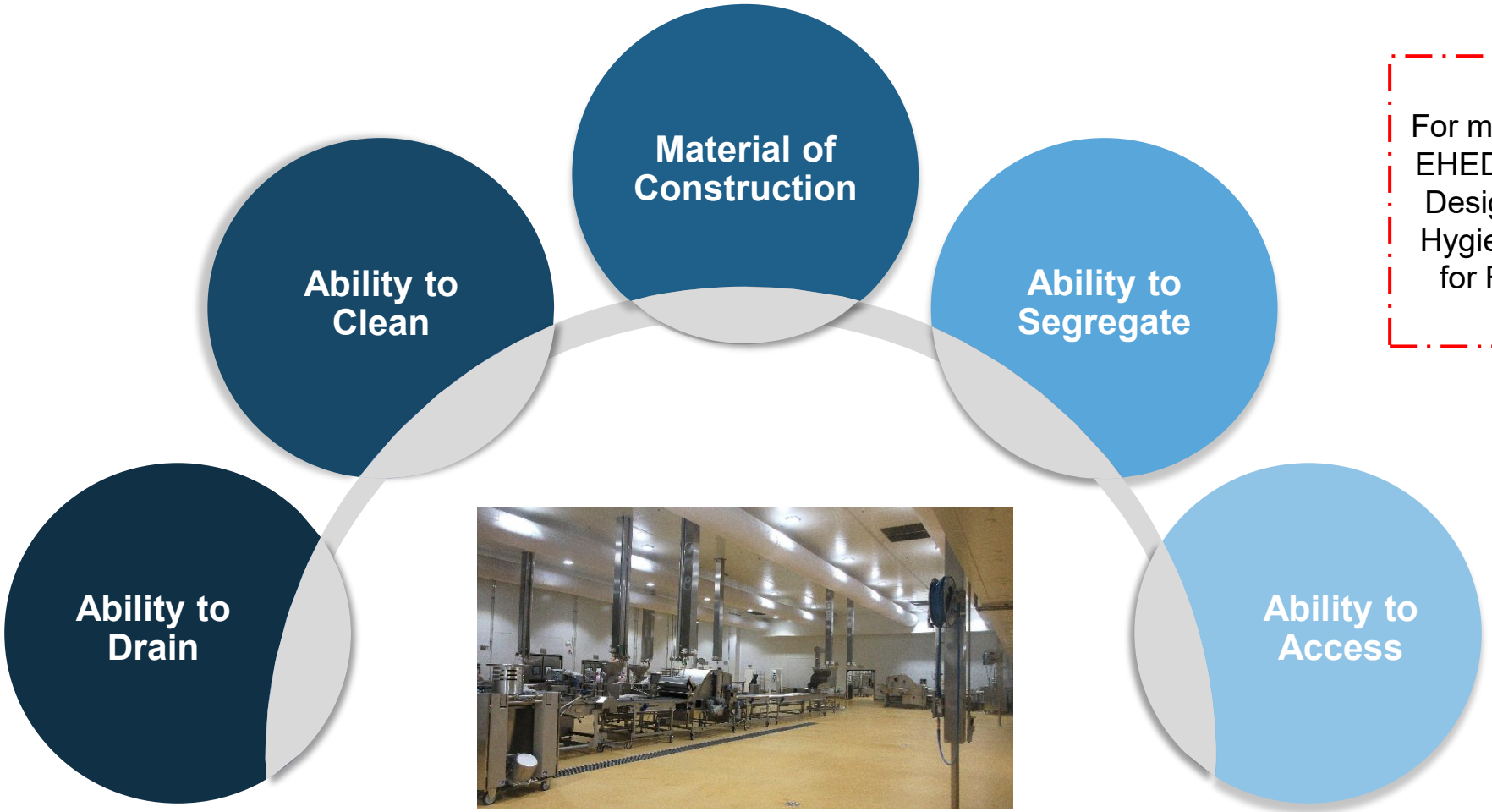
Building Envelope

Docking station	Loading station
External doors	Roof
External walls	Roof drains
External windows	Drainage

Building Construction

Superstructures

Hygienic Design Principles



For more information check EHEDG Guideline Hygienic Design Principles n° 8 and Hygienic Design Principles for Food Factories n° 44

Plant Layout and Zoning

Definition: The physical or visual division of the plant into sub-areas, leading to segregation of different activities with different hygiene levels.

Each factory will have 3 zoning area

High Hygiene Zones

Areas where products with high-risk category are exposed and vulnerable to contamination, especially ready-to-eat (RTE) foods that won't undergo further lethal processing.

Medium Hygiene Zones

Can be a process area for products where the consumer group is not especially sensitive and/or where no further growth is possible in the supply chain.

Medium hygiene areas can be the intermediate area before entering a high hygiene zone.

Low Hygiene Zones

Areas with minimal risk of direct product contamination and where products are not susceptible to (re) contamination, being already protected in their final packaging; such areas can be at the end of a packaging line or the finished goods warehouse.

Hygienic Building Design - Ceilings

Requirement

- And overhead fixtures should be constructed and finished to minimize the buildup of dirt and condensation, and the shedding of particles
- **Should be -** smooth surface, washable and light color
- **Design and constructed to minimize -** growth of mould, accumulation of dirt and condensation

Solution:

- Follow design and application hygienic requirements from EHEDG Guideline n° 44 - Hygienic Design Principles for Food Factories

Hygienic Building Design - Walls

Requirement

- The wall surface mush be washable, smooth, uniform and constructed of non toxic material. Joints at wall to wall, wall to ceiling and wall to floor must be *rounded.*
- **should be -** weather, water, insect and rodent-proof.

Solution:

- Follow design and application hygienic requirements from EHEDG Guideline n° 44 - Hygienic Design Principles for Food Factories

Hygienic Building Design - Floors

Requirement

- Floors and finishes should be chosen according to hygiene levels types of cleaning and food material.
- Should be designed to reduce the possible retention of water and static water pools.

Solution:

- Follow design and application hygienic requirements from EHEDG Guideline n° 44 - Hygienic Design Principles for Food Factories

Hygienic Building Design - Drain

Requirement

Dry Production – Controlled Wet Cleaning

- Drains only if strictly necessary
- Effective drying directly after cleaning

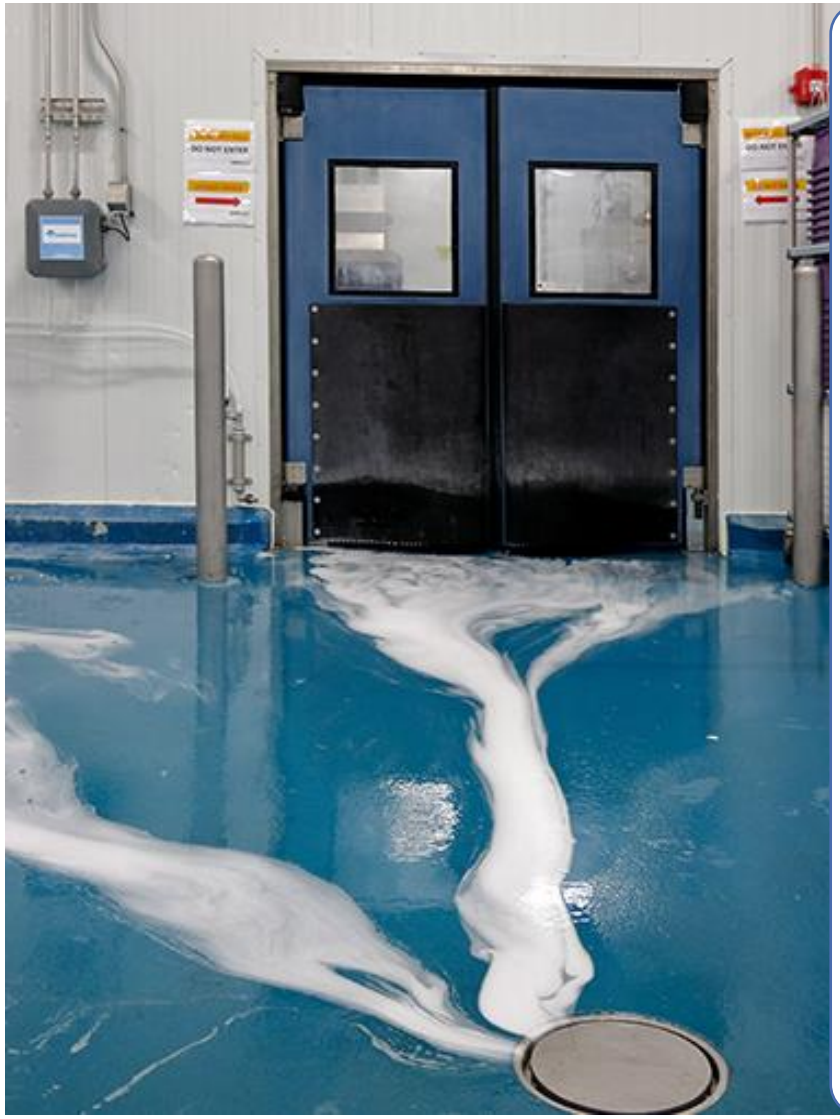
Wet Production – Wet Cleaning

- Smooth, crevice-free surfaces to avoid bacterial growth

Solution:

- Wet cleaning areas in dairy production should use hygienic drainage systems made of corrosion-resistant stainless steel, designed to withstand frequent cleaning, chemical exposure, and high humidity
- Follow design and application hygienic requirements from EHEDG Guideline n° 22 - General hygienic design criteria for the safe processing of dry particulate materials, Guideline n° 44 - Hygienic Design Principles for Food Factories and Guideline n° 13 - Hygienic design criteria for equipment used in wet-cleaned open food-processing environments

Hygienic Building Design - Drain

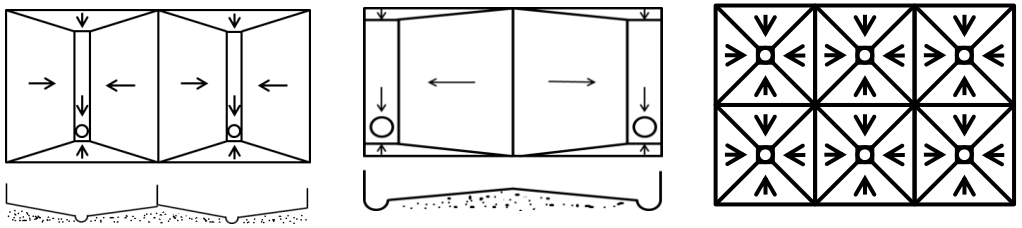


Requirement

- Floor and gully/channel design should avoid risk of stagnant water
- Inclined floor (slope 2%)
- Correct location of the gullies by understanding discharge of equipment / process

Solution:

- Follow design and application hygienic requirements from EHEDG Guideline n° 44 - Hygienic Design Principles for Food Factories



Hygienic Building Design – Platform Design

Requirement

- Horizontal ledges, projections and pockets should be avoided.
- Should be constructed of impervious, non-corrodible, easy to clean and impact resistant

Solution:

- Enough space clearance > 30 cm (easy to clean).
- Follow design and application hygienic requirements from EHEDG Guideline n° 44 - Hygienic Design Principles for Food Factories

Hygienic Building Design - Doors

Requirement

- Should have smooth, non-absorbent surfaces, easy to clean, and where necessary, disinfect
- Must be tight fitting (close without gaps), and pest proofed

Solution:

- Processing areas should be designed with a limited number of entry and exit points to minimize contamination risk.
- Follow design and application hygienic requirements from EHEDG Guideline n° 44 - Hygienic Design Principles for Food Factories

Hygienic Building Design - Air Quality

Requirement

- Humidity, temperature and particle control.
- Determination of the right specification based on e.g.; climate, product properties, processing conditions, type of cleaning.

Solution:

- Follow design and application hygienic requirements from EHEDG Guideline n° 47 - Air Handling Systems in the Food Industry - Air Quality Control for Building Ventilation

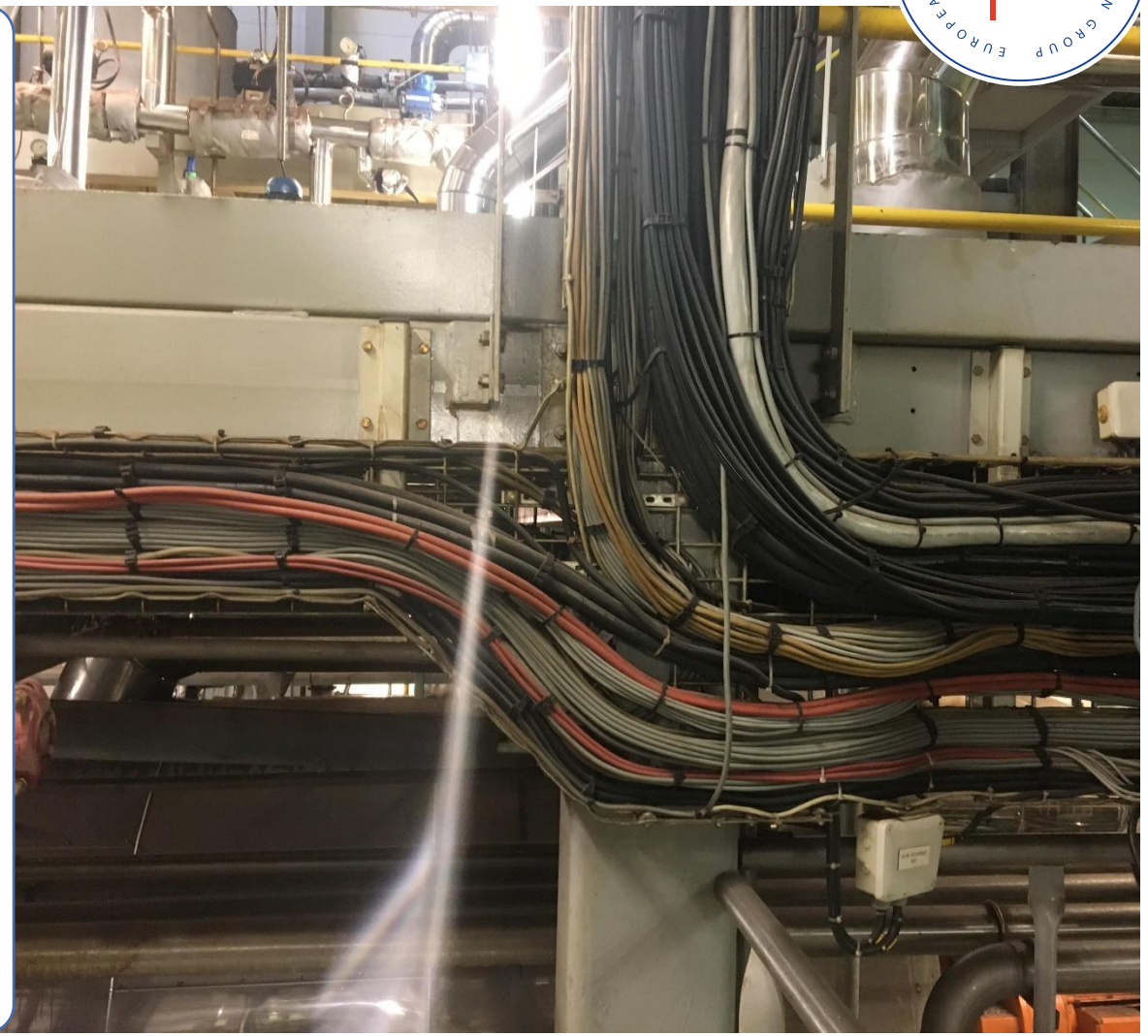
Hygienic Building Design - Cabling System

Requirement

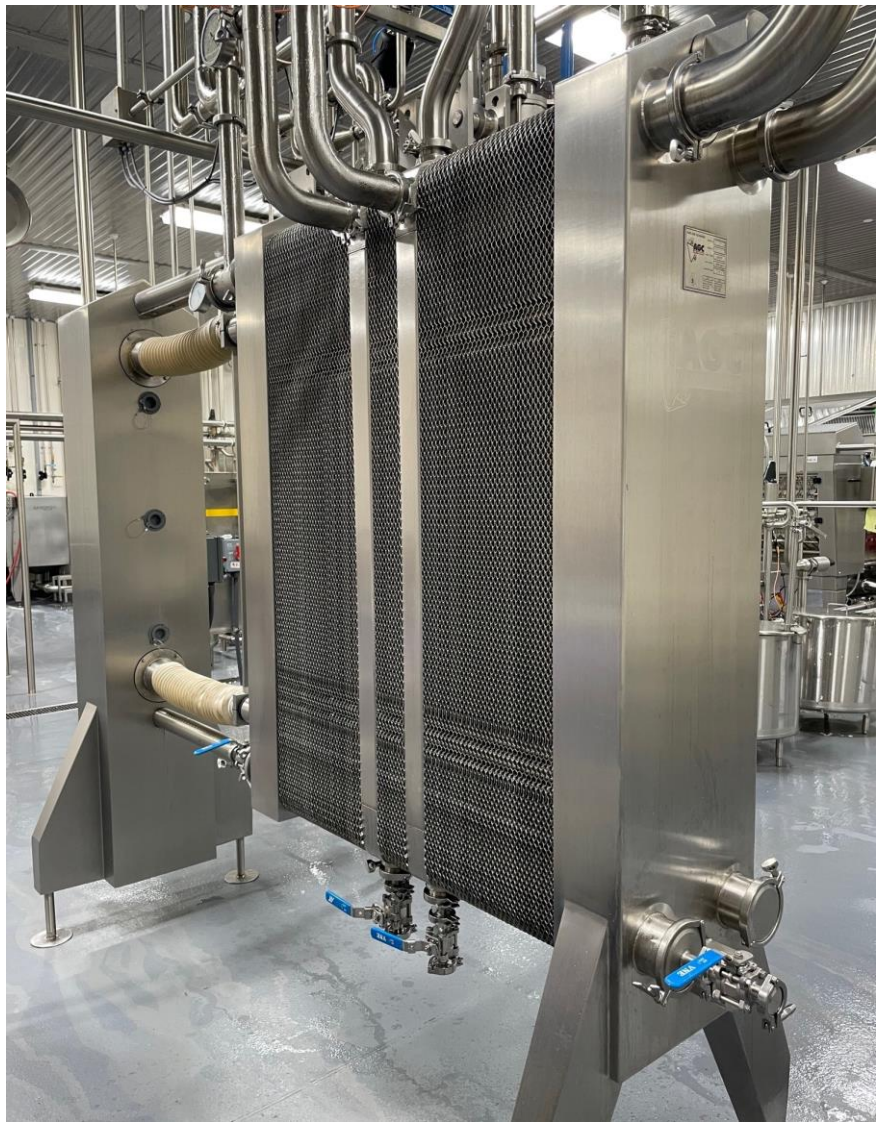
- Prevent harboring and growth of micro-organisms, pests and vermin
- Be easily cleanable
- Kept to a minimum in production areas
- Special zone: no corrosion – Stainless Steel or other materials

Solution:

- Vertical cable trays should be used wherever possible, as they are more accessible and easily cleaned.
- Follow design and application hygienic requirements from EHEDG Guideline n° 44 - Hygienic Design Principles for Food Factories



Hygienic Design - Dairy Equipment



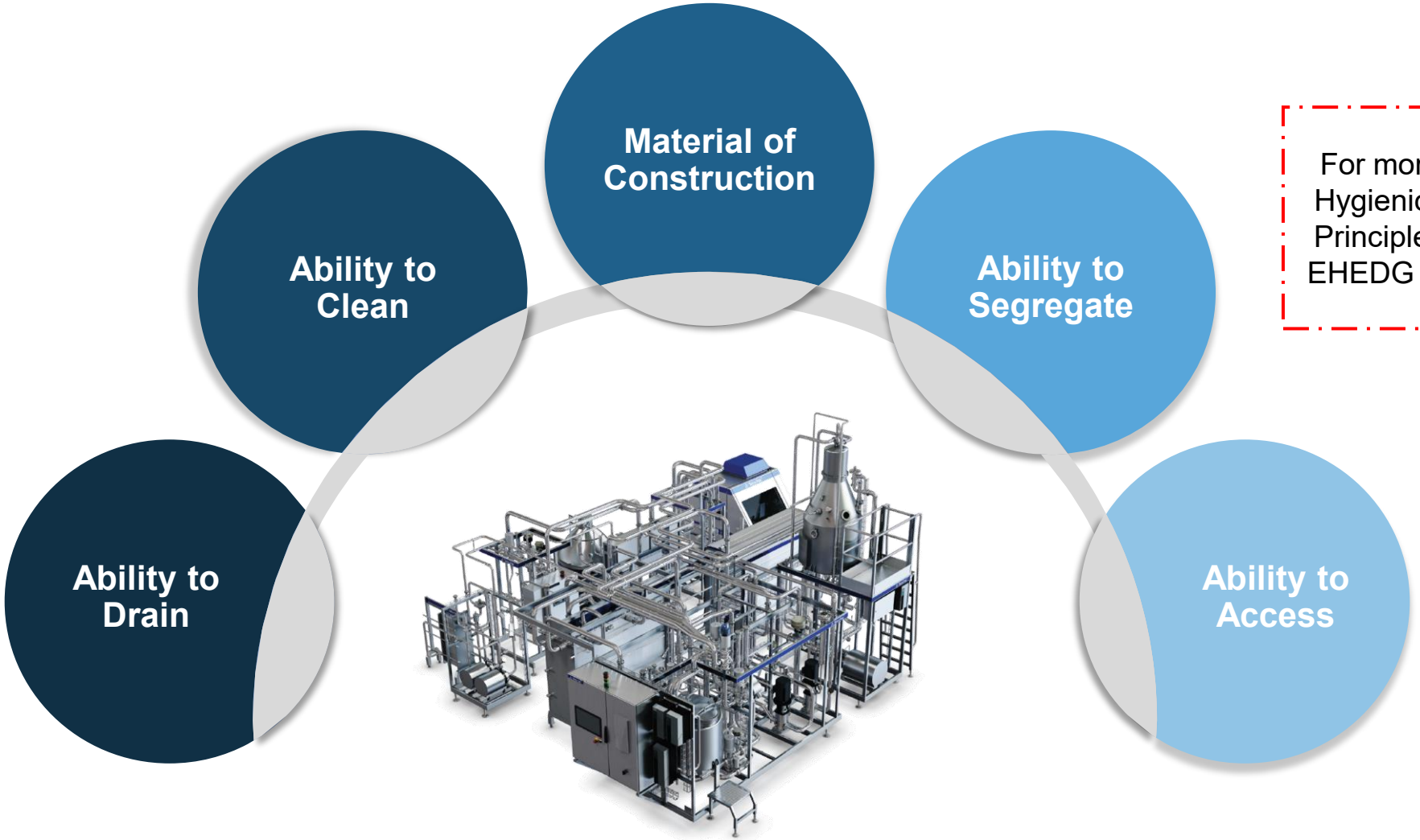
Test Methods
Cleanability – Closed equipment
Cleanability – Open equipment
Hygienic weld joint

Design Principles & Others	
Open equipment	Hygienic welding
Closed equipment	Lubricants
Hygienic design criteria	Tank and vessel cleaning
Chemical treatment stainless steel	Mechanical, elastomeric seals
Continuous UHT sterilization of liquid food	Continuous pasteurization of liquid food

Equipment	
Pumps	Transfer systems
Rotary valves	Sieve and filters
Pipe couplings	Diverter valves
Belt conveyors	Sensors
Discharging systems	CIP installations
Hopper and silo design	(Sampling) valves for liquids
Aseptic and Hygienic Filling Machines	Design packaging systems for solid food
Disc stacks centrifuges	Spray dryer and fluid bed

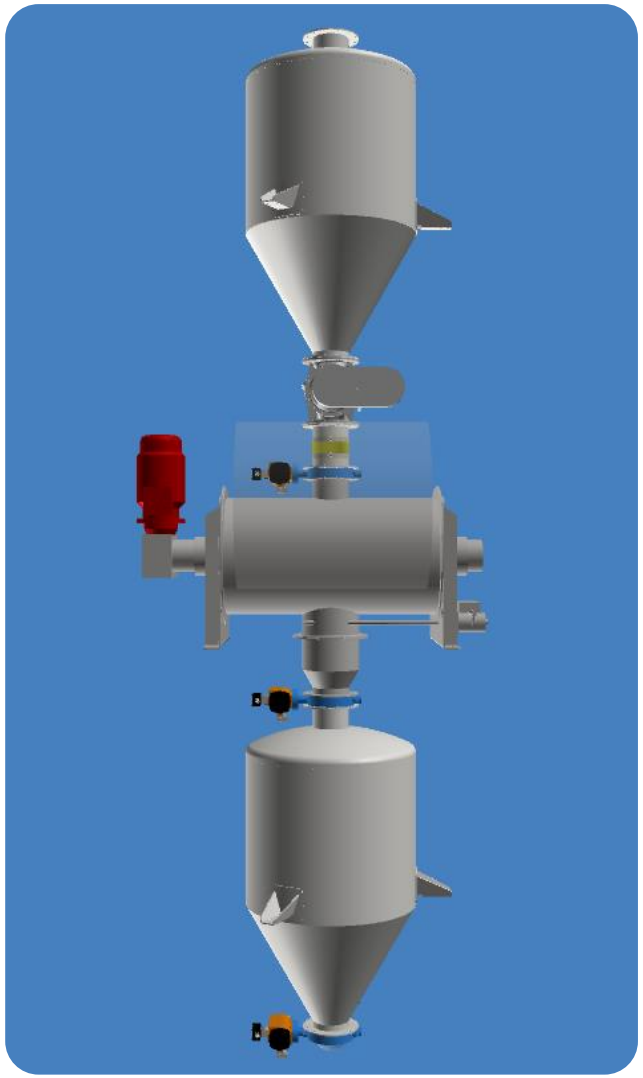
Hygienic Design Integration
Integration principles
Hygienic design risk management

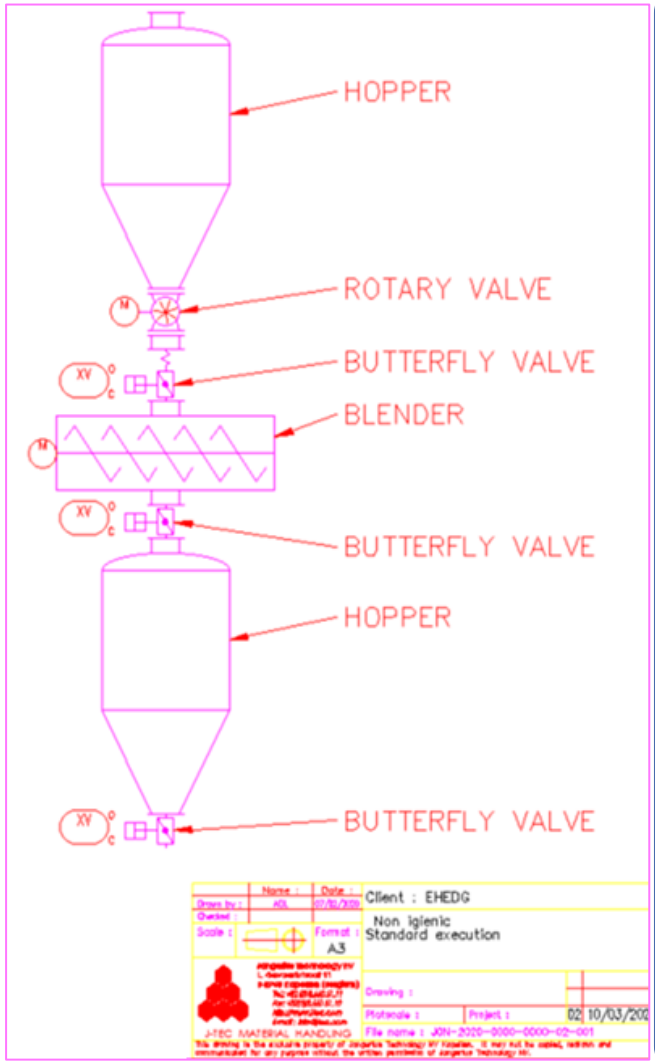
Hygienic Design Principles



For more about Hygienic Design Principles check EHEDG Doc n° 8

Process Flow Diagram





Requirement

- What specific hygienic design elements can be incorporated into this PFD to ensure greater compliance with hygiene and food safety regulations?
- What structural modifications could be implemented to enhance the cleanability of the components presented in the diagram?
- How does the selection of valve types and equipment influence compliance with hygienic design principles?

Hygienic Equipment Design - Materials of Construction

Requirement

- Correct selection of materials to use for product contact surfaces (metals, plastic, ceramics)
  - Prevention of corrosion
  - Regulatory compliance
  - Prevention of foreign material

Solution:

- Follow design and application hygienic requirements from EHEDG Guideline n° 8 - Hygienic Design Principles for Food Factories and Guideline n° 22 - Materials of Construction in Contact with Food n° 32

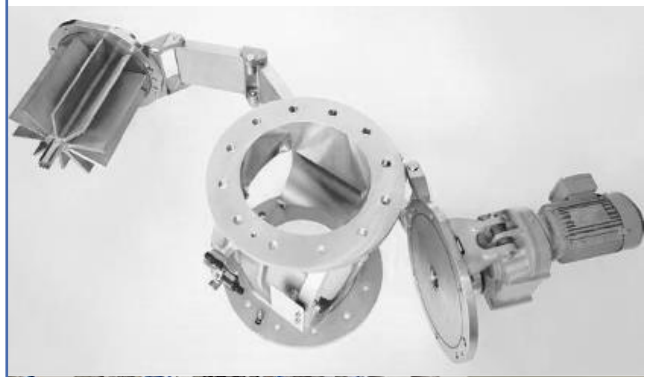
Hygienic Equipment Design - Rotary Valve

Requirement

- Determination of the right specification based on e.g., application considerations, product characteristic, cleaning and maintenance

Solution:

- Follow design and application hygienic requirements from EHEDG Guideline n° 38 - Hygienic Engineering of Rotary Valves in Process Lines for Dry Particulate Materials



Hygienic Equipment Design - Welding

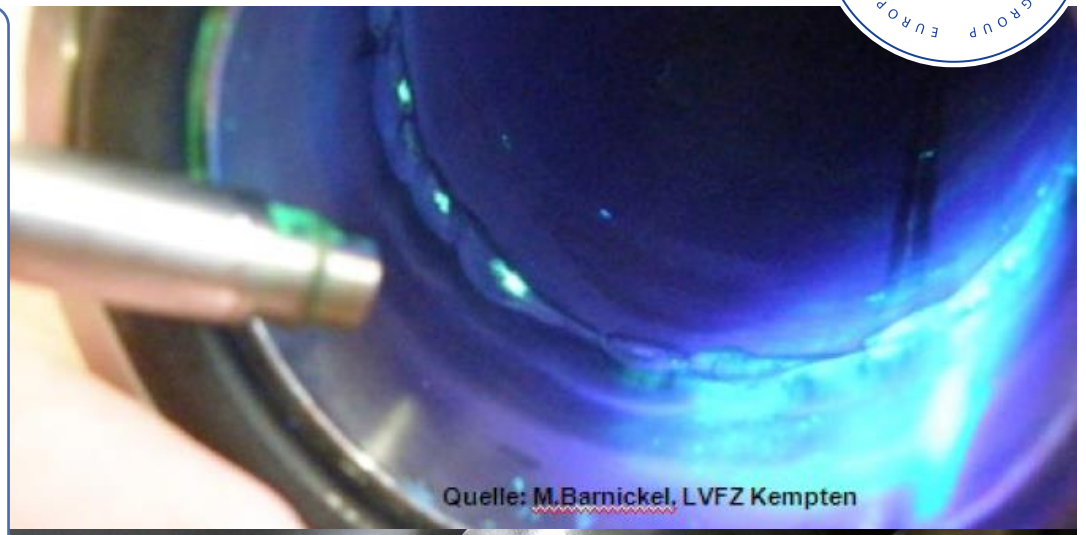
Requirement

- Smooth surfaces

< 0.80 µm Ra / (< 32 µin Ra)

Solution:

- Follow design and application hygienic requirements from EHEDG Guideline n° 8 - Hygienic Design Principles for Food Factories, Guideline n° 9 - Welding stainless steel to meet hygienic requirements, Guideline n° 35 Hygienic Welding of Stainless-Steel Tubing in the Food Processing Industry and Guideline n° 54 – Testing of hygienic weld joint



Hygienic Equipment Design - Flexible Connections

Requirement

- Selection of flexible material based on movement requirements and cleaning
- Sealing of duct ends to prevent crevices and product retention
- Clamp positioning close to duct end to minimise dead zones
- Use of smooth-surfaced material to reduce product build-up

Solution:

- Follow design and application hygienic requirements from EHEDG Guideline n° 22 - General hygienic design criteria for the safe processing of dry particulate materials

Hygienic Equipment Design - Accessibility

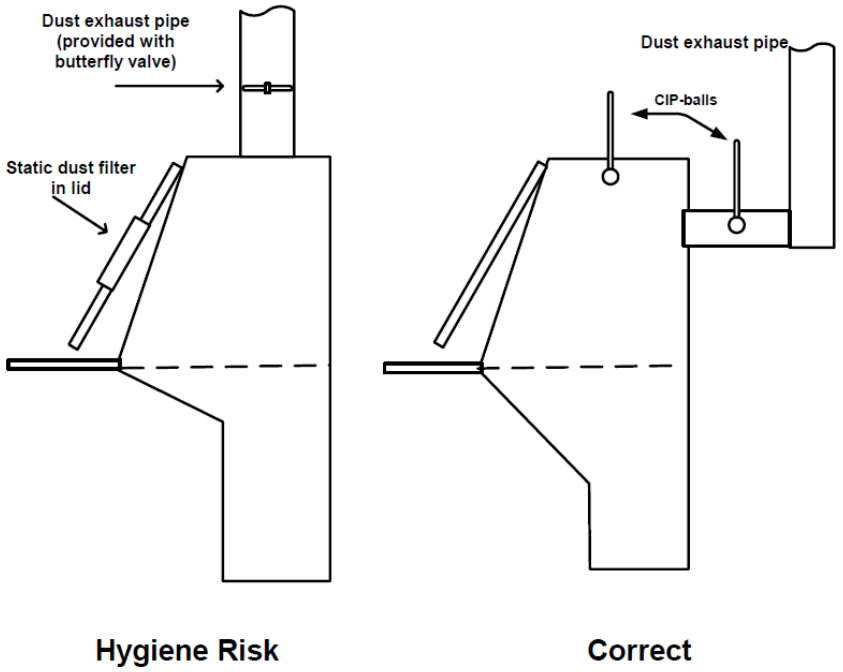
Requirement

- All product contact surfaces should be accessible for cleaning and sanitation

Solution:

- Follow design and application hygienic requirements from EHEDG Guideline n° 22 - General hygienic design criteria for the safe processing of dry particulate materials and Guideline n° 13 - Hygienic design criteria for equipment used in wet-cleaned open food-processing environments

Hygienic Equipment Design for Discharge System



Requirement

- Prevent product accumulation by sloped surfaces and no ledges
- Select correct material of construction

Solution:

- Follow design and application hygienic requirements from EHEDG Guideline n° 33 - Hygienic engineering of discharging systems for dry particulate materials

Hygienic Equipment Design - Drainability

Requirement

- Sharp corners should be eliminated to ensure proper alignment and smooth transitions
- Windows, manholes, and inspection ports must be flush with adjacent surfaces
- Surfaces should have a slight slope to enhance drainage and prevent residue buildup

Solution:

- Follow design and application hygienic requirements from EHEDG Guideline n° 8 - Hygienic Design Principles for Food Factories and Guideline n° 9 - Welding stainless steel to meet hygienic requirements

Hygienic Equipment Design - Valves

Requirement

- Valves mounted on the tank wall should be flush and designed to allow full access for cleaning and sanitation
- Should permit forced-flow cleaning of all internal product contact surfaces
- Avoid dead legs on pipeline branches to valves

Solution:

- Follow design and application hygienic requirements from EHEDG Guideline n° 14 - Requirements for valves in hygienic and Aseptic Processes and Guideline n° 51 - Hygienic design aspects for tank and vessel cleaning in the food industry

Hygienic Equipment Design – Tank

Requirement

- Manhole and its hinge mechanism should be designed to prevent buildup on door surfaces and to avoid ingress of contaminants during opening
- Gasket and closure system must be constructed to minimize areas requiring manual cleaning
- Components and instrumentation should be designed for hygienic integration and ease of maintenance

Solution:

- Follow design and application hygienic requirements from EHEDG Guideline n° 37 - Hygienic design and application of sensors, Guideline n° 51 - Hygienic design aspects for tank and vessel cleaning in the food industry

Hygienic Equipment Design - Segregation

Requirement

- Proper sealing and prevention of emission to production environment
- Minimise product exposure

Solution:

- Dust tight machinery design
- Follow design and application hygienic requirements from EHEDG Guideline n° 22 - General hygienic design criteria for the safe processing of dry particulate materials

Hygienic Equipment Design - Insulation

Requirement

- Hygienic insulation to prevent pest and moist ingress

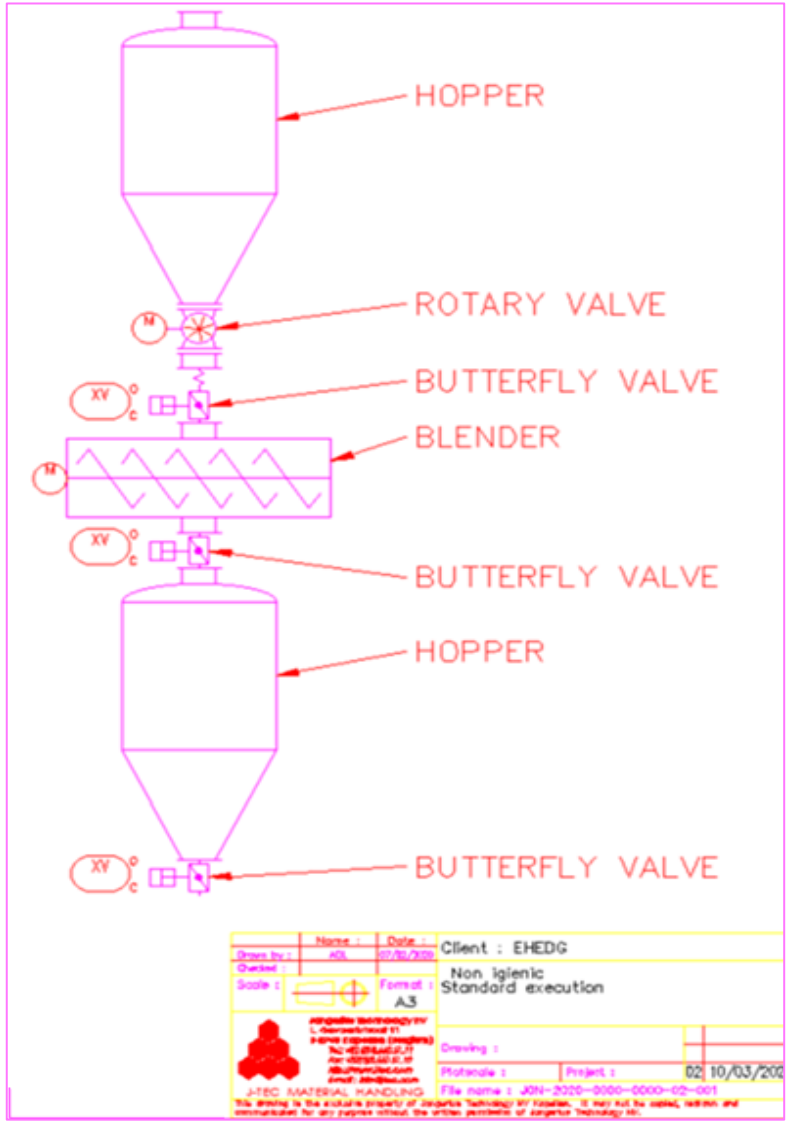
Solution:

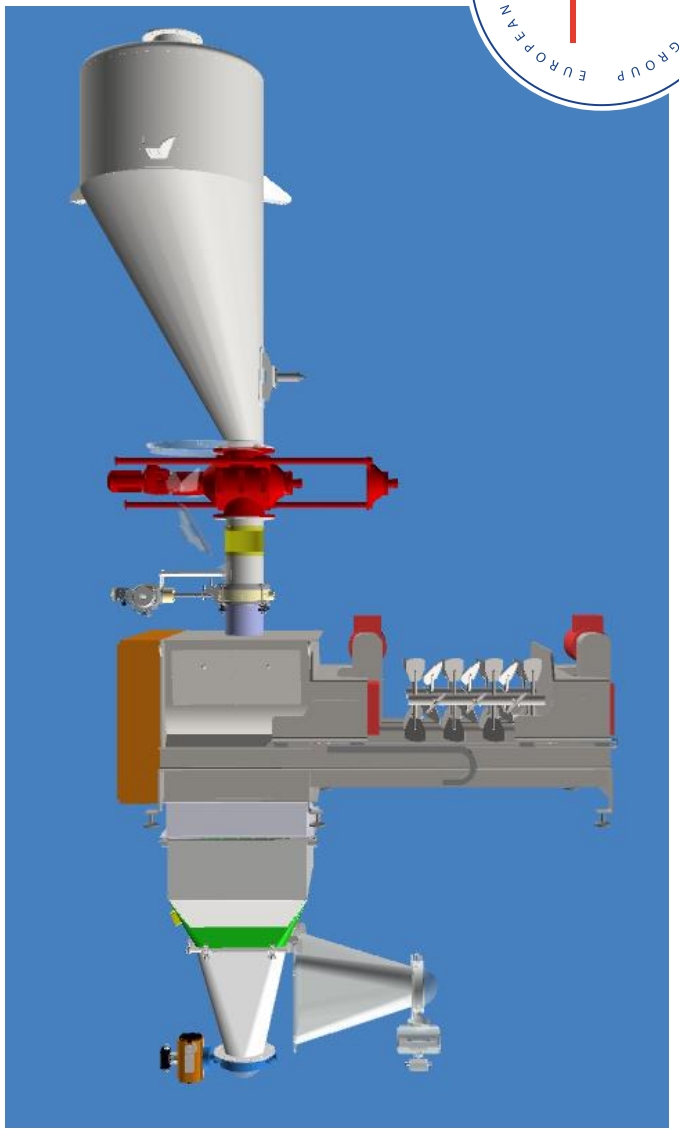
- Follow design and application hygienic requirements from EHEDG Guideline n° 8 especially for insulation in wet cleaning environment

Improved Hygienic Equipment Design

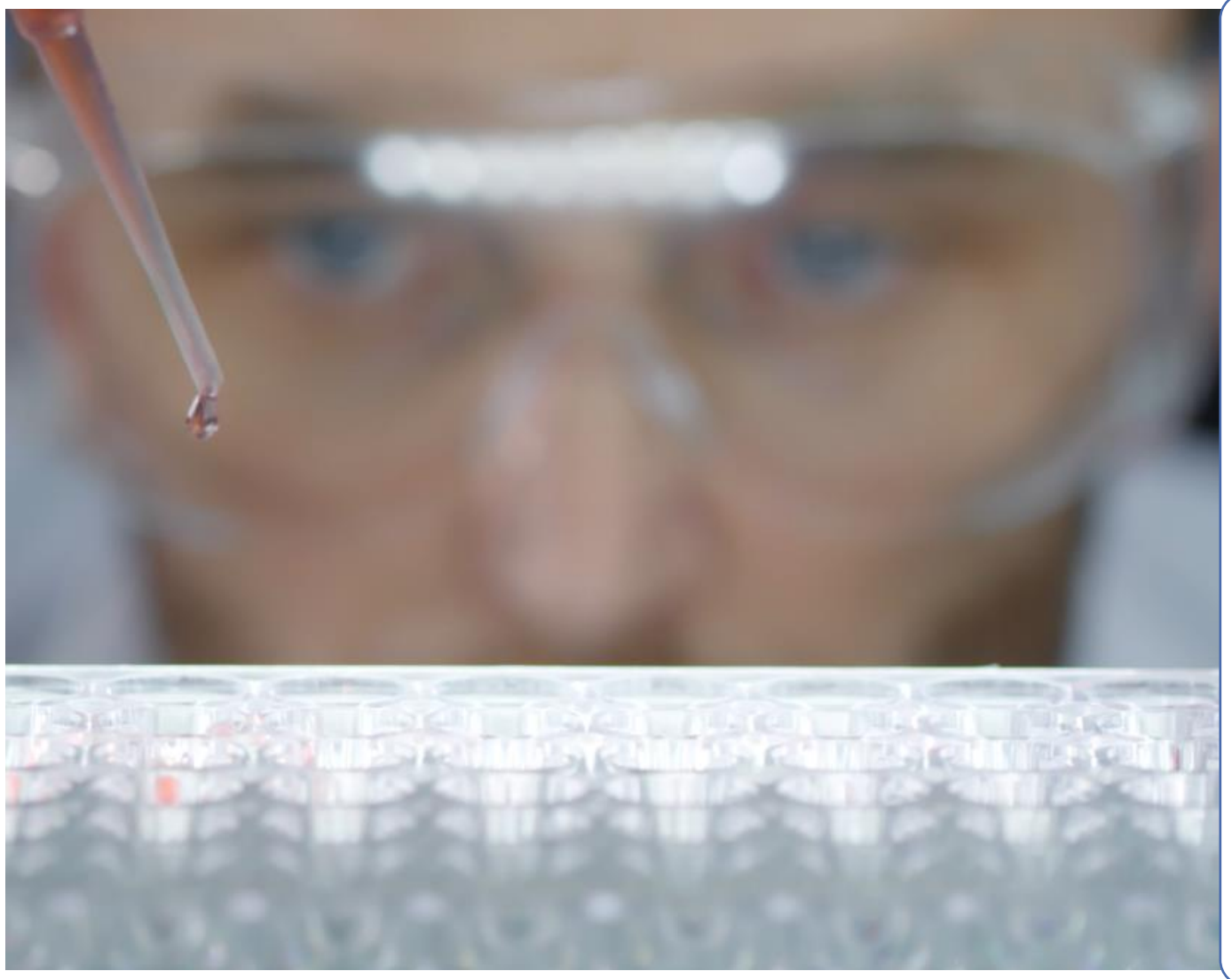
Solution:

- The process has been made more accessible for cleaning and disinfection, by installing e.g., easy dismantlable rotary valves, pipe connections, retractable auger and opening of hopper.





Importance of Validation and Documentation



Requirement

- Validation of performance with all risk reduction measures in place (including cleaning) to verify that the hygiene risk measurements are in place and are effective
- Document the results to monitor and review that the measures remain effective

Solution:

- Follow qualification approach from EHEDG Guideline n° 34 - Integration of Hygienic Entities and design application from Guideline n° 45 - Cleaning Validation Monitoring and Verification

Benefits of Hygienic Design

Documented Cost Savings & ROI

1. **Nestlé Dairy Facility**
   30% reduction in CIP water use, shorter CIP cycles also meant energy savings, less chemical usage due to more efficient cleaning.

2. **GEA Brewery Implementation**
   Product yields increase by 2–5%, because leftover beer in the lines could be reclaimed, water needed for flushing lines decreased significantly.

3. **Retrofit Meat Processing Plant**
   Fewer cleaning hours, lower maintenance labour, and spare-part costs. Longer intervals between major overhauls. Equipment lifespans increased by several years.

4. **Krones Beverage Processing Line:**
   Downtime between production runs dropped by 15–20%, due to shorter CIP cycles. More predictable maintenance schedule, reducing unplanned stoppages.

5. **Tetra Pak CIP system in confectionery plant:**
   Reduced risk of chemical exposure for operators, lower volume of cleaning chemicals due to more effective use of targeted sprays.

Documented Benefits of Hygienic Design

Water Usage: Companies consistently see 20–40% reduction in CIP water use

Energy: Heating less water (or pumping less through CIP) cuts steam or electricity consumption.

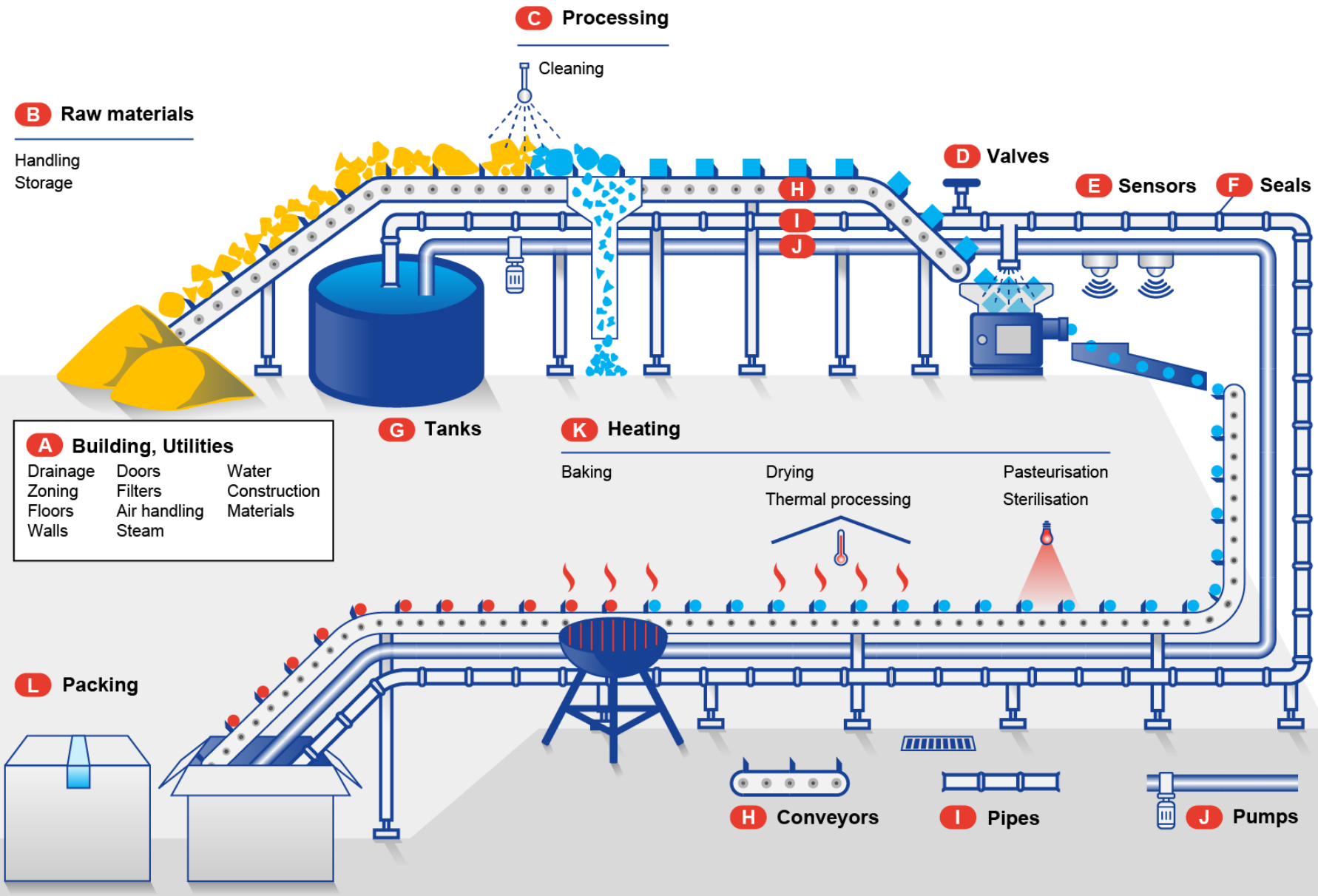
Chemicals: Reduced cleaning agents (up to 50% less) because of quicker, more thorough coverage.

Labour: Fewer cleaning hours or manual interventions.

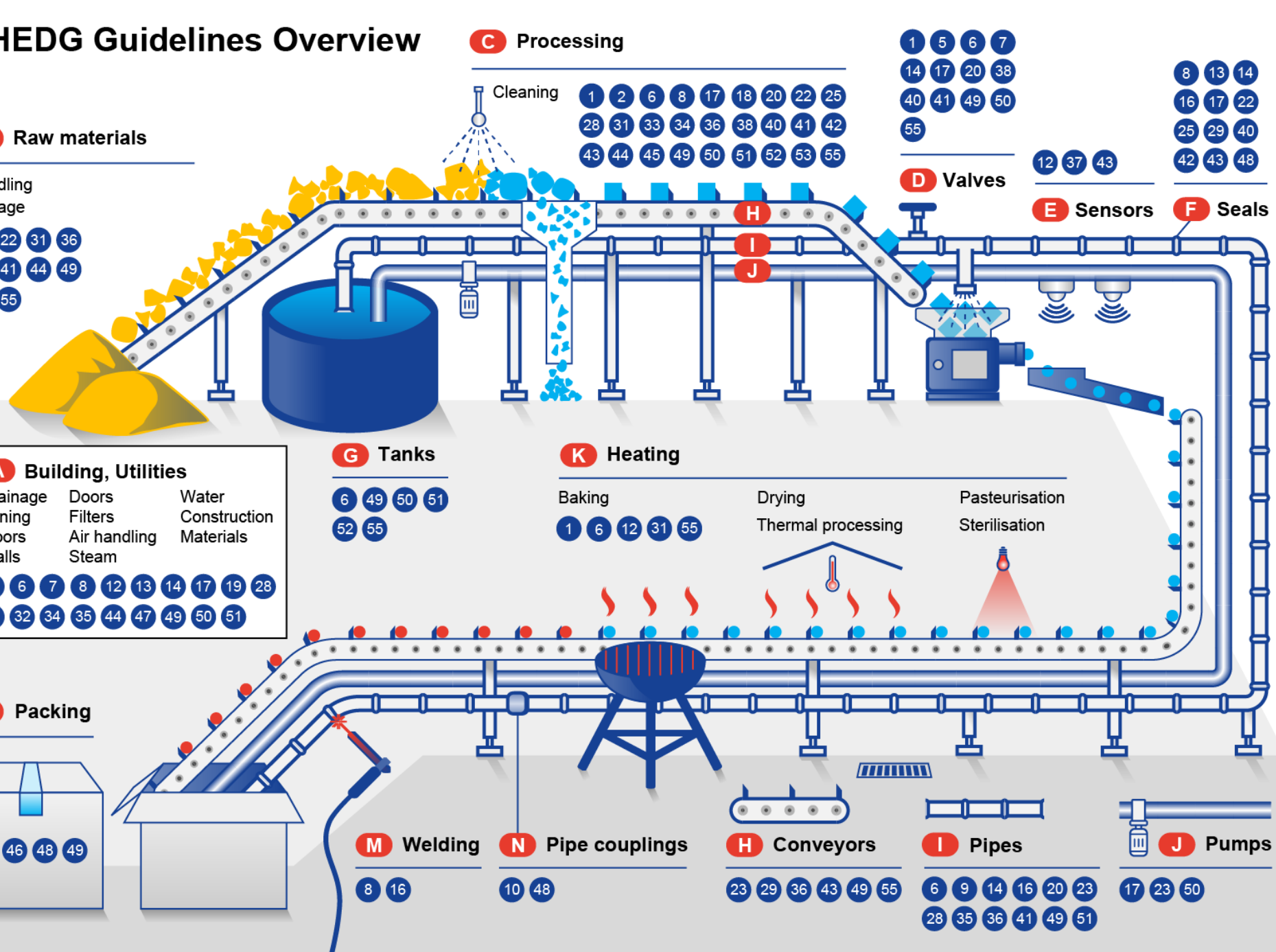
Maintenance: Longer equipment life, fewer part replacements, more time in operation.

Waste Handling: Fewer by-products and lower disposal costs.

EHEDG Guidelines Overview



EHEDG Guidelines Overview



C Processing

Cleaning

1 2 6 8 17 18 20 22 25
28 31 33 34 36 38 40 41 42
43 44 45 49 50 51 52 53 55

B Raw materials

Handling
Storage

12 22 31 36
40 41 44 49
53 55

A Building, Utilities

Drainage	Doors	Water
Zoning	Filters	Construction
Floors	Air handling	Materials
Walls	Steam	

5 6 7 8 12 13 14 17 19 28
31 32 34 35 44 47 49 50 51

G Tanks

6 49 50 51
52 55

K Heating

Baking

1 6 12 31 55

Drying
Thermal processing

Pasteurisation
Sterilisation

L Packing

29 46 48 49
53

M Welding

8 16

N Pipe couplings

10 48

H Conveyors

23 29 36 43 49 55

I Pipes

6 9 14 16 20 23
28 35 36 41 49 51

J Pumps

17 23 50

D Valves

1 5 6 7
14 17 20 38
40 41 49 50
55

E Sensors

12 37 43

F Seals

8 13 14
16 17 22
25 29 40
42 43 48

In Summary

Hygienic design not only mitigates food safety risks but also significantly influences food quality compliance operational performance – including efficiency and sustainability.

Risk

A structured risk management approach, combined with proper validation and maintenance, ensures compliance and product integrity.

By applying hygienic design principles, companies can optimize their processes while minimizing contamination risks.

From facility layout to equipment accessibility, every element must prioritize cleanliness, safety, and efficiency.

Thank you!

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