FSSC INSIGHTS

presents

FSSC 22000

ONE YEAR OF VERSION 6: TOP NONCONFORMITIES AND GUIDANCE

25 March 2025

FSSC 22000

OUR SPEAKERS

Kelly Mulholland

Technical Manager Safety & Quality
FSSC

Patrick Wouters

Cargill Global Hygienic Design Lead
EHEDG Working Groups Chair

PRESENTER: COLIN MORGAN

MARKET DEVELOPMENT DIRECTOR
FSSC

TODAY'S TOPICS

01 About Foundation FSSC

02 Most Common Version 6 Nonconformities of 2024

03 Most Common Version 6 Nonconformities for New Additional Requirements

04 EHEDG Guideline 58: Hygienic Design Risk Management

05 Q&A Session

PRACTICALITIES

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

ABOUT FOUNDATION FSSC

- ✓ Foundation FSSC is the independent non-profit owner of the **FSSC 22000 & FSSC 24000** Schemes, delivering trust and impact beyond certification.

- ✓ We support the consumer goods industry in protecting its brands and achieving its targets through the implementation of an effective **ISO-based management system.**

- ✓ We are a lean and collaborative Foundation that aims to help organizations contribute to the global **SDGs** and thus **create a better world.**

FSSC 22000

FSSC BRAND IDENTITY

FSSC 22000

MOST COMMON VERSION 6 NONCONFORMITIES OF 2024

KELLY MULHOLLAND

TOP 15 NONCONFORMITIES

	Requirements		
1	Quality Control	9	Food Loss and Waste
2	Physical Contamination	10	Control of Monitoring and Measuring
3	Food Safety and Quality Culture	11	Competence
4	Traceability System	12	Equipment Management
5	Preventive and Corrective Maintenance	13	Storage of Food, Packaging Materials, Ingredients and Non-Food Chemicals
6	Internal Structures and Fittings	14	Cleaning and Sanitizing Programs
7	Environmental Monitoring	15	Management of Services and Purchased Materials
8	Management of Allergens		

*Figure is based on 2024 Data Trending for FSSC 22000 Version 6

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COMMON CRITICAL NONCONFORMITIES

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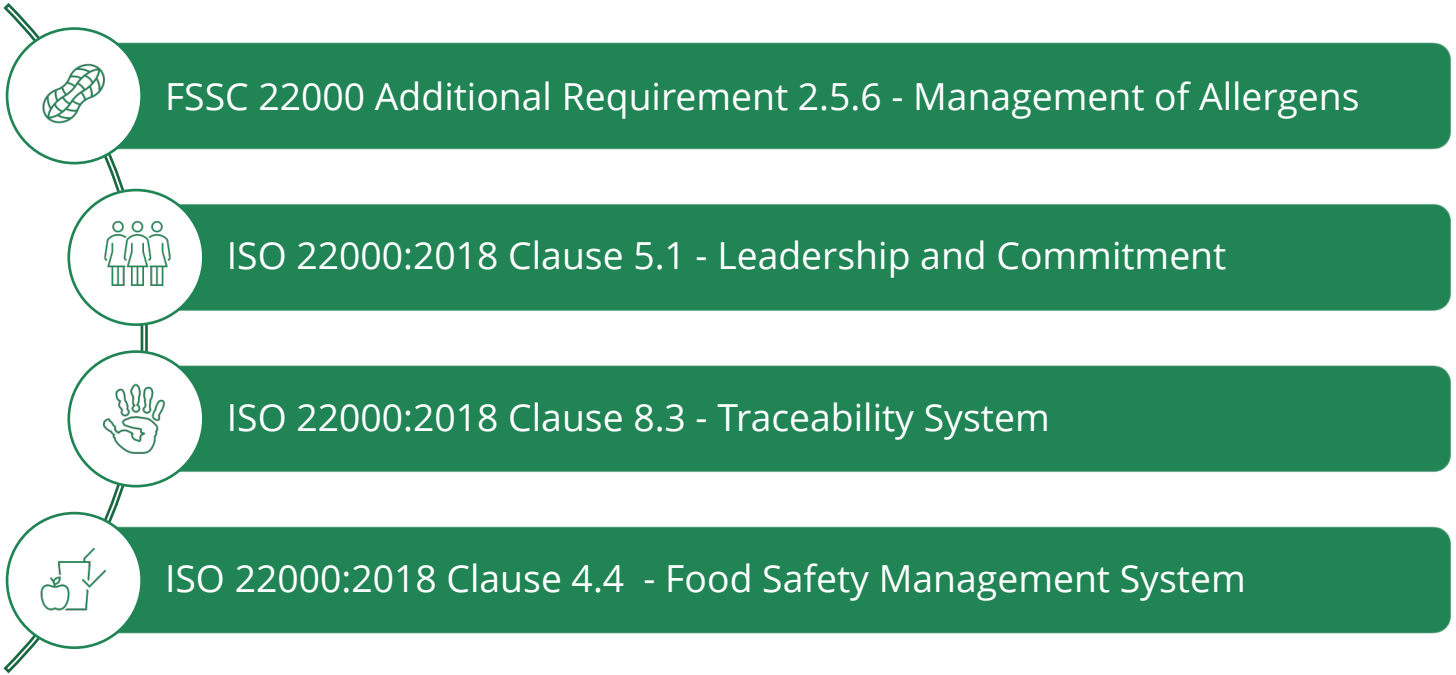

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TOP 15 MAJOR NONCONFORMITIES

	Requirements		
1	Internal Audits	**9**	**Food Loss and Waste**
2	Traceability System	**10**	**Quality Control**
3	Nonconformity and Corrective Action	**11**	**Product Labeling and Printed Materials**
4	Monitoring Systems at CCPs and OPRPs	**12**	**Equipment Management**
5	**Environmental Monitoring**	13	Competence
6	**Management of Allergens**	14	Validation of Control Measure(s)
7	**Food Safety and Quality Culture**	15	Preventive and Corrective Maintenance
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TOP 15 MINOR NONCONFORMITIES

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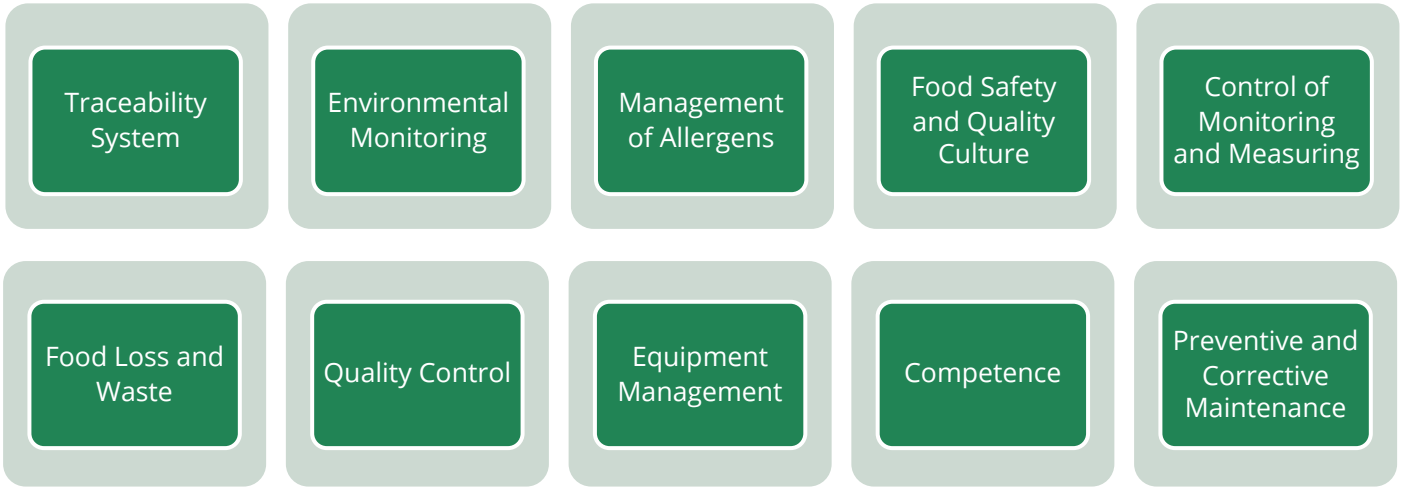
MAJOR AND MINOR NONCONFORMITIES

Requirements resulting in common major and minor nonconformities:



MOST COMMON V6 NONCONFORMITIES FOR NEW ADDITIONAL REQUIREMENTS

QUALITY CONTROL

The four most common areas for nonconformities include:

Quality Parameters, Implementation and Release

Quantity Control Procedures

Removal of Labeling and Packaging from Previous Run

Line Start-Up and Change Over Procedures

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QUALITY CONTROL

- Mandatory Scheme interpretation article
- Available for download on fssc.com

Click here to access the Quality Control Scheme Interpretation Article

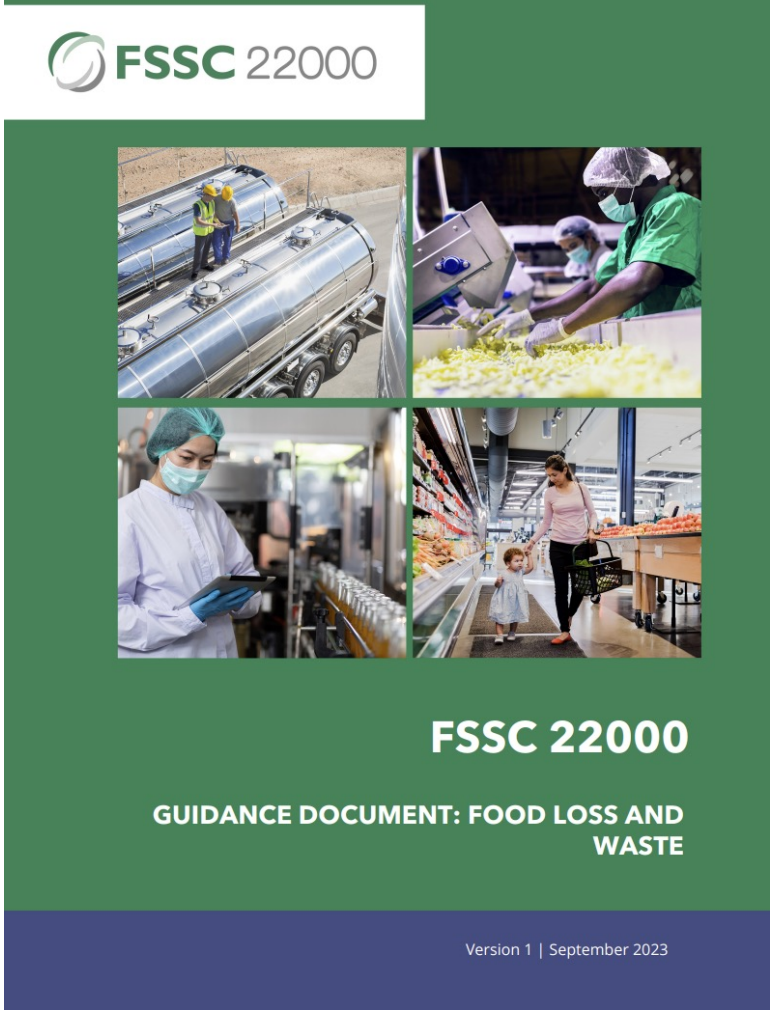
FOOD LOSS AND WASTE

Most common NC related to Food Loss and Waste:

FOOD LOSS AND WASTE

- Voluntary Guidance document
- Freely available for download on fssc.com

Click here to access the Food Loss & Waste Guidance Document



EQUIPMENT MANAGEMENT

Documented Purchase Specification

Risk-Based Change Management Process

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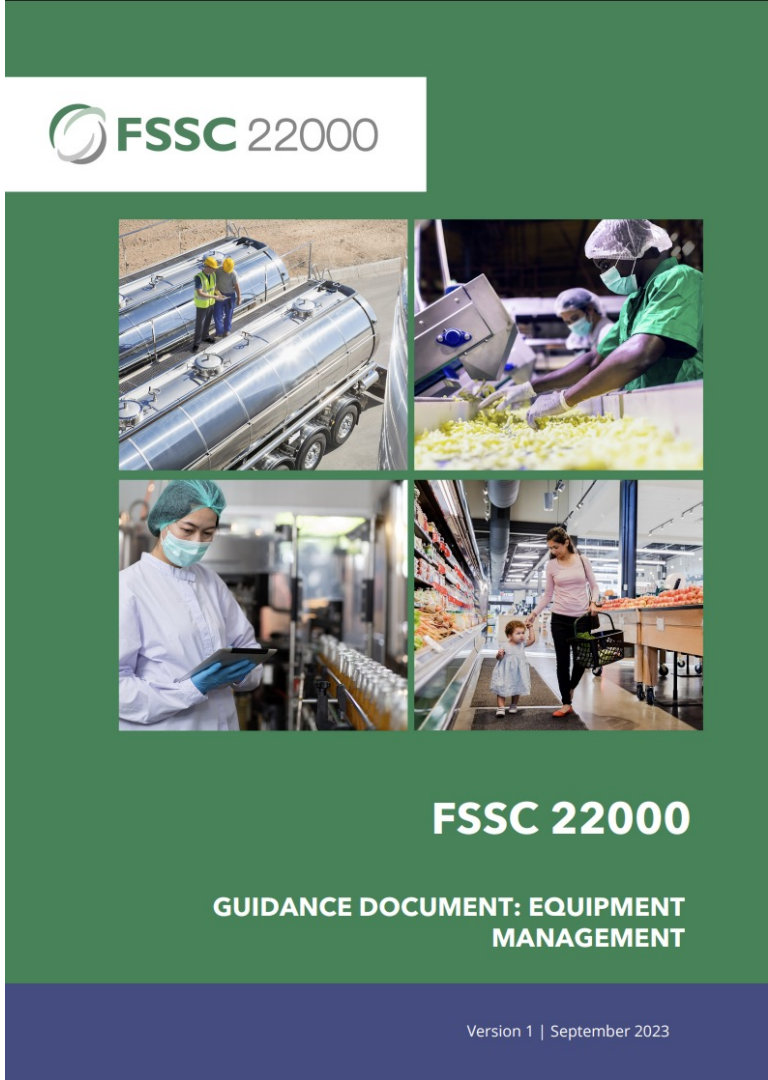
EQUIPMENT MANAGEMENT

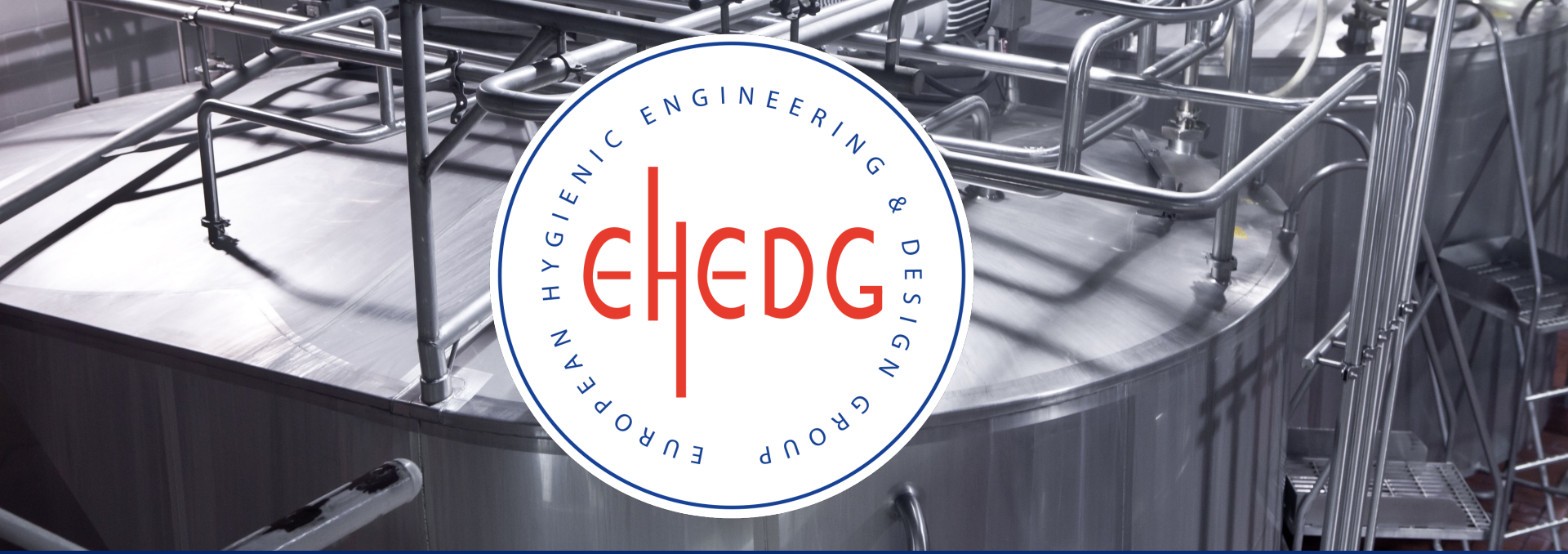
- Voluntary Guidance document
- Freely available for download on fssc.com

Click here to access the Equipment Management Guidance Document



EHEDG GUIDELINE 58: HYGIENIC DESIGN RISK MANAGEMENT

PATRICK WOUTERS

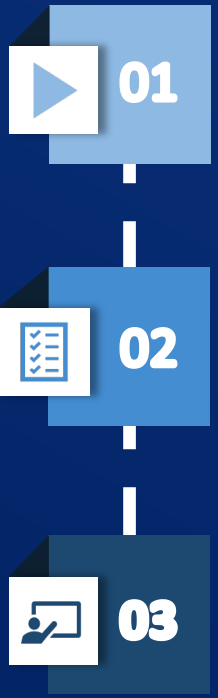


EHEDG Guideline 58; Hygienic Design Risk Management

Patrick Wouters (PhD) - Hygienic Design Lead Cargill and EHEDG Working Groups Chair

March - 2025

Agenda



Introduction

EHEDG Doc 58 HDRM Guideline Explained

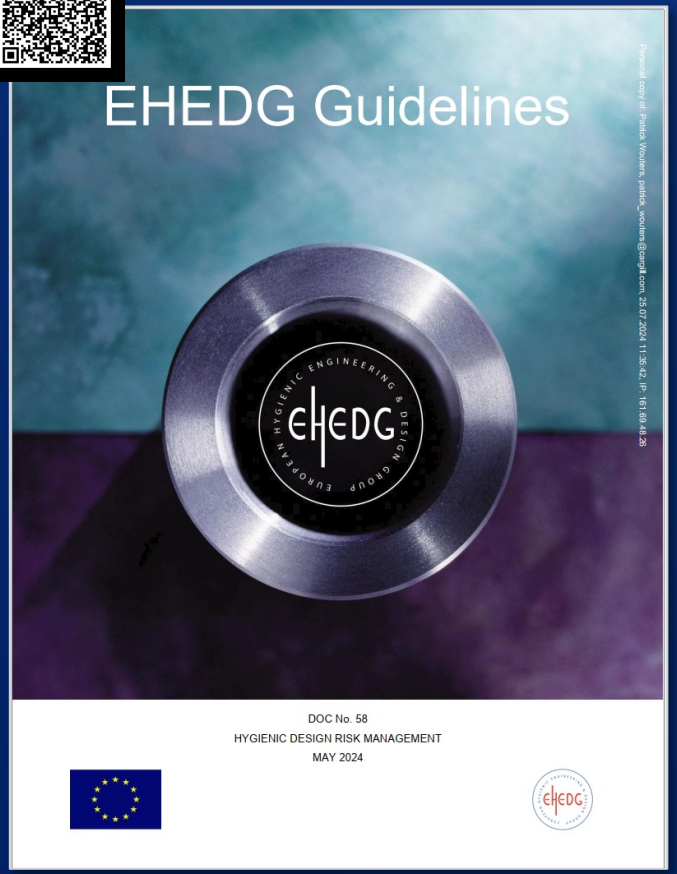
Examples and Closing Remarks

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, efficient and sustainable operations



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.

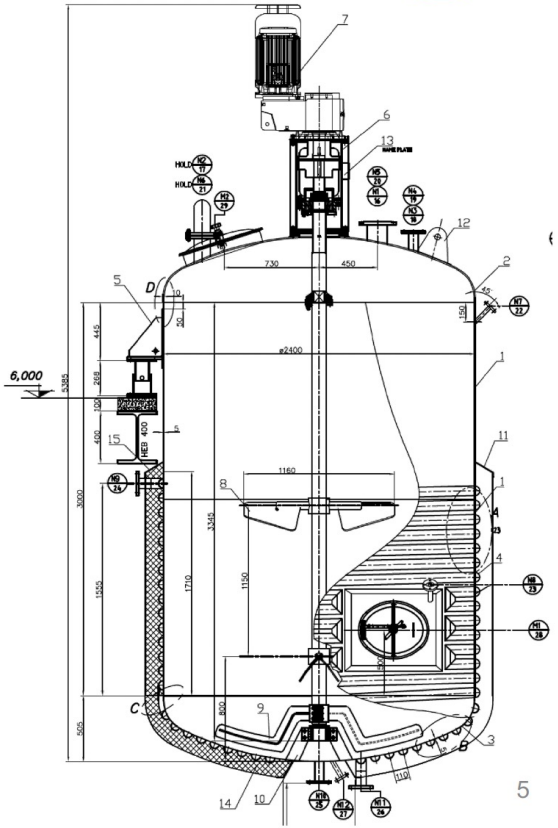
Scope

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)

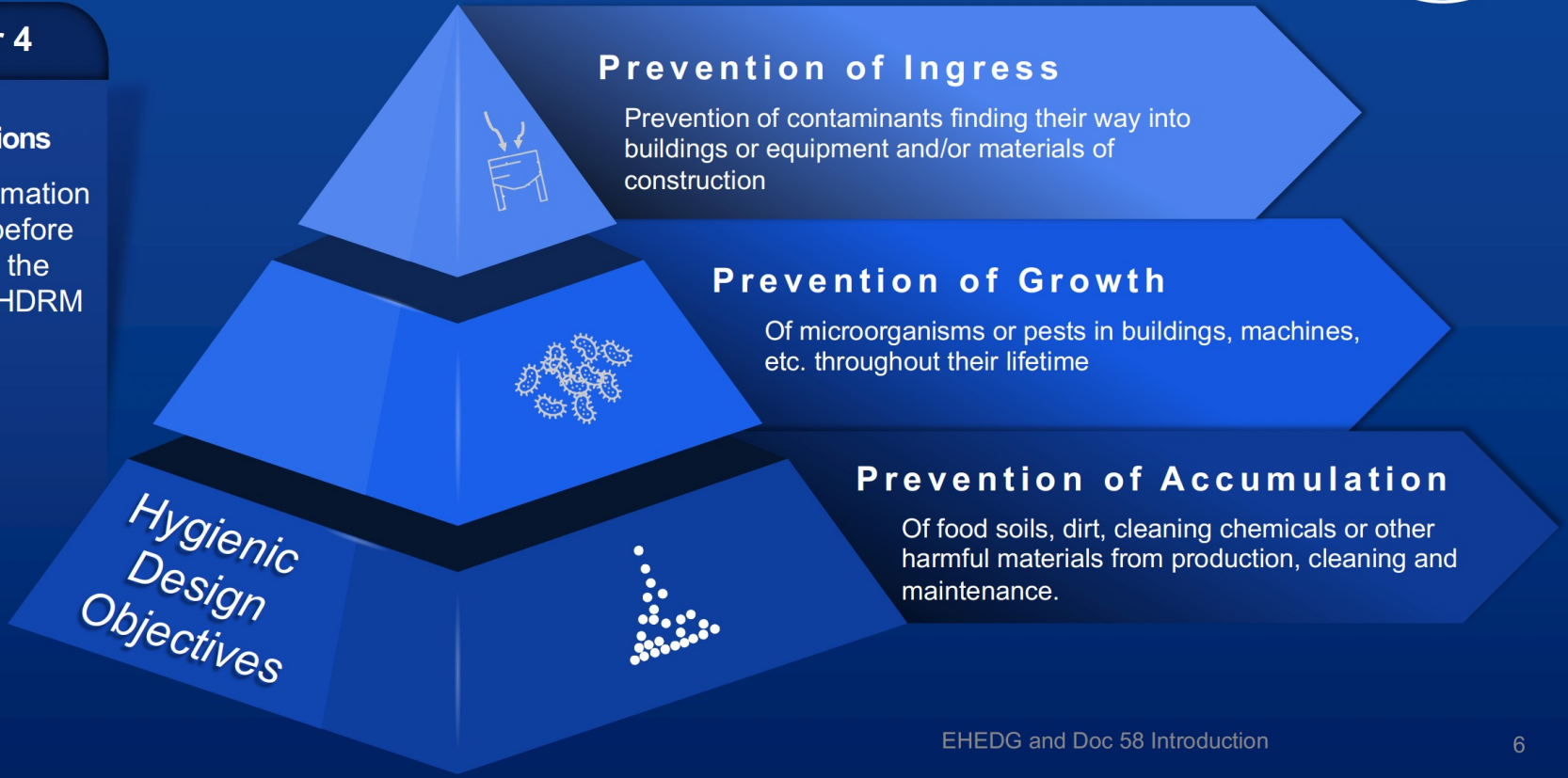


General

Chapter 4

Considerations

Provides information to consider before and during the execution of HDRM



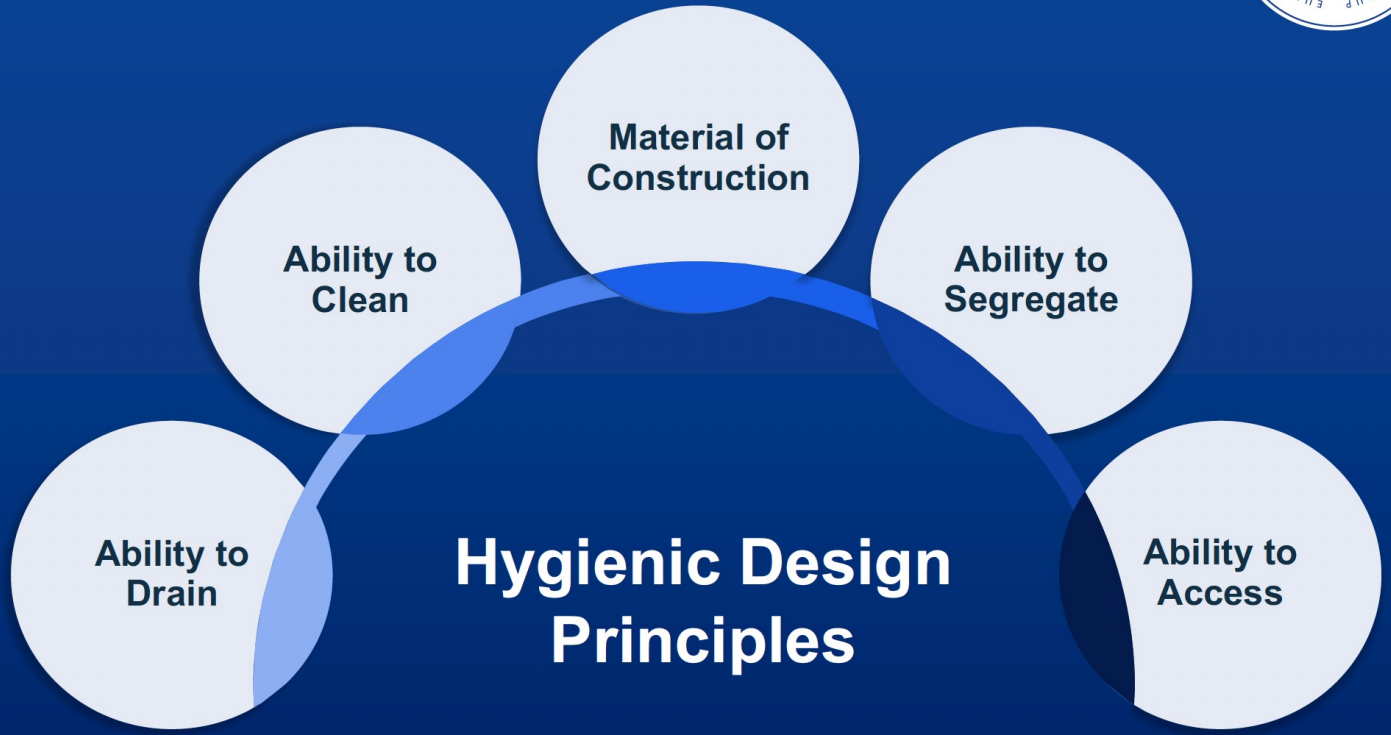
General

Chapter 4

Considerations

It is advisable to familiarise yourself with the content before starting the HDRM study

For more about Hygienic Design Principles check Doc n° 8



Hygienic Design Risk Management Approach

Create multidisciplinary team

Define design requirements based on product and process requirements and conditions

Determine/review operational procedures and validate/verify to manage remaining risks

Understand scope, context, criteria

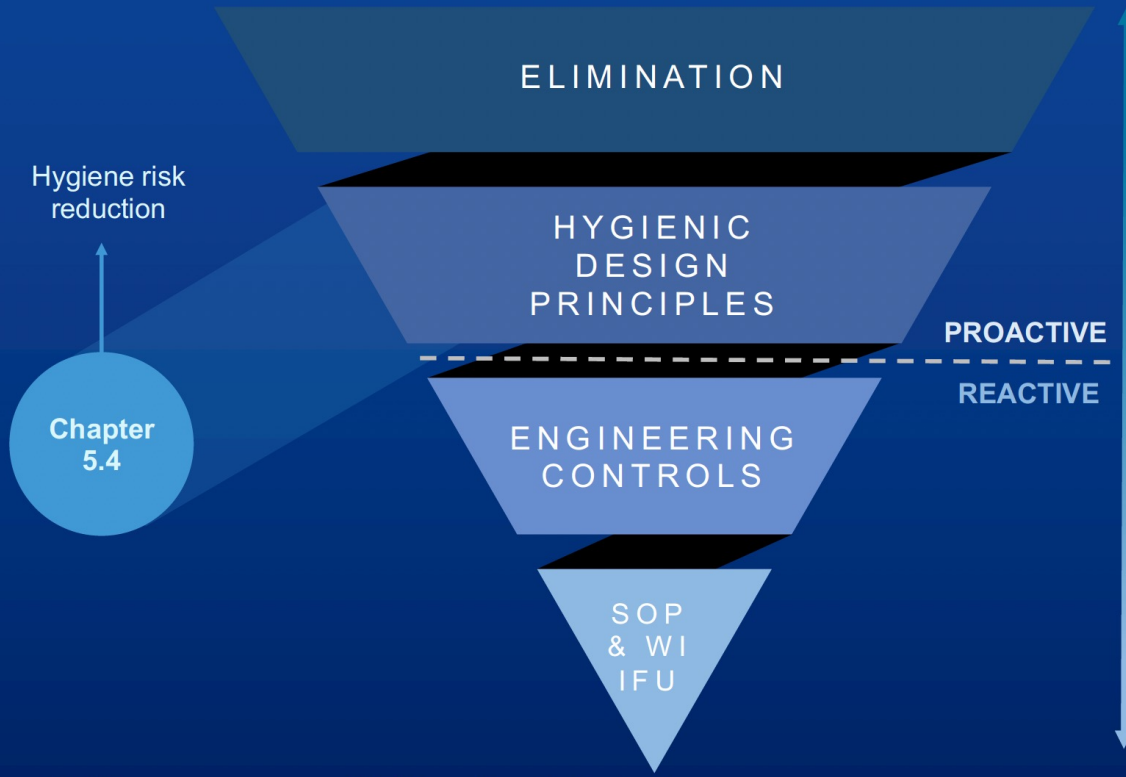
Perform HD risk-assessement taking into account the life cycle stages of buildings and equipment

Review technical engineering documents e.g. drawings, plot diagrams, PI&D's, plant visit (legacy)

The design phase and physical life cycle of equipment and facilities

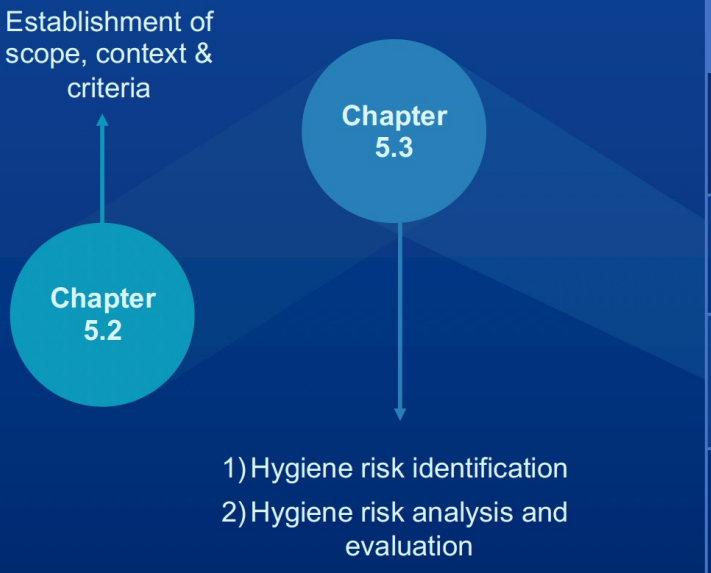
Design Phase 1	Engineering & Construction 2	Installation & Commissioning 3
Operations - Remaining Hazard Mitigation by SOP's 4	Maintenance 5	Change Management 6

Hygienic Design Risk Management



Hygiene risk identification	Hygiene risk reduction through design
Hygiene risk description justification	**Risk reduction measure [from more efficient & reliable to less efficient & reliable]**
lubricants	[Elimination] Design out Lubricant
water or other liquid residues remaining in the pump during idle time leading to microbiological growth potential	HD Principle Ability to Drain - Install the pump in a drainable position when delivered e.g. on a framework
due to static seal breakage / deterioration: (Pieces of) Machine components or material of construction, e.g. rubber, (corroded) metal, plastic	HD Principle Material Compatibility - Select correct materials of construction for replacement parts

Hygienic Design Risk Management

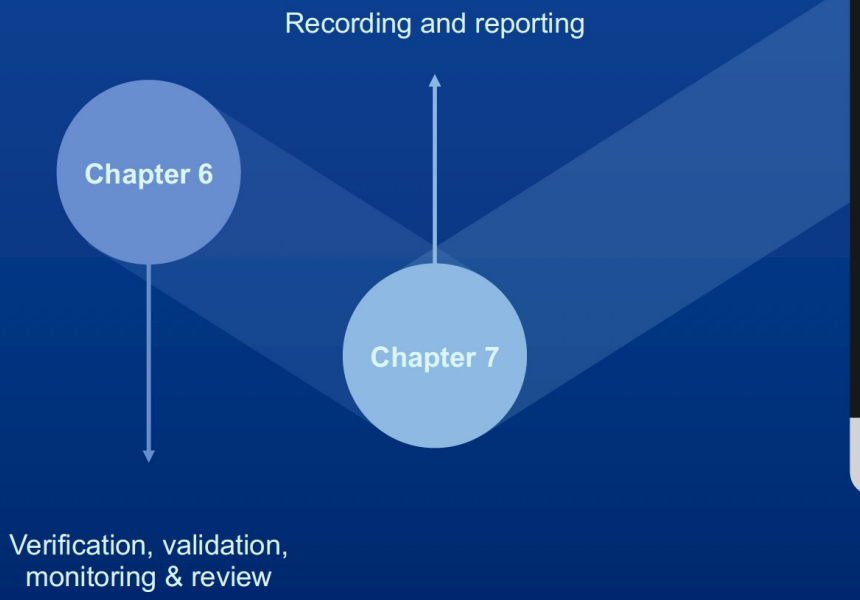


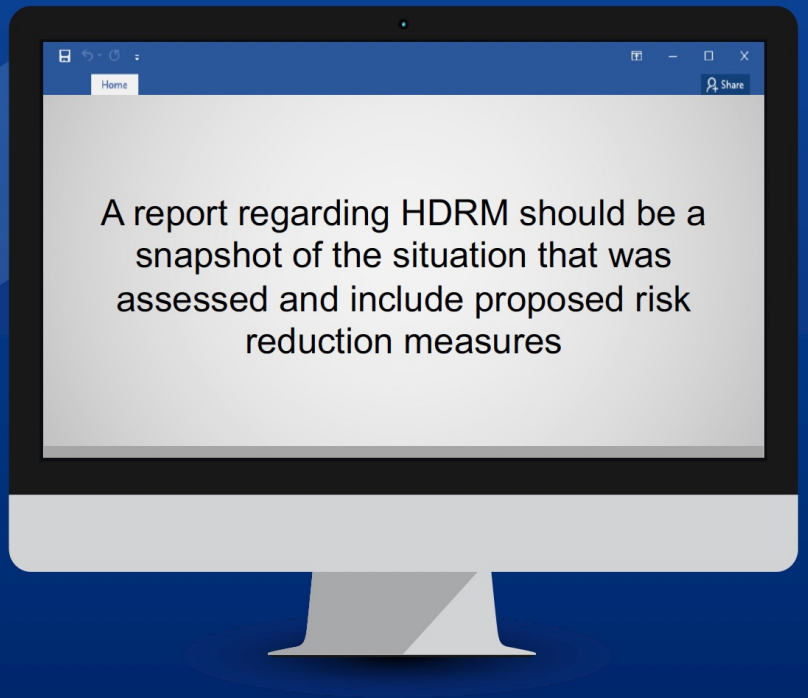
Hygiene risk assessment - Example

Hygiene risk identification					Hygiene risk analysis & evaluation		
No	**Physical life cycle**	**Contaminant** incl. food safety hazards and quality threats	**Mechanism** ingress-accumulation-growth	**Hygiene risk description** justification	**Likelihood**	**Negative Impact**	**Risk Level**
1	Processing	chemical	ingress – entry from outside	lubricants	ME	HI	HI
2	Cleaning	biological	accumulation	water or other liquid residues remaining in the pump during idle time leading to microbiological growth potential	ME	ME	ME
3	Maintenance	physical	ingress – generation within inside	due to static seal breakage / deterioration: (Pieces of) Machine components or material of construction, e.g. rubber, (corroded) metal, plastic	HI	ME	ME

Likelihood x Negative Impact = Risk Level

Hygienic Design Risk Management





Hygienic Design Risk Management

Appendix 1
Key Learning points

Appendix 2
Checklist - Scope, Context & Criteria

Appendix 3
Checklist Hygiene Risk Identification

Appendix 4
Checklists Hygienic Design Principles

- 4-1 Checklist and Related Criteria to Manage Various Contaminants
- 4-2 Checklist HD Principles Equipment and Risk Reduction Measures
- 4-3 Checklist HD Principles and Hygiene Risk Reduction Guidance for Buildings

Appendix 5
HDRM Examples

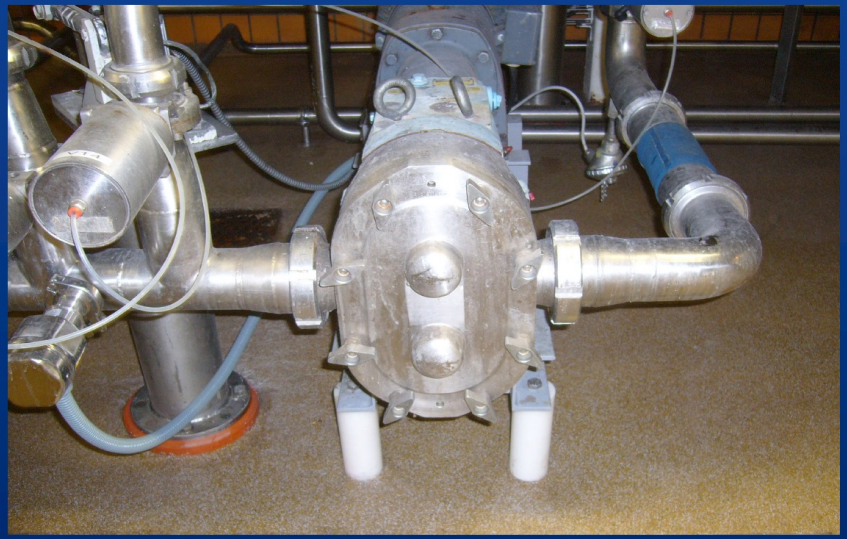
- 5-1 Generic Pump
- 5-2 URS Pasteurised milk pump
- 5-3 Room Design
- 5-4 Incident investigation legacy situation
- 5-5 Example Conveyor
- 5-6 Process line
- 5-7 Mix-proof valve
- 5-8 Change intended use legacy equipment

Examples

Hygienic Design Risk Management (HDRM) Example of a Legacy and New Building Situation

Legacy

Context: Lobe pump for tomatopaste

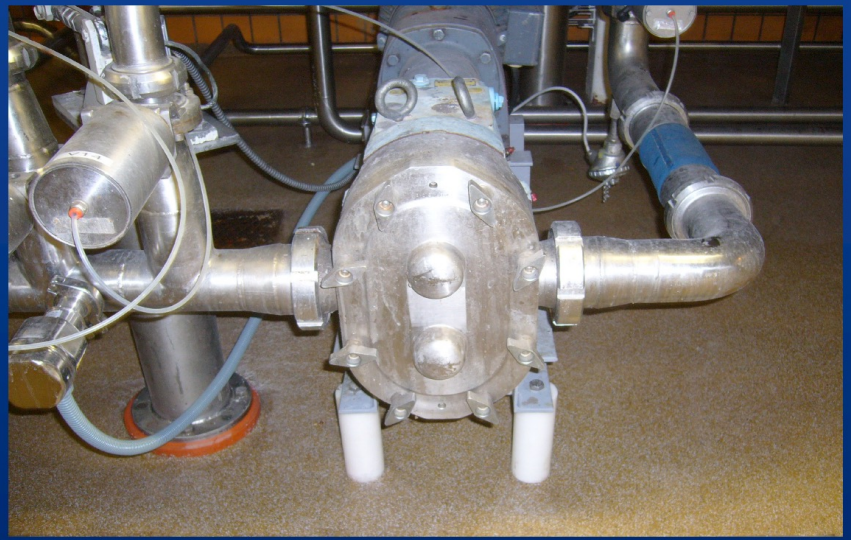


Hygienic Design Risk Management - Example

Hygiene risk identification					Hygiene risk analysis & evaluation		
No	**Physical life cycle**	**Contaminant** incl. food safety hazards and quality threats	**Mechanism** ingress-accumulation-growth	**Hygiene risk description** justification	**Likelihood**	**Negative Impact**	**Risk Level**
1	Processing	chemical	ingress – entry from outside	Lubricants entry into the product stream	ME	HI	HI
2	Cleaning	biological	accumulation	water or other liquid residues remaining in the pump during idle time leading to microbiological growth potential	ME	ME	ME
3	Cleaning	biological	growth	Product residues remaining due to inadequate the cleaning	HI	HI	HI

Legacy

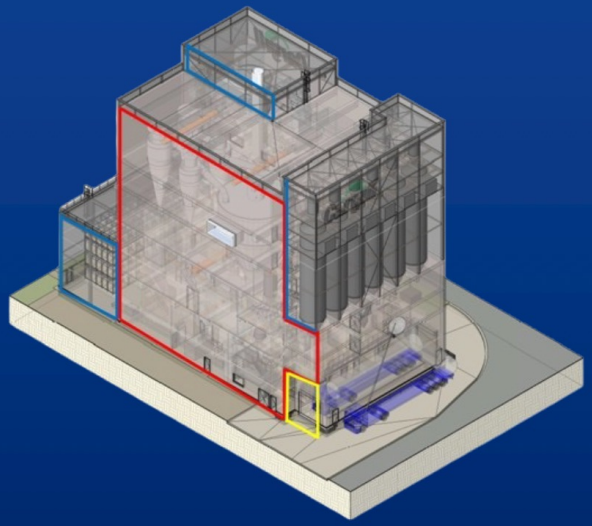
Context: Lobe pump for tomatopaste



		Risk reduced to an acceptable level?
		Yes/No
		Yes
		Yes
		Yes

New – Building Design

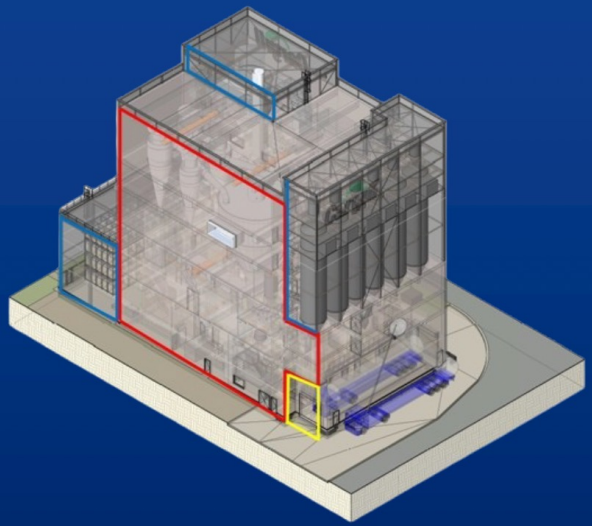
Context: New room design for milk packaging line



Scope, Context, Criteria (information about the room)	Why relevant?	Room (number) 1
Room purpose / processing activity	This will provide an idea of what the room is for – e.g. storage, dry ingredients blending, pasteurisation, packaging etc.	Milk packaging / filling room
Hygiene zone / transition zone	Level of hygiene influences, design requirements and finishing levels, materials of construction	Medium Hygiene Zone (MHZ)
Zone/room cleaning method	Will determine if, for example, drains are needed. Influences construction materials	Wet
Frequency of zone/room cleaning	Influences the rigidness of the design	At least twice per week
Types of chemicals	Influences floor materials and other materials of construction	Caustic, acid
Environmental temperature	Will determine level of insulation, risk of condensation formation, etc.	Ambient
Traffic	This will impact floor construction, types of doors, space requirements to prevent cracks/floor damage, which could lead to hygiene issues, etc.	Medium, with people and materials
Product (ingredients) information (e.g. stickiness, pH) - what's the risk of dust formation?	These aspects will influence the choice of construction materials, floor, wall design, from an ability to clean or other perspectives	Product is of neutral pH; however, cleaning will be done with many chemicals. No risk of excessive dust formation
Other requirements as defined by the team	List here any other aspects regarding room design that should be taken into consideration to manage hygiene issues.	For example: Dedicated area for small equipment COP cleaning activities

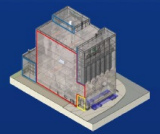
New – Purchase/Design

Context: New room design for milk packaging line



Element	Hygiene risk Identification			Hygiene risk analysis & evaluation		
	Contaminant	Contamination mechanism	Hygiene risk description	Likelihood	Negative impact	Risk level
Ceilings	Dust, pest	Accumulation	Ceiling to be designed to prevent pest entry and be easy to clean	Medium	Medium	ML
Doors (external)	Microorganisms and pests	Ingress	Air movement	High	Medium	HL
Doors (internal)	Microorganisms and pests	Ingress	Movement of air, people, materials, connection between different hygiene zones	High	Medium	ML
Drain	Microorganisms, pests	Accumulation & growth	Growth of microorganisms, pest entry	High	Medium	HL
Lifts	Microorganisms	Ingress	Connection between different hygiene zones	Medium	Medium	ML
Floors	Product residues/microorganisms	Accumulation and growth	Water accumulation on floor may result in microbiological growth	High	Medium	HL
Junctions	Microorganisms, pests	Accumulation and growth	Junctions are the perfect spots for dirt and debris accumulation, which can attract pests and result in microbiological growth	High	Medium	HL
Lighting	Pests, foreign material	Growth	Lights may attract pests or can accumulate dust or can break	Medium	Medium	ML
Secondary structures	Microorganisms	Growth	Platform design may result in microbiological growth if not designed to be cleanable	Medium	Medium	ML
Walls (internal)	Pest and microorganisms	Accumulation & growth	Wall	Medium	Medium	ML
Windows	Foreign material	Ingress	Risk of breaking	Low	High	ML

New – Purchase/Design

Element	Examples of design requirements for each HD Principle				
	Material compatibility	Ability to clean	Ability to drain	Ability to segregate	Ability to access
Ceilings	Ceiling to be designed using light-coloured, dense, tough (made of materials unable to provide harbourage for pests), impact-resistant, durable, rustproof, unable to absorb grease or food particles.	Sandwich panel / FRP panel. Surfaces without exposed structures.	Design should not allow for accumulation of moisture.	Ceiling to be designed to segregate utilities and roof structures and to be insulated to prevent condensation.	Ceiling to be installed so as to allow access for inspection, maintenance and cleaning.
Doors (external)	All external (emergency) doors to be weatherproof and waterproof, effectively sealed against pest ingress and not opening directly into food production areas (except emerg doors which have to be alarmed).	Doors, especially on the inside, designed for cleanability, no ledges, smooth surface.		Doors fitted with kick plates, push plates and self-closing. Doors designed to prevent (un)intentional opening from the outside.	Closing plates of the door lock trimmed into the frame to avoid gaps where pests can enter, or which may be difficult to clean.
Doors (internal)	Internal doors made of light-coloured, solid, tough, impact-resistant, durable materials. Internal doors rustproof, able to withstand cleaning chemicals, non-absorbent and constructed of non-toxic materials.	Door closing device must not accumulate residues. Doors having smooth surfaces, no sharp corners or ledges.	Internal doors must close tightly to the floor and frames to prevent excessive air movements and pest access.	Closing plates of the door lock trimmed into the frame to avoid gaps where pests can enter, or which may be difficult to clean. Sliding doors have all gaps closed between the door and the frame.	
Drain	Drainage system components (gullies, channels, gratings, etc.) made from compatible materials to prevent corrosion or wear (e.g. stainless steel or concrete).	Drain components easy to clean, free of crevices or dead spaces, with continuous welding of joints, radiused corners, smooth surfaces.	Drain location allows easy drainage of (waste) water/fluids. Drain design capable of removing all wastewater from the drain itself and the floor, and of preventing puddles around drains.	Drainage system installation prevents contaminated water leakage. Process lines physically segregated from the drain by an atmospheric break. Drainage system has sediment baskets to capture solid material.	Drain location allows easy access for cleaning, inspection and maintenance. Channel design allows easy access for manual cleaning and complete visual inspection - slot channels must be avoided.
Lifts	Lifts made from materials that are durable, dense, tough and able to withstand the cleaning chemicals and methods used.	Lifts designed to be easy cleanable.		Lift doors opening in corridor, not in production area.	Lift base (and headspace) protected from pest access and easily accessible for cleaning.
Floors	Floor material rigid, durable, slip-resistant, resistant to food products and ingredients, resistant to chemicals and corrosion, impervious, non-absorbent, non-toxic, causing no cracks, holes or other defects.	Equipment floor fixings effectively sealed. Number of joints in the floors minimised and positioned in less critical areas. Floor joints designed not to create any hygiene risk and accommodate the anticipated movements in the process area.	Floors designed to slope or fall towards drains effectively to ensure that all process and cleaning water is removed from the process area. Floor penetrations at least 10 cm high and watertight and the junction to the floor rounded.	Damp course installed to protect the floor from rising damp (where applicable).	

Benefits of Doc 58 HDRM Guideline

HDRM Model: systematic, iterative process, considers all life cycle phases from the entity assessed

Highlights importance of user-supplier communication

Risk reduction pyramid

Risk identification checklist

Checklists with risk reduction measures

Aligned with V-model approach (incl. qualification phases) – EHEDG Doc 34

Any questions?

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Thank you!

Patrick Wouters PhD

Global Hygienic Design Lead

Patrick C. Wouters is the Global Hygienic Design Lead at Cargill. He has 34 years of experience in Food and Beverage Production, R&D, Hygienic Design & Engineering and Quality Management.

Joined Cargill 10 years ago Patrick and before worked at Unilever and in the dairy industry in The Netherlands (AMC & Melkunie). He is the Working Groups Chair of the European Hygienic Engineering & Design Group (EHEDG) and an authorized hygienic design trainer.

Patrick holds a PhD degree on food preservation technologies from the Technical University of Berlin, Germany. Prior to his professional career he was in the Dutch Army.

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Q&A

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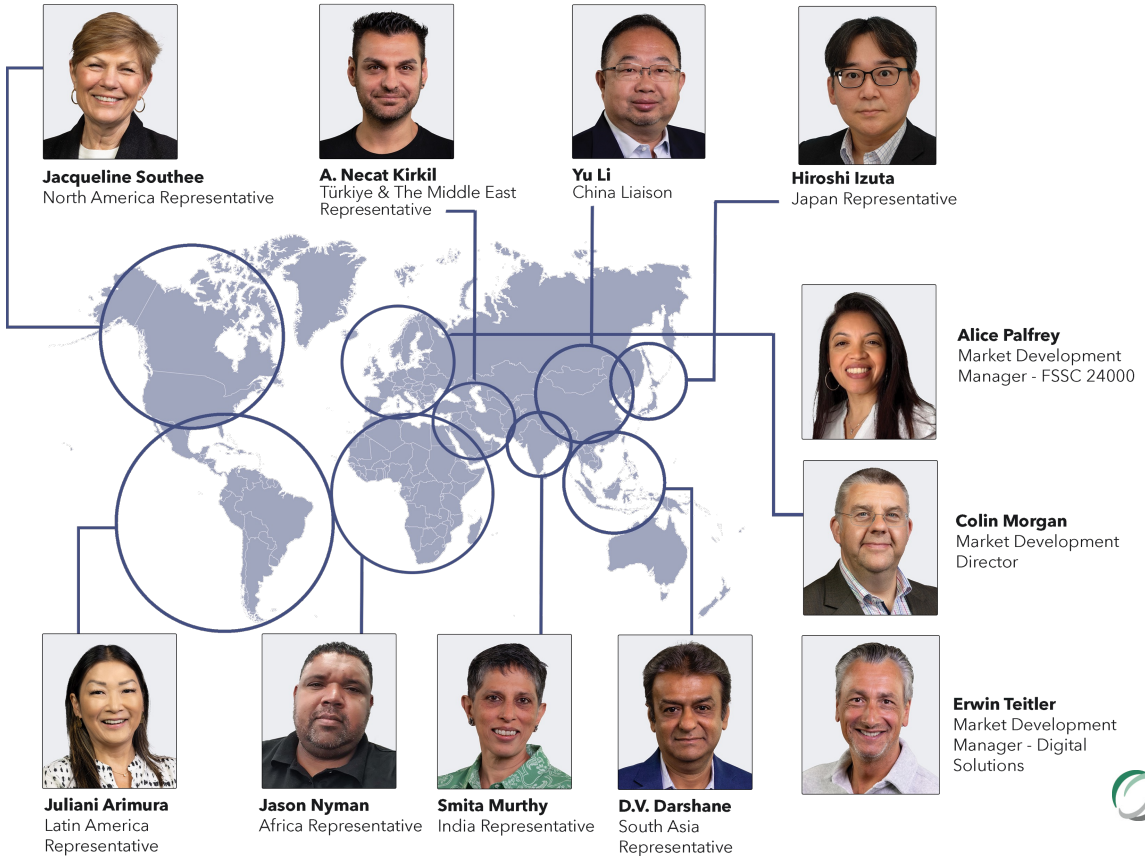

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