

# GFSI Hygienic design initiatives vs industry push?

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### A 100 year history

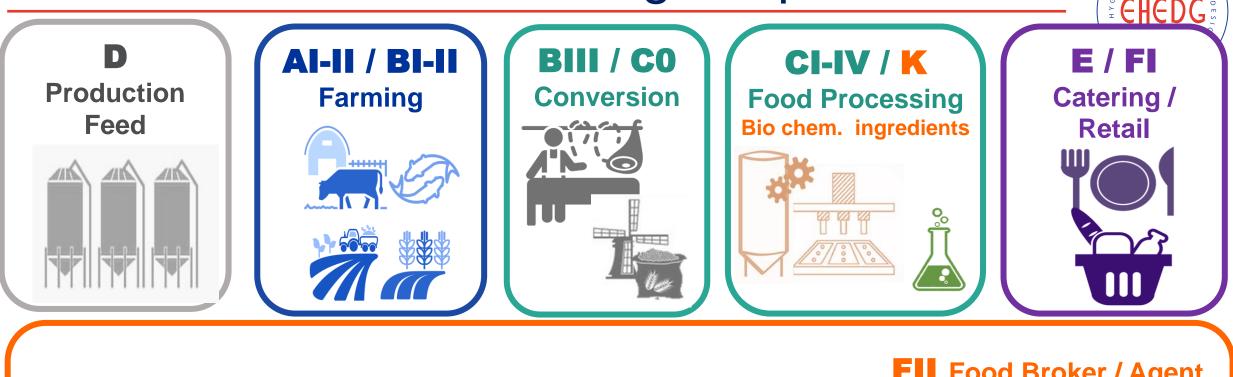
- 89/392/EEC
- GFSI Technical
   Working Group: Hygienic design of facilities and
   equipment. 2018/19





- EHEDG
- 3-A
- NSF
- GMA
- NAMI
- ISO 14159
- EN 1672-2
- Books
- BSc/MSc programmes
- Training courses

#### **GFSI 2020 Benchmarking Scopes**



 $\bigotimes$ 

 $\checkmark$ 

FII Food Broker / Agent
 G Storage & Distribution
 H Food Safety Service
 I Food Packaging
 J I-II Hygienic Design

#### 4.6 Equipment

All production and product-handling equipment shall be suitable for the intended purpose and shall be used to minimise the risk of contamination of product.

Clause	Requirements
4.6.1	There shall be a documented purchase specification for any new equipment detailing the site requirements for the equipment. This may, for example, include:
	<ul> <li>any relevant legislation</li> <li>where applicable, requirements for food contact surfaces to meet legal requirements</li> <li>details of intended use of the equipment and the type of materials it will be handling.</li> </ul>
	Depending on its intended use, new equipment to site (including second-hand equipment) may require authorisation from a multi-disciplinary team.
	The supplier should provide evidence that equipment meets these site requirements prior to supply.
4.6.2	The design and construction of equipment shall be based on risk, to prevent product contamination. For example, the use of the correct seals, impervious surfaces or smooth welds and joints, where they are exposed to product and could otherwise result in foreign-body, microbiological or allergen contamination of the product.
	Equipment that is in direct contact with food shall be suitable for food contact and meet legal requirements where applicable.
4.6.3	A documented, risk-based commissioning procedure shall be in place to ensure that food safety and integrity is maintained during the installation of new equipment to site.
	Installation work shall be followed by a documented hygiene clearance procedure.
	New equipment to site shall be inspected by an authorised member of staff before being accepted into operation.
	The commissioning procedure shall include the update of any other site procedures that are affected by the new equipment, for example, training, operating procedures, cleaning, environmental monitoring, maintenance schedules or internal audits.
	The design and placement of equipment shall ensure that it can be effectively cleaned and maintained.

#### CNGINEER NO <sup>4</sup> <sup>4</sup> <sup>5</sup> <sup>5</sup> <sup>6</sup> <sup>6</sup> <sup>6</sup> <sup>6</sup> <sup>6</sup> <sup>6</sup> <sup>6</sup> <sup>6</sup> <sup>6</sup> **GFSI** Certification Program Owners Auditing Bodies

BRGS

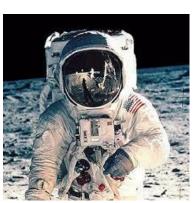
Global Standard FOOD SAFETY ISSUE 9

#### **Risk assessment basis**

• ISO/IEC 31010:2019 Risk management — Risk assessment techniques https://www.iso.org/standard/72140.html

• ISO/TR 22100-1:2021 Safety of machinery — Relationship with ISO 12100 — Part 1: How ISO 12100 relates to type-B and type-C standards <u>https://www.iso.org/standard/80420.html</u>

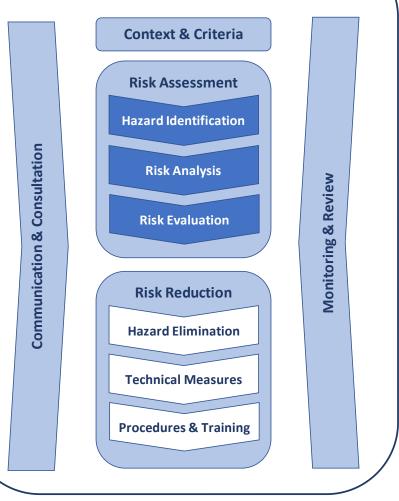
• ISO 12100:2010 Safety of machinery — General principles for design — Risk assessment and risk reduction <u>https://www.iso.org/standard/51528.html</u>

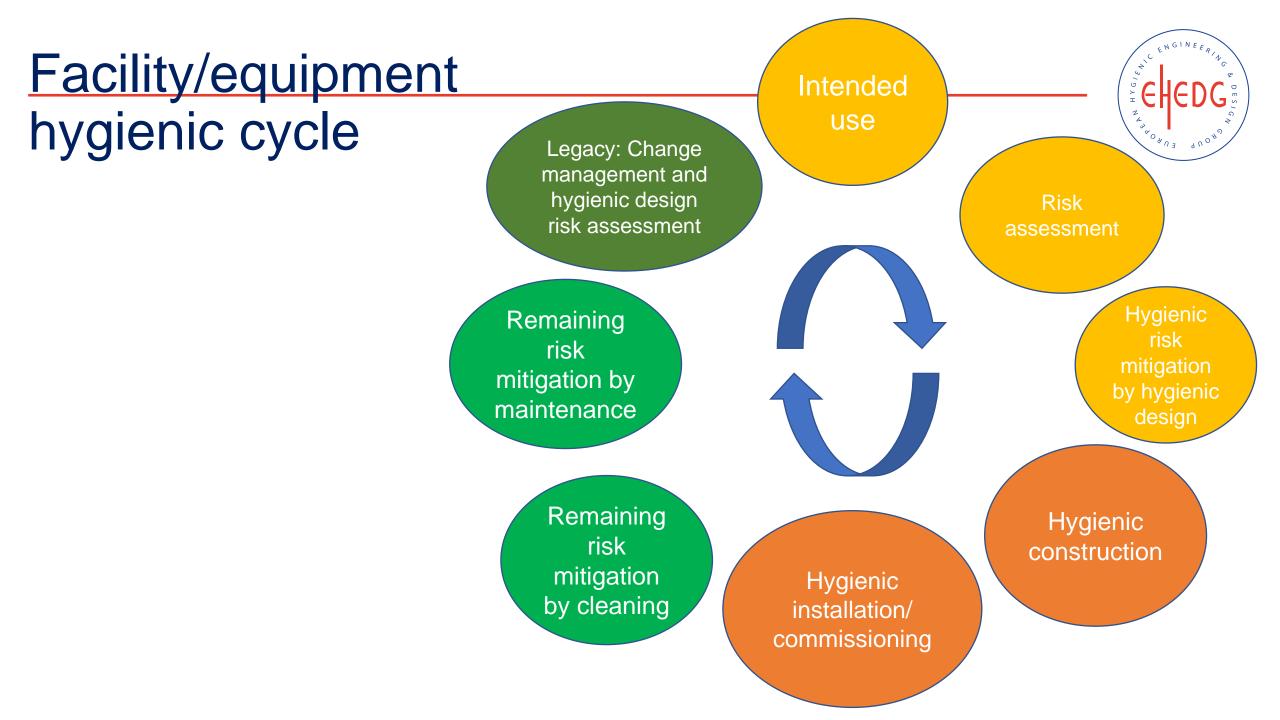


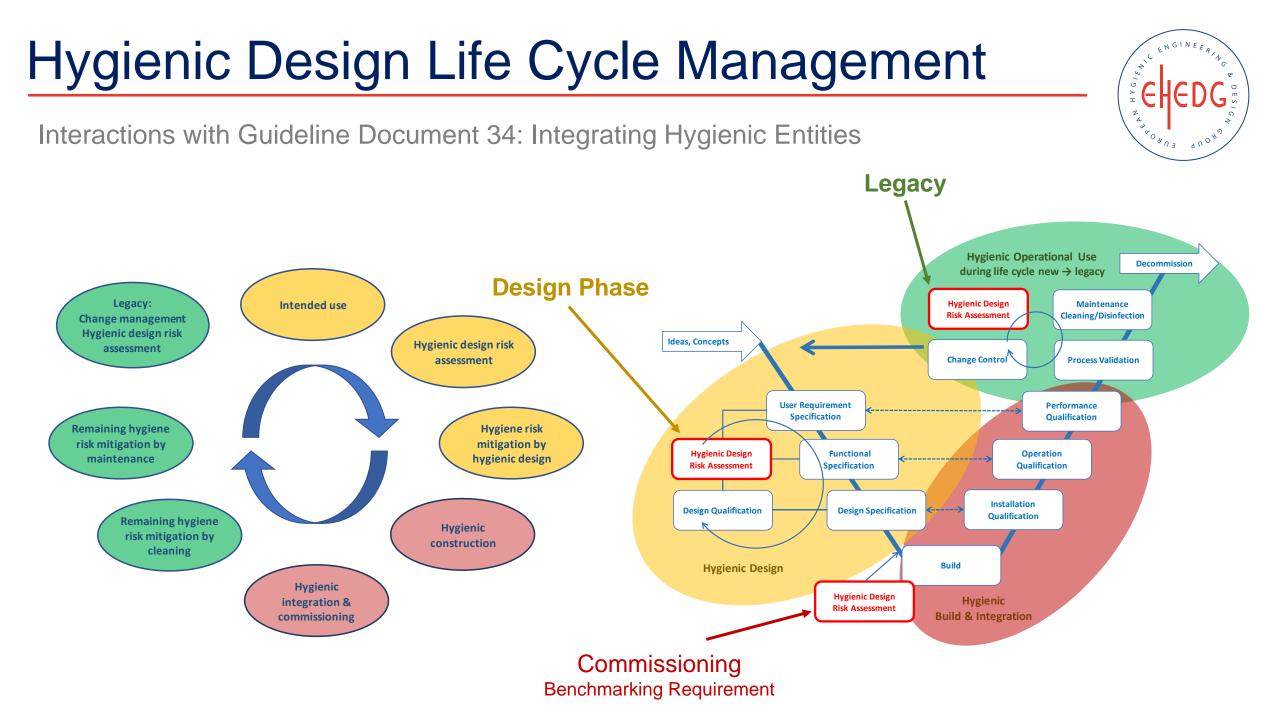




#### Risk Management







### HDRM multidisciplinary team

#### Disciplines

- Design
- Engineering
- Architecture and building construction
- Production & Operations
- Food Technology
- Food Safety and Quality
- Cleaning & Disinfection (Sanitation)



#### Knowledge base

- The basics of hygienic design requirements and principles for equipment and facilities
- The principles of hazard analysis and risk assessment methods and root cause assessments
- The basics of hygienic zoning
- Requirements and capabilities of the concerning products and processes
- Operational considerations that could affect hygienic design (e.g. cleaning method, operating conditions, possible future applications, etc.)
- Legal requirements and industry standards

#### Intended use

- Products
- Process
- Final consumer
- Cleaning conditions



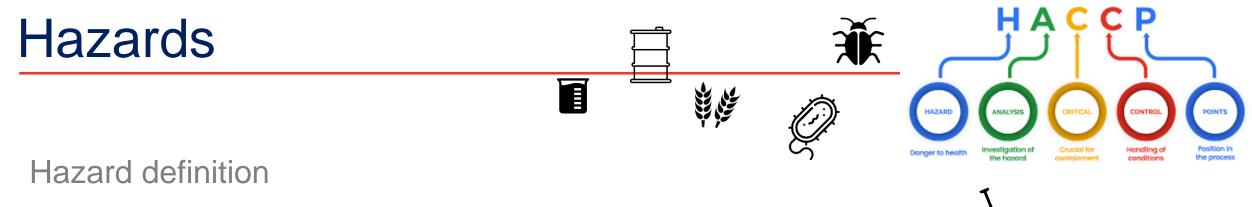
- Purpose
- Operating conditions
- Hygiene zone
- Operating environment
- Operating mode
- Life cycle
- Maintenance requirements
- Legal/standard requirements
- Customer requirements



#### Present, future, past



- Present. What products and volumes do I want to manufacture immediately that the factory is built, or the equipment installed? This will be the basis of the intended use.
- Future. What is my 5-year plan? What products and volumes could my customers expect from me in the future? Following horizon scanning, what trends are apparent that could change my ingredients, products or processes?
- Past. If I have been producing similar products in the past, in the same location, what lessons have I learnt? For example, environmental concerns and weather patterns, pest infestations, data from microbiological sampling of the equipment and environment, equipment cleaning and maintenance problems, hazards from equipment that have given rise to customer complaints.



- Could cause an adverse health effect to the consumer;
- could be introduced to the building or equipment
- and could be transferred to the food being processed
- These hazards typically include:-
- Chemical; allergens, lubricants, pesticides, cleaning chemicals Biological: microorganisms (bacteria, fungi, fungi), parasites, pests Physical: glass, plastic, rubber, metal, environmental debris

- 1. Hazard introduction. Hazards not initially present in the building/equipment may enter the building or equipment and become harboured within them. This may promote hazard survival.
- 2. Hazard accumulation. Hazards may accumulate through production processes in poor hygienic design areas, particularly dead spaces, or via inaccessibility for acceptable cleaning. Accumulation in this sense is the physical increase of the quantity of the hazard and will be dependent on process time and the applied cleaning programme.
- 3. Hazard growth. Under the correct environmental conditions (nutrient, water, temperature, time) some hazards such as microorganisms or pests may increase in number by biological growth. The degree of growth will also be dependent on process time.





### Other parameters also mitigated by hygienic design

Operational issues:-

- Poorly designed equipment may foul more quickly
- Poorly designed equipment may take longer to clean
- Well-designed equipment will be more sustainable due to lower lifecycle costs

Organoleptic issues:-

- All product flowing down the line flows at the same rate, ensuring that any changes in product quality due to the process are consistent
- Residues of a previous batch, on entering a subsequent batch, could result in organoleptic issues

Brand protection issues:-

- Arise if individual items of equipment are used for producing multiple food products whose residues (following any between-batch cleaning activities), may be incompatible with subsequent food products.
- Vegetarian, vegan, meat species, legality, religious, GMO free









Consider the size or quantity of the hazard or issue that needs to be present to trigger a health or quality issue. Size or quantity considerations should be determined by the user (with reference to appropriate legislation/guidance)

Amount of protein detected by PCR (10<sup>-12</sup>g) to breach a defined limit of absence in the subsequent food product – unlikely to be controlled by hygienic design or subsequent cleaning due

Individual or low numbers of harboured microorganisms

High numbers of microorganisms developed through growth (water, temperature, nutrients, time)

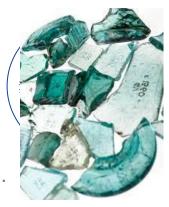
Mg to g of chemical residue to exceed an MRL in the subsequent food product

Mg to g of allergenic material sufficient to breach a defined limit in the subsequent food product

Size of a sharp foreign body to cause a 'cutting' hazard

Size of a foreign body to cause a 'choking' hazard

g to kg of product sufficient to breach a legal limit (e.g. 1%) in the subsequent product



#### Hazard and processing issues template



				Foo	d Saf	ety H	azard	s and	d Pro	cessi	ng Is	sues		
			Che	mical		Biolo	gical		Phys	sical			Quality	/
Contaminatio	on dynamics	Cleaning agents	Lubricants	Allergens	Material migration	Pathogens	Insects / Pest	Metal	Rubber	Plastic	Glass	Processing	Organolepttic residue	Brand protection residue
Size of ha	zard/issue													
Ingress	At installation													
	In production													
Accumulation	Accumulation during processing or from cleaning residues													
Growth										1 <u>4</u>				



HDRA Working Group

#### **HDRA**

- sorting
- washing
- sieving
- magnetic metal removal
- cooking
- freezing
- modified atmosphere packing
- in-pack pasteurisation

• Prioritise the hazards identified as significant hazards by the HACCP study;



- Whether the hazard could be present in the equipment following installation.
- Whether the hazard could be introduced and harboured in the building or equipment during use.
- Whether the hazard could increase in the building or equipment through accumulation or growth;
- Whether the hazard could be transferred to the food being processed;

		Likelihood of occ or equipment	currence of hazard	in the building
		Unlikely to be present or hazard not- relevant	Process issue, organoleptic issue, brand protection issue or HACCP hazard likely to be present	Likely to be present, accumulate or grow or be a significant hazard (allergen, pathogen)
Likelihood of presence of	Hazard would not be removed	Low risk	Medium risk	High risk
hazard at point of	May be present but infrequently	Low risk	Medium risk	High risk
consumption	Hazard subsequently removed	Low risk	Low risk	Medium risk

#### HDRA template



	Point of	risk asses	sment										
Hazards	Cleaning agents	Lubricants	Allergens	Material migration	Pathogens	Pests	Metal V	Rubber	Plastic	Glass	Processing	Organoleptic residue	Brand protection residue
Likelihood of occurrence in the food at the time of processing													
Likelihood of presence in the food to be consumed following any further processing/controls													
Overall risk													

				Foo	d Saf	ety Ha	azard	s and	d Pro	cessi	ng Is	sues		
			Che	mical		Biolo	gical		Phy	sical			Quality	r -
Food is contamin	n mechanisms: nated via building ipment	Cleaning agents	Lubricants	Allergens	Material migration	Pathogens	Insects / Pest	Metal	Rubber	Plastic	Glass	Processing	Organolepttic residue	Brand protection residue
	lative to quality or equent products		ш		бш			7mm	7mm	7mm	7mm			
Ingress in the building or equipment	Entry from outside (including during equipment manufacture and subsequent food production													
	Generation within inside		Х		х			Х	Х	Х	Х			
during processing	ulation g or from cleaning dues													
Gro	owth		3											
										-	-	-	-	Co

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#### Intended use specification

- Cutting cereal crops
- Field raw material
- Frequency of cleaning will be between seasons

	Combine	e harveste	r										
Hazards	Cleaning agents	Lubricants	Allergens	Material migration	Pathogens	Pests	Metal	Rubber	Plastic	Glass	Processing	Organolepticresidue	Brand protection residue
Likelihood of occurrence in the food at the time of processing													
Likelihood of presence in the food to be consumed following any further processing/controls													
Overall risk													





	3			Foo	d Saf	ety H	azard	ls an	d Pro	cess	ing Is	sues		
			Che	mical		Biolo	ogical		Phy	sical			Qualit	у
Food is contamir	n mechanisms: nated via building ipment	Cleaning agents	Lubricants	Allergens	Material migration	Pathogens	Insects / Pest	Metal	Rubber	Plastic	Glass	Processing	Organolepttic residue	Brand protection residue
	lative to quality or equent products	MRL	6		gm			7mm	7mm	7mm	7mm			<kg< td=""></kg<>
Ingress in the building or equipment	Entry from outside (including during equipment manufacture and subsequent food production	x					x							
	Generation within inside		Х		Х			Х	Х	Х				Х
Accum	ulation													
during processing resid														
Gro	owth		S					с	50		2			. S



#### Intended use specification

Mincer for multiple raw meats. •



- Run time of each product batch approximately 2 hours
- The position of the equipment will be in the low hygiene zone, operating at 8°C.
- Frequency of in-process cleaning will be between batches

	Raw mea	at mincer	5 										
Hazards	Cleaning agents	Lubricants	Allergens	Material migration	Pathogens	Pests	Metal	Rubber	Plastic	Glass	Processing	Organoleptic residue	Brand protection residue
Likelihood of occurrence in the food at the time of processing													
Likelihood of presence in the food to be consumed following any further processing/controls													
Overall risk													

	-			Foo	d Saf	ety Ha	azard	ls an	d Pro	cessi	ing Is	sues				
			Che	mical		Biolo	gical		Phy	sical			Qualit	у	1	
Food is contamin	n mechanisms: nated via building iipment	The sector of th		Ir	ntende											
	lative to quality or equent products	MRL	6		gm	A few pathogen cells		7mm	7mm	7mm	7mm			>kg	•	Slic
Ingress in the building or equipment	Entry from outside (including during equipment manufacture and subsequent food production	â					х								•	Rui The zor
	Generation within inside		Х		х	Х		Х	х	х				х		201
during processing resi	dulation g or from cleaning dues													x	•	Fre
Gro	owth					х				12.					Cooked m	neat slicer

#### Intended use specification

- Slicing machine for RTE cooked meats.
- Run time of each product batch approximately 24 hours
- The position of the equipment will be in the high hygiene zone, operating at 10°C.
- Frequency of in-process cleaning will be every 8 hours

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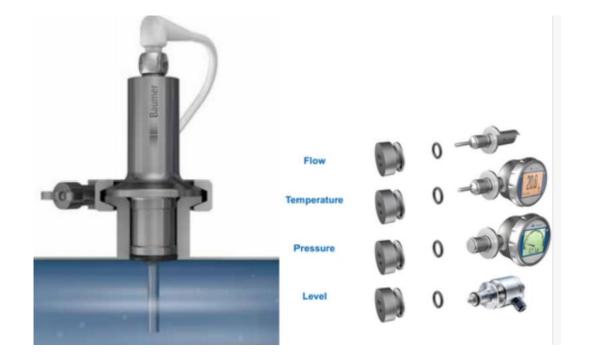
Hazards	Cleaning agents	Lubricants	Allergens	Material migration	Pathogens (spoilage microrganisms)	Pests	Metal	Rubber	Plastic	Glass	Processing	Organoleptic residue	Brand protection residue
Likelihood of occurrence in the food at the time of processing													
Likelihood of presence in the food to be consumed following any further processing/controls													
Overall risk													



URS

- Intended use
- HDRA
- Hazard control requirements
- Additional engineering requirements (e.g.)
  - Software language
  - Parts compatibility
  - Available space for the item
  - Available building load capacity
  - Available services

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## Risk mitigation via hygienic design: New opportunity



- Materials of construction
- Surfaces
- Joints
- Fasteners
- Drainage
- Dead spaces
- Bearings
- Shaft entry
- Lubricants
- Instruments
- Covers
- Control boxes
- Insulation



Hygienic design	Identified	hazards		9
principle	Material migration	Lubricants	Pathogens	Allergens
Segregation		Х	Х	Х
Cleanability			Х	Х
Accessibility		Х	Х	Х
Drainibility			Х	
Materials of construction	Х		Х	
Surfaces and geometry			Х	Х

### Mitigating hazards checklist

Principle	Criteria	Hazards or processing issues controlled												
		Cleaning agents	Lubricants	Allergens	Material migration	Pathogens	Insects/pests	Metal	Rubber	Plastic	Glass	Processing	Organoleptic	Brand protection
1. Segregation	Product contact areas are sufficiently segregated for equipment and process steps where (re-) contamination can occur. Examples include, post process steps which are eliminating microorganisms (aseptic processes must be impermeable to microorganisms); non-allergen containing foods in an environment manufacturing food with different allergen profiles; cleaning fluids; lubricants; cooling media; foreign bodies	X	X	X		x	X	X	x	x	X		X	X
	<ul> <li>1.1. Exposed product contact surfaces maintain enough clearance from surrounding structures. Includes services, platforms, floors, walls and ceilings</li> </ul>						X	X	X	X	X			
2. Cleanable	2.1. Surfaces are easily cleanable to a pre- determined level given the anticipated method of cleaning	X	X	X		X	X					X	X	X
	2.2. Product contact surfaces can be disinfected (sanitized) or sterilized, if required.					X	X							
	2.3. Cleaning methods are supported by appropriate utilities and chemical systems to allow for effective and timely cleaning	X	X	x	X	X	X	X	X	X	X	X	X	X

### 'Supplier specification' - Technical file

- Technical file
- Residual risks
- Cleaning instructions
- Maintenance requirements

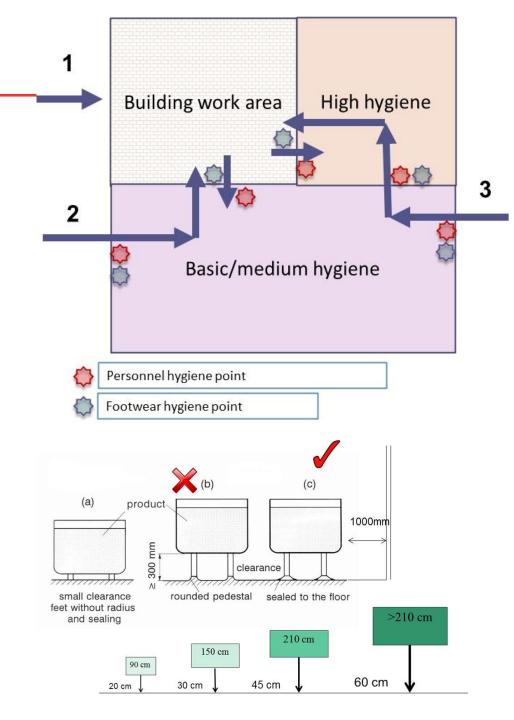
Currently no requirement for specific hazard mitigation (or to meet BRC v9)

- Need to compare URS with physical examination of the supplied equipment and assessing the Technical file to ensure all hazards identified in the URS are mitigated (confirmation of specification)
- Remaining hazards have to be managed by user prerequisites



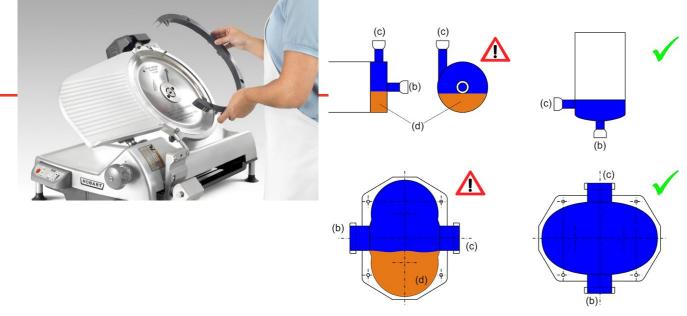
#### Hygienic construction and installation

- Risk assessment required for
  - Emergencies e.g. drain blockages, new and second hand equipment installation, maintenance work, building/refurbishment work
- Prior to installation
  - Confirmation that the equipment is free of construction hazards
  - Confirmation that the equipment is free of microbiological or allergen contamination prior to installation
- Installation to allow processing, cleaning and maintenance
- Post installation risk assessment (in production)



### Hazard mitigation during operation

- Foreseen hazards e.g. the need to remove a blade guard and blade for cleaning. Contained in the OEMs technical documents
- Hazards identified after comparing the URS to the SS (for unassigned equipment)
- Hazards created during installation e.g. the installation of a pump, which is intrinsically hygienically designed, in an orientation that is undrainable
- Control is via PRPs/OPRs, primarily cleaning and disinfection and maintenance



Risk	Hazard risk assessment/ processing issues	Cleaning frequency				
	Pathogens	Secondary, periodic decontamination also required				
	Allergen	Between batches				
	Brand protection issues					
	Organoleptic issues					
	Spoilage organisms	Daily				
	Process performance (short term)					
	Product quality (long term)	>Daily				
	Process performance (long term)					
	Health and safety	>Monthly				

## (Change management)

CHANGE ----SAME ----

#### Changes

- Changes to the building or equipment
- New sources of the same raw materials
- New raw materials
- New finished products
- New process parameters
- New cleaning chemicals or methods
- Legislation, industry standards
- PRP failures (cleaning, micro)
- Sustainability

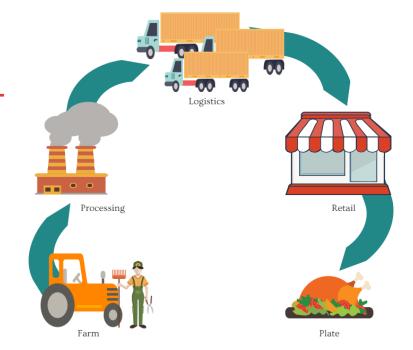
#### Outcomes

- The building or equipment remains fit for its intended purpose
- Attention is required: hazard mitigation via PRPs or products (e.g. more preserved/shorter shelf-life)
- Needs improvement: modifications/refurbishment
- (Rarely) New processing equipment is required



### **EHEDG** essential learnings

- Multidisciplinary team
- Intended use
- Hazard analysis
- URS (user) SS (supplier residual risks)
- URS/SS analysis (URS unmitigated risks)
- Installation/construction risk assessment
- Post installation risk assessment
- Residual, URS unmitigated, installation, risk mitigation practices
- Legacy change management









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