FSSC 22000: EQUIPMENT MANAGEMENT

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FSSC 22000

TODAY'S TOPICS

01. Introduction

02. EHEDG Perspective

03. Scheme Requirement

04. Guidance Document

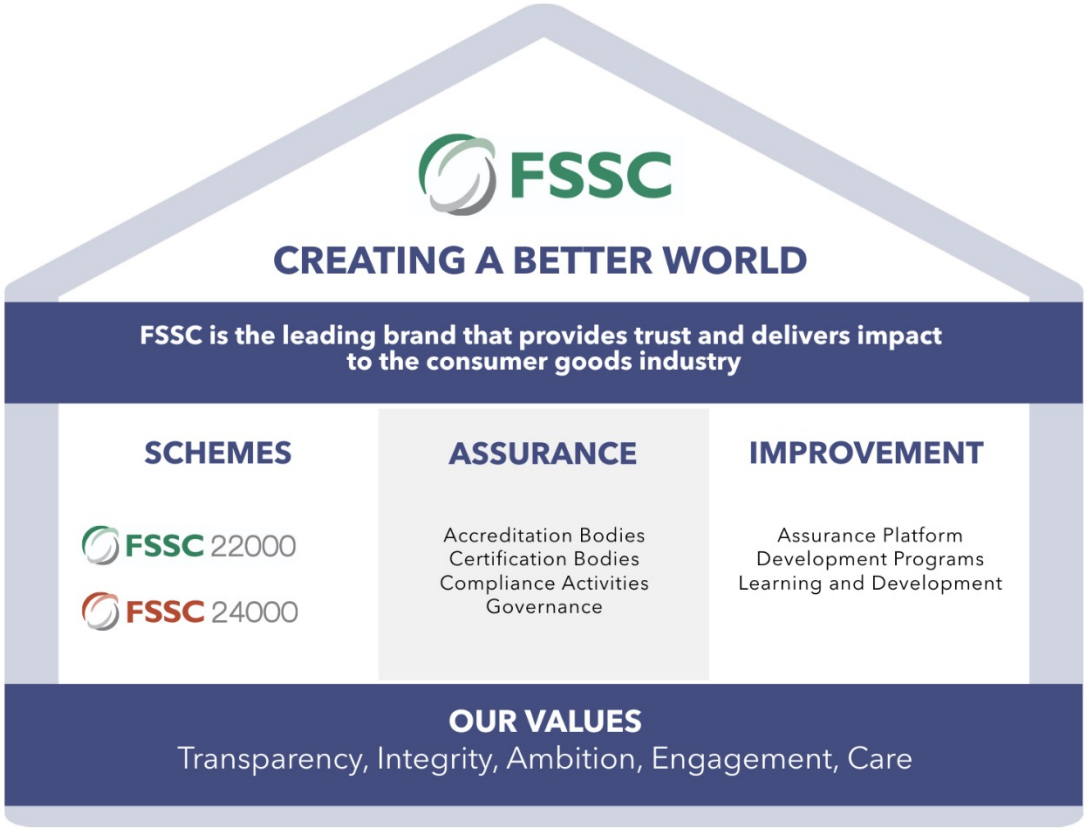
05. Industry Perspective

06. Q&A

PRACTICALITIES

- You’re all muted
- Please use the Q&A functionality for questions
- This webinar will be recorded
- Recording and presentations will be shared via e-mail

FSSC BRANDED HOUSE



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EQUIPMENT MANAGEMENT

- Survey to general stakeholders as part of V6 consultation.
- Not include category JI and JII in the Scheme on hygienic design – too specific.
- Identify need for more detailed requirement on equipment management, including management of change.

EHEDG PERSPECTIVE

FSSC Insights Webinar

FSSC Additional Requirements on Equipment Management

Patrick Wouters – Cargill Global Hygienic Design CoE Lead & EHEDG Vice-President

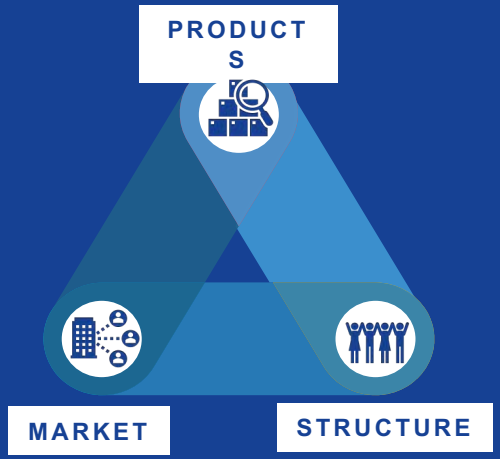
Today's Topics

Who is European Hygienic Engineering & Design Group (EHEDG)?

EHEDG was founded in 1989 as a non-profit consortium of

Objective:
Develop Hygienic Engineering & Design knowledge to manage food safety and quality

EHEDG Vision



MARKET

All stakeholders in production of safe and quality food

- Producers & retailers
- Equipment & system suppliers
- Service providers
- Academia
- Legislators and enforcement agencies

PRODUCTS

Consensus-based comprehensive product portfolio

- Guidelines on hygienic design requirements and associated practices to manage food safety and quality
- Equipment testing and certification
- Training & Education

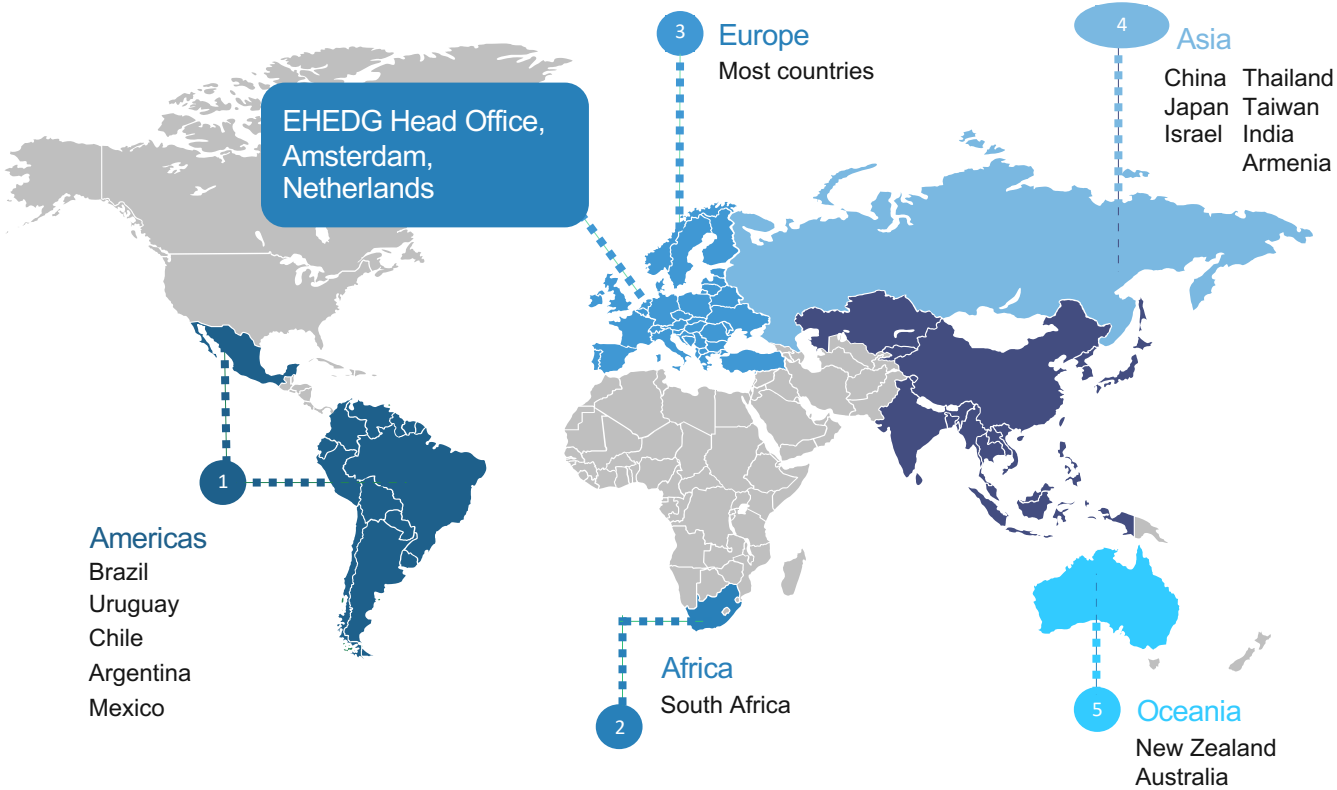
STRUCTURE

A well-balanced membership with global coverage

- Funded by strongly committed members
- Relying upon voluntary contribution and active involvement
- Attractive for large and small companies

EHEDG – European based – global reach

Our regional sections



Partner Program

Discuss and review each other's documents
Exchange expert knowledge

Developing standards (ANSI) & 3-A Symbol
Support U.S. Regulatory Objectives

EHEDG Product Portfolio

Guidelines

30+ Working Groups and
50+ published documents

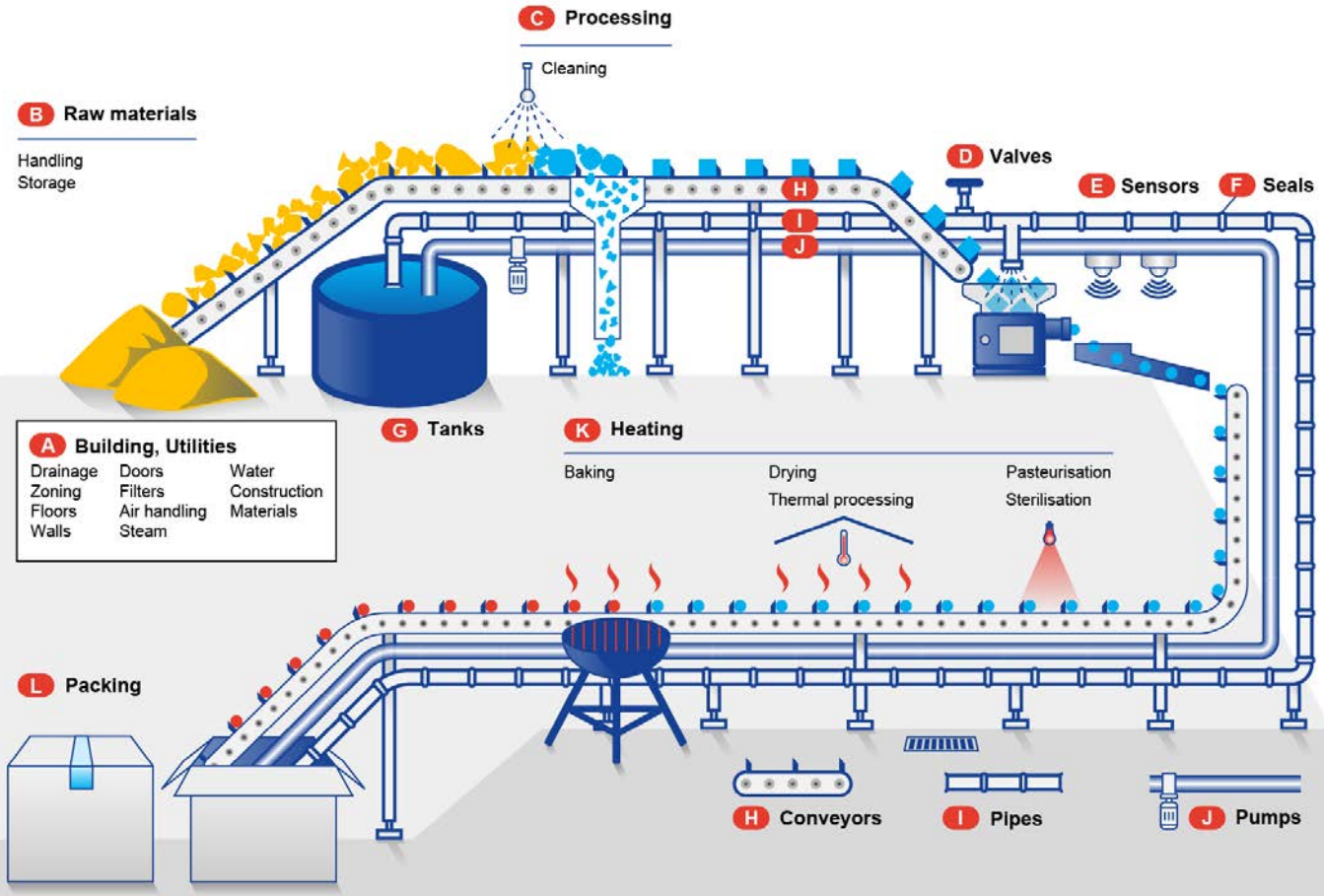
Testing & Certification

300+ certified equipment

Training & Education

Hygienic design training,
online and in-person

EHEDG Guidelines overview



Working Groups – Join us!

Hygienic Design Principles

1

Materials of Construction, Hygienic Welding, Hygienic Maintenance, Hygienic Design Risk Management

Hygienic Equipment Design

2

Closed, Open, Wet, Dry

Hygienic Building Design

3

Zoning, Civil Structural Architectural, Environmental Air system design

Hygienic Process and Utilities Design

4

Hygienic Integration of Entities Packing process, Heat Treatment. Safe Water

Test Methods

5

Certification process. Open Equipment testing, Cleanability test, Bacteria tightness

Cleaning Systems design & Procedures

6

CIP Design, Tank Cleaning, Cleaning Validation, Cleaning & Disinfection Principles

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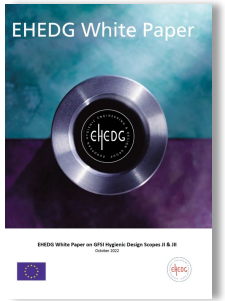
Equipment Management in Food Safety Management Systems

2020

GFSI Benchmarking scopes published

Scope	End User
JI – Hygienic Design of Food Facilities and Processing Equipment	Facility Constructors, Equipment Manufacturers
JII - Hygienic Design of Food Facilities & Processing Equipment	Facility and Equipment Users



Oct 2022

Interpreted and explained by EHEDG

April 2024

Guidance on process of performing Hygienic Design Risk Management for both food producers as well as suppliers

EHEDG World Congress 2024

'Achieving hygienic excellence by design'

Register now!

2-3 October | Nantes, France

Breakout sessions, Poster area, Sponsor tours, Networking

FSSC 22000 SCHEME REQUIREMENTS ON EQUIPMENT MANAGEMENT

NEW ADDITIONAL REQUIREMENTS

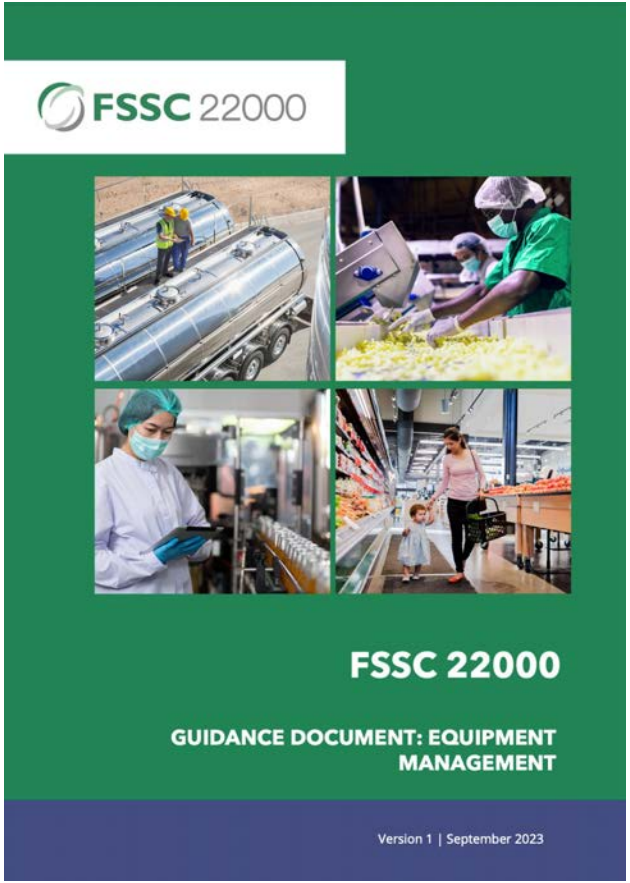
2.5.15 - Equipment Management (All Food Chain Categories, excl. FII):

- Documented purchase specifications and evidence of meeting them.
- Risk-based change management process for equipment (new & existing).
- Evidence of successful commissioning.
- Effects on existing systems and controls implemented.

GUIDANCE DOCUMENT EQUIPMENT MANAGEMENT

EQUIPMENT MANAGEMENT

- 1st Edition – September 2023
- Purpose: how to implement equipment management in food safety management systems.
- FSSC Additional Requirement 2.5.15 for all categories except subcategory FII (Brokering and Trading).
- Translated into 5 languages.



GENERAL GUIDANCE

- Significant changes to equipment – not cover replacement of pieces or parts (fuse, conveyor belt – clause 8.6 – ISO 22000).
- Existent equipment – ensure adequate control measures are implemented to address any hazards and food safety.
- Purchasing second-hand equipment – considered as new.
- Hazards and associated risks related to current equipment are addressed within hazard analysis (clause 8.5 – ISO22000).

PURCHASE SPECIFICATION

Document a purchase specification for each piece of equipment prior to purchasing the equipment, addressing:

- Specific hygienic design parameters
- Intended use of the equipment and product handled
- Relevant customer and legal requirements

To develop the purchase specification, organizations should:

- Conduct an equipment design risk assessment
- Determine hygienic design principles based on outcome of risk assessment

Evidence of meeting the purchase specification must be supplied

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RISK-BASED CHANGE MANAGEMENT

- **Risk-based change management consists of:**
  - Undertaking a risk assessment
  - Determining risk mitigation based on hygienic design principles
  - Documenting the change

Successful installation, commissioning and validation is vital.

Assess possible effects on existing systems.

Determine and implement necessary control measures, e.g. :

- Increase the frequency of monitoring, or
- Establish additional control measures.

SECTIONS TO REVIEW AND UPDATE

- Hazard analysis
- Environmental monitoring program
- Cleaning and sanitation program
- Allergen management program
- Maintenance program
- Training program
- Production records
- Verification activities

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RELATED INDUSTRY INFORMATION

- Refer to the last page of the Guidance Document on Equipment Management.
- Find the translations of the Guidance Document.

8. RELATED INDUSTRY INFORMATION

The references below are not an exhaustive list and are for information purposes only, and may not apply to all organizations. The requirements of the Scheme shall be adhered to in all cases.

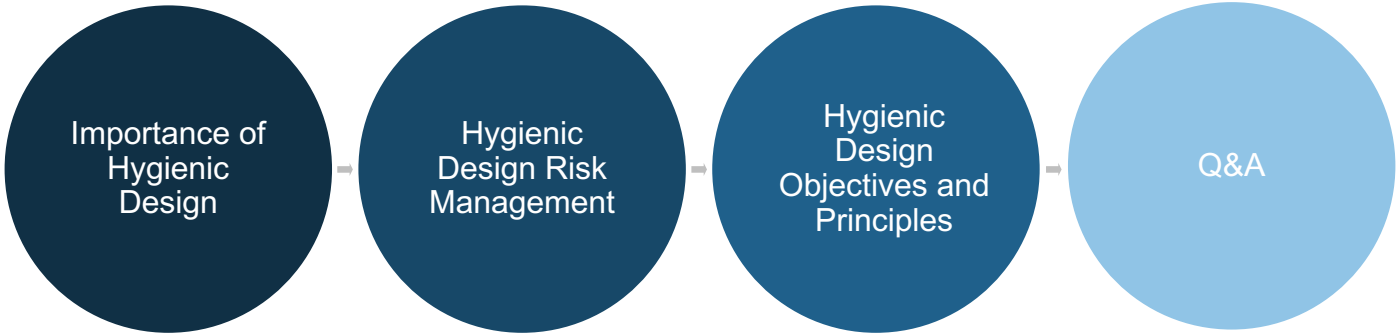
- EHEDG, The European Hygienic Engineering and Design Group. URL: EHEDG. Examples of some of the guideline documents established by EHEDG include:
  - Guideline Doc. 32:2005 Materials of construction for equipment in contact with food
  - Guideline Doc. 35:2006 Hygienic welding of stainless-steel tubing in the food processing industry
  - Guideline Doc. 44:2014 Hygienic Design Principles for Food Factories
  - Guideline Doc. 8:2018 Hygienic Design Principles
  - Guideline Doc. 50:2019 Hygienic Design Requirements for CIP Installations
  - Guideline Doc. 55:2020 Hygienic Design Requirements for Bakery Equipment
- The European Committee for Standardization. URL: CEN-CENELEC
- FDA, The US Food and Drug Administration. URL: U.S. Food and Drug Administration
- NAMI, The North American Meat Institute. URL: North American Meat Institute
- The International Organization for Standardization (ISO), ISO 14159:2002. URL: ISO 14159:2002 - Safety of machinery — Hygiene requirements for the design of machinery
- BS EN 1672-2:2020. Food processing machinery. Basic concepts – Hygiene and cleanability requirements. URL: BS EN 1672-2:2020
- Codex Alimentarius CXC 1-1969:2020. URL: CXC 1-1969 General Principles of Food Hygiene.

INDUSTRY PERSPECTIVE

FSSC 22000 Webinar – Equipment Management

Patrick Wouters – Cargill Global Hygienic Design CoE Lead & EHEDG Vice-President

Today’s Topics



Hygienic Equipment Design: Why important?

EU Legislation

Hygienic design:
- *EC 42/2006 - Machinery Directive*

Materials of construction:
- *EC 1935/2004 - Framework Regulation: materials & articles intended to come into contact with food*
- *EU* 10/2011 - Plastics Regulation
- *EC 2023/2006 – GMP for materials & articles intended to come into contact with food Regulation*
- *EC 852/2004 - Hygiene of Foodstuffs Regulation*

EFSA

Recently published scientific opinion

Common risk factors for persistence of food pathogens* in food and feed processing environment are:
- lack of hygienic design of equipment and machines
- inadequate zoning and hygiene barriers
- inadequate cleaning and disinfection

**such as Salmonella, Listeria monocytogenes, Cronobacter sakazakii*

USA Legislation

21 CFR 117.40 – Equipment & utensils design & maintenance
21 CFR 117.20(b) – Plant construction and design
FSIS published Sanitary Performance Standards Compliance Guide as references methods already proven to be effective in maintaining sanitary conditions in meat and poultry establishments

Requirements being incorporated in GFSI Recognized Food Safety Management Certification Programs

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How to manage this in equipment design?

- Legacy (existing) equipment
- New Equipment Purchases

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Cargill - Our enterprises

Various Products and Manufacturing Technologies

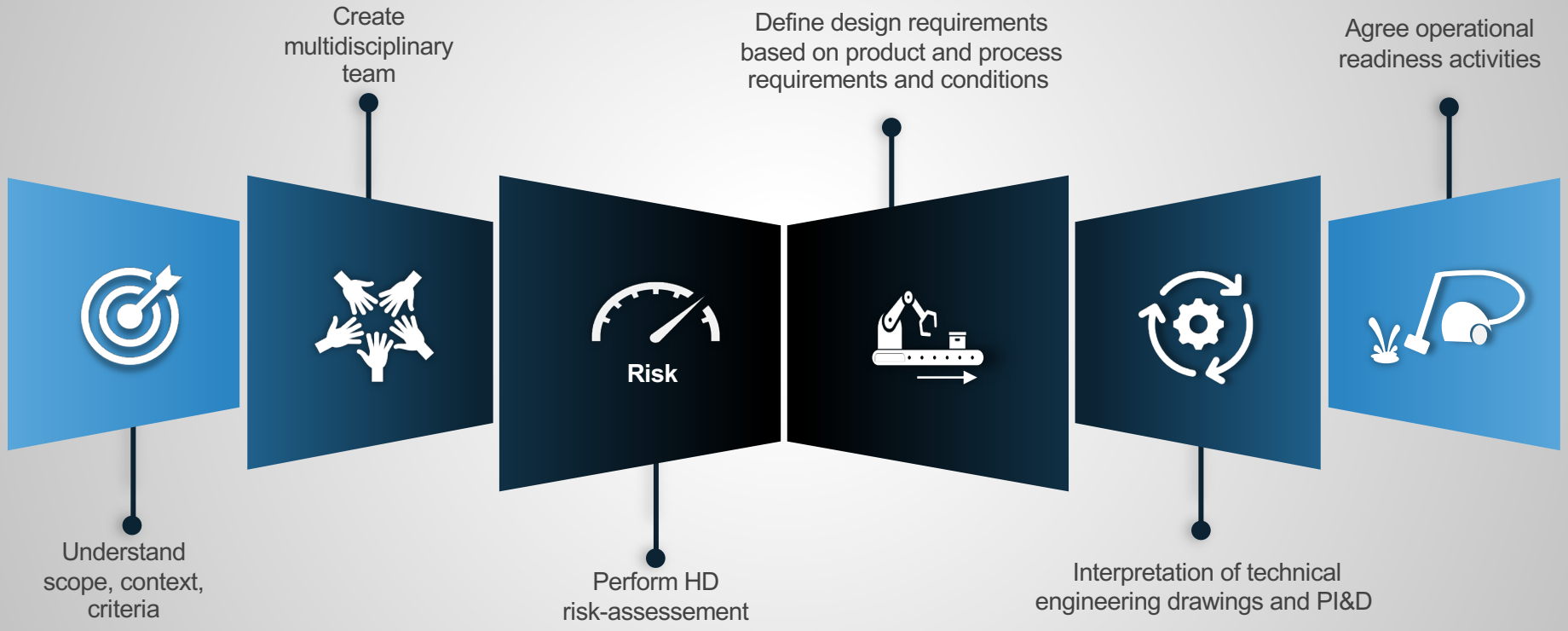
Agricultural Supply Chain

Animal Nutrition & Health

Protein & Salt

Food & Bio

Hygienic Design Risk Management Approach – For equipment



Hygienic Design Risk Assessment – What are key input parameters

Scope, context and criteria

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Hygienic Design Objectives

Prevention of Ingress

Prevent unwanted materials entering equipment or process, by insufficiently closed/protective equipment or materials from inside processing equipment getting into the food

Prevention of Growth

Eliminate any areas where microorganisms can harbor and/or grow, e.g. dead areas, gaps, cracks and crevices

Prevention of Accumulation

Prevent increase by continuous addition of e.g., remaining product residues, liquids, soil or cleaning chemicals

of
- Physical
- Chemical
- Biological

hazards and contaminants

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5 Hygienic Design Principles

- Internal and external equipment surfaces minimize product collection or water pooling, sloped to outlet and avoid back flow or condense formation
- Liquids not to drip, drain, or be drawn in/on to product zone areas

- Distance and clearances between equipment and floor/wall to be large enough to clean, maintain, inspect

- Product contact surfaces to be smooth and free of imperfections
- Equipment to be designed without sharp corners, dead ends, crevices, nooks and crannies

- Product contact areas are segregated for equipment and process steps where (re-) contamination can occur with e.g., cleaning fluids, lubricants, cooling media, foreign matter, microorganisms

- Non-toxic and inert to product detergents and disinfectants
- Mechanically stable
- Corrosion resistant
- Easily cleanable
- Non-absorbent

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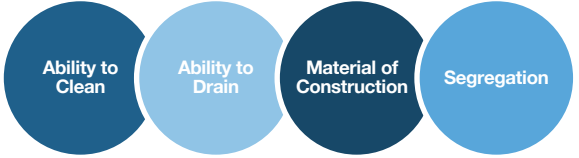
Categorization Hygienic Design for Equipment Design
Example Pumps



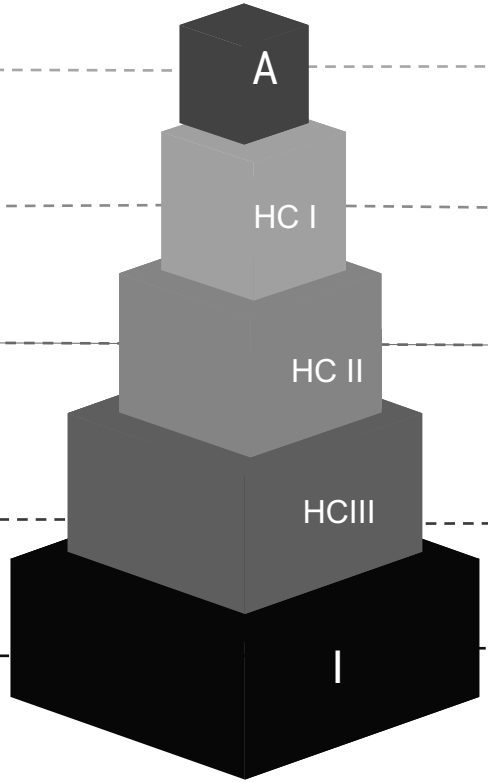
Aseptic
Cleanable in place (or by disassembly) sterilizable, prevention of microbial ingress

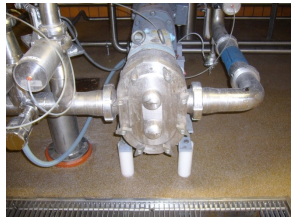
Hygienic Class I
Cleanable in place, full drainability

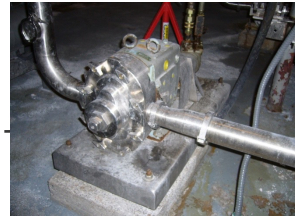
Hygienic Class II
Cleanable, but disassembly needed

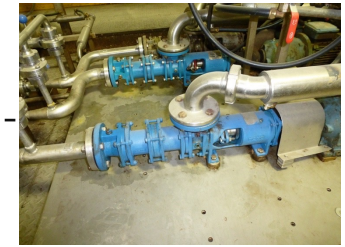
Hygienic Class III
Limited cleanability, validated for intended use

Industrial
Materials of construction fit for food product contact surface









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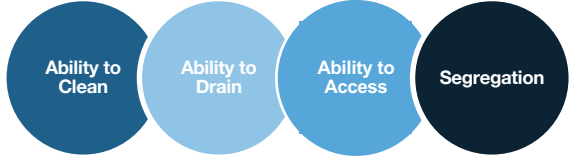
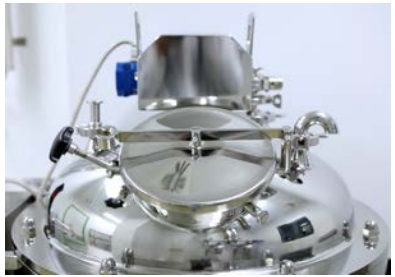
Hygienic Design Requires Integration



Part

Module

Unit



Line

e.g.,
Hygienic welding
Hygienic cabling
Hygienic process control/automation
Hygienic installation

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Outcomes of HDRM for legacy or new equipment

LEGACY

- *No immediate action required* - equipment remains fit for its intended purpose
- *Operational changes required* – risk mitigation can be applied by changes in e.g.,
  - maintenance practices
  - cleaning programmes
  - operating procedures
  - product restrictions
- *Needs improvement* - modifications / refurbishment of equipment is required to restore entity to “fit for purpose”

NEW EQUIPMENT

Final HDRM report typically includes

- Scope, context, criteria
- Considered contaminants
- Identified hygiene risks and priority

Risk reduction measure decisions

- HD principles – part of purchase specifications
- Instructions for Use
- Operational procedures, PRPs/OPRP’s

Resulting in residual, but accepted hygiene risks

In addition

- Date & Team members
- Coding and references to (technical) documentation
- Proof of verification
- Adding evidence e.g., pictures, drawings, Declaration of Compliance

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IN SUMMARY

- Equipment design is essential to manage food safety
- Within Cargill, we have an established risk-based approach to achieve this goal

Contact: Patrick Wouters


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Helping the world thrive

Q&A

SAVE THE DATE

The next FSSC Insights Webinar is scheduled for:

Date: 23 May 2024

Time: 1 PM CEST

Topic: FSSC 22000: A Market Perspective

THANK YOU

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