The growing influence of hygienic design in the food service sector

Dr. John Holah, Kersia-Group

EU food poisoning stats

Table 2: Reported hospitalisations and case fatalities due to zoonoses in confirmed human cases in the EU, 2019

Disease	Number of confirmed human cases	Hospitalisation				Deaths			
		Status available (%)	Number of reporting MS[b]	Reported hospitalised cases	Proportion hospitalised (%)	Outcome available (%)	Number of reporting MS[b]	Reported deaths	Case fatality (%)
Campylobacteriosis	220,682	29.1	16	20,432	31.8	78.0	17	47	0.03
Salmonellosis	87,923	44.5	15	16,628	42.5	71.8	17	140	0.22
STEC infections	7,775	37.3	18	1,100	37.9	61.0	20	10	0.21
Yersiniosis	6,961	27.4	15	648	33.9	57.0	14	2	0.05
Listeriosis	2,621	51.1	19	1,234	92.1	65.1	20	300	17.6
Tularaemia	1,280	22.8	12	149	51.0	21.6	13	1	0.36
Echinococcosis	739	33.3	14	109	44.3	31.4	14	2	0.86
Q fever	950	NA[c]	NA	NA	NA	67.3	13	4	0.63
West Nile virus infection[a]	443	83.7	9	347	93.5	99.3	11	52	11.8
Brucellosis	310	44.5	11	98	71.0	36.8	12	2	1.75
Trichinellosis	96	16.7	5	6	37.5	25.0	7	1	4.20
Rabies	4	NA[c]	NA	NA	NA	75.0	3	3	100.0

MS: Member State.
(a): Instead of confirmed human cases, the total number of human cases was included.
(b): Not all countries observed cases for all diseases.
(c): NA: Not applicable as the information is not collected for this disease.

Table 2: Reported hospitalisations and case fatalities due to zoonoses in confirmed human cases in the EU, 2020

Disease	Number of confirmed human cases	Hospitalisation					Deaths				
		Status available (N)	Status available (%)	Number of reporting MS[b]	Reported hospitalised cases	Proportion hospitalised (%)	Outcome available (N)	Outcome available (%)	Number of reporting MS[b]	Reported deaths	Case fatality (%)
Campylobacteriosis	120,946	41,037	33.9	14	8,605	21.0	83,744	69.2	15	45	0.05
Salmonellosis	52,702	20,562	39.0	13	6,149	29.9	30,355	57.6	15	57	0.19
Yersiniosis	5,668	1,214	21.4	12	353	29.1	3,072	54.2	13	2	0.07
STEC infections	4,446	1,593	35.8	16	652	40.9	3,094	69.6	19	13	0.42
Listeriosis	1,876	803	42.8	18	780	97.1	1,283	68.4	18	167	13.0
Tularaemia	641	123	19.2	9	64	52.0	200	31.2	10	0	0
Echinococcosis	488	73	15.0	12	44	60.3	204	41.8	14	0	0
Q fever	523	NA	NA	NA	NA	NA	235	44.9	14	5	2.1
West Nile virus infection[a]	322	239	74.2	8	219	91.6	322	100	8	39	12.1
Brucellosis	128	56	43.8	8	36	64.3	55	43.0	9	2	3.6
Trichinellosis	117	22	18.8	5	16	72.7	24	20.5	6	0	0
Rabies	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

MS: Member State(s); NA: Not applicable, as information is not collected for this disease.
(a): Locally acquired infections – for West Nile virus infection, the total number of cases was used (includes probable and confirmed cases).
(b): Not all countries observed cases for all diseases.

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Down in 2020





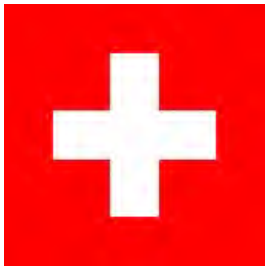









Up in 2021





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Potential reasons?

- Additional personal hygiene
- Did no want to go to the GP
- Less samples taken/processed
- More home cooking
- **No access to food service establishments**

Foodservice establishments continue to cause the greatest percentage of foodborne illness outbreaks each year (around 60 percent), among all causes of foodborne illness outbreaks in the U.S.

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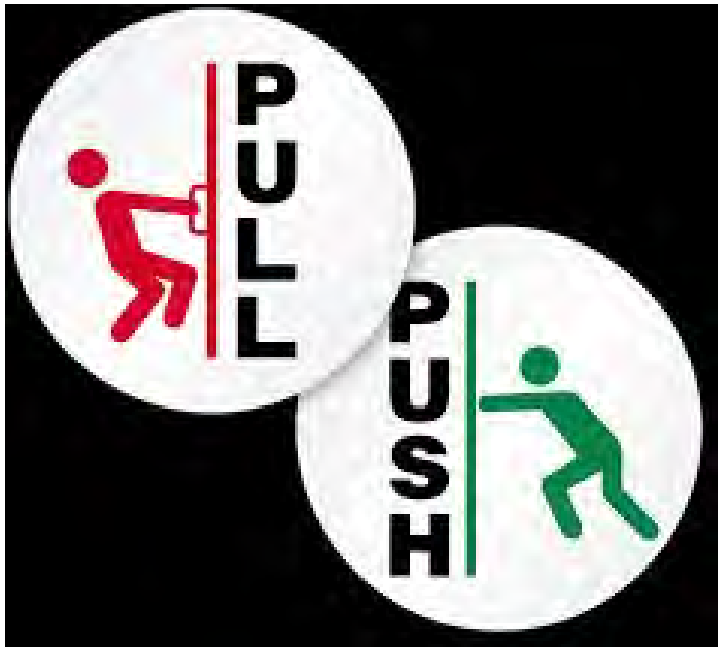
Positive pandemic handwashing trend not maintained, finds FSA

By Joe Whitworth on September 7, 2022

There has been a decline in consumer handwashing from mid-2020 during the COVID-19 pandemic, based on results from a Food Standards Agency (FSA) survey.

A 100 year history of hygienic design



- Directive 89/392/EEC
- GFSI

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

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GFSI

- Initiated by Consumer Goods Forum
- Non-profit foundation, industry-driven
- World wide, end-to-end SC presence
- Safe food for consumers, everywhere
- Continuous improvement Food Safety Management Systems

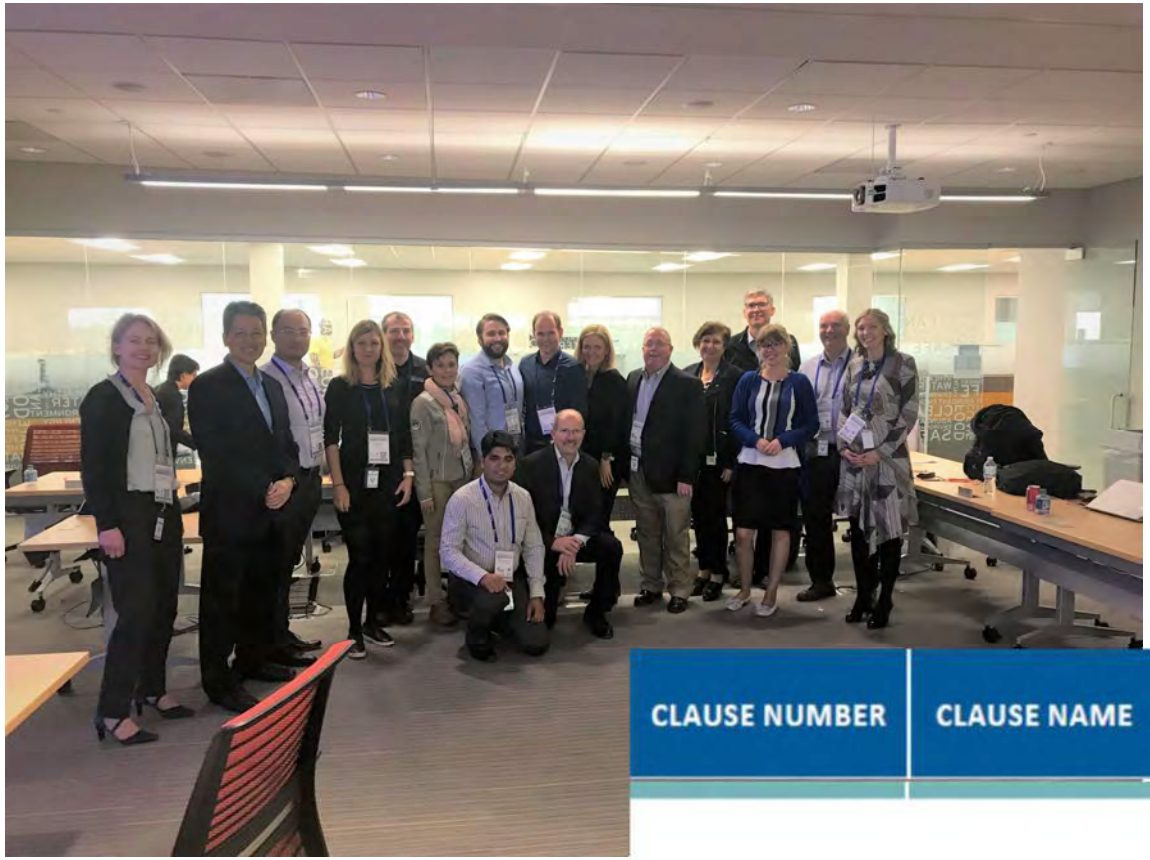
Benchmarking Requirements

CPO Standards

Auditing schemes

GFSI "certification pyramid"

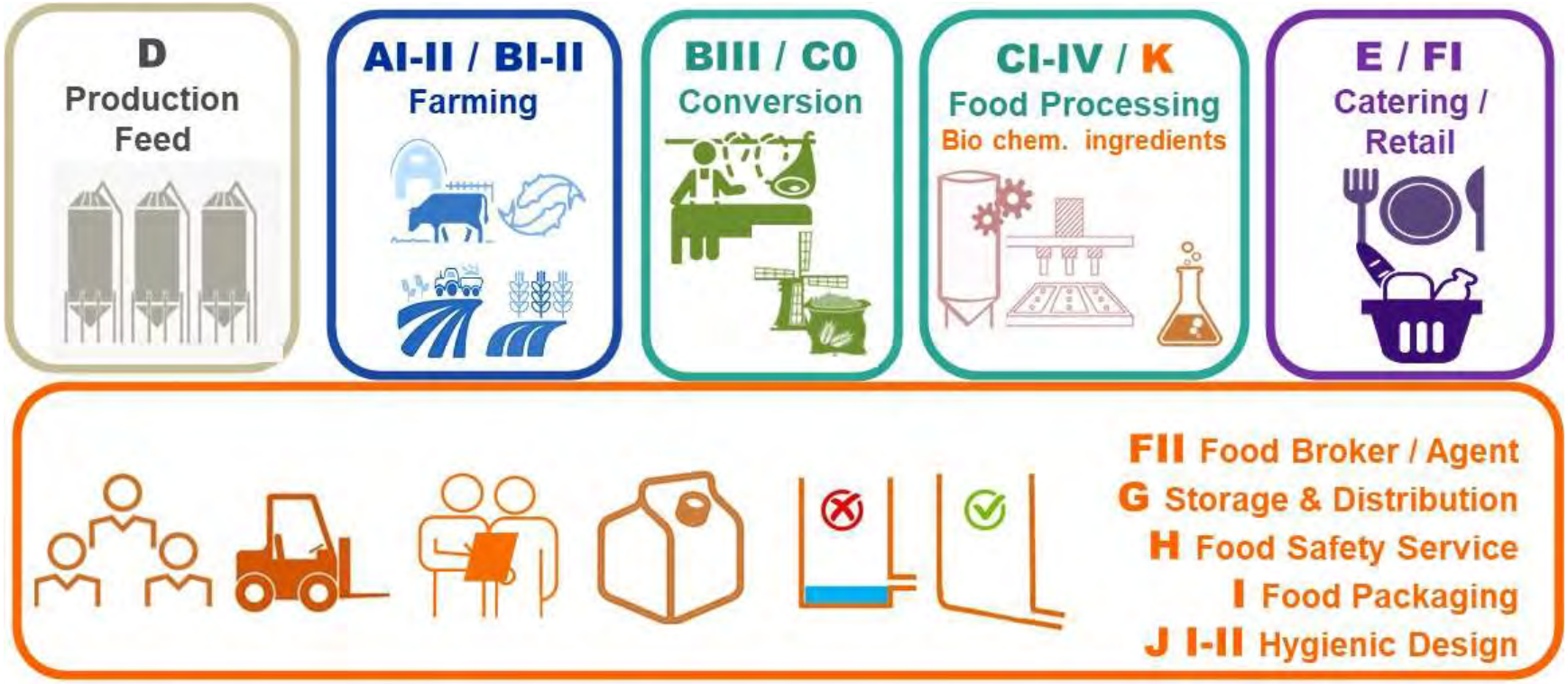
TWG Hygienic design of facilities and equipment



To develop hygienic design elements covering food processing equipment and facilities - from farm to fork.

CLAUSE NUMBER	CLAUSE NAME	REQUIREMENTS
GMP EIV 5	Equipment	The standard shall require that equipment is suitably designed for the intended purpose and shall be used and stored so as to minimise food safety risks.

GFSI 2020 Benchmarking Scopes



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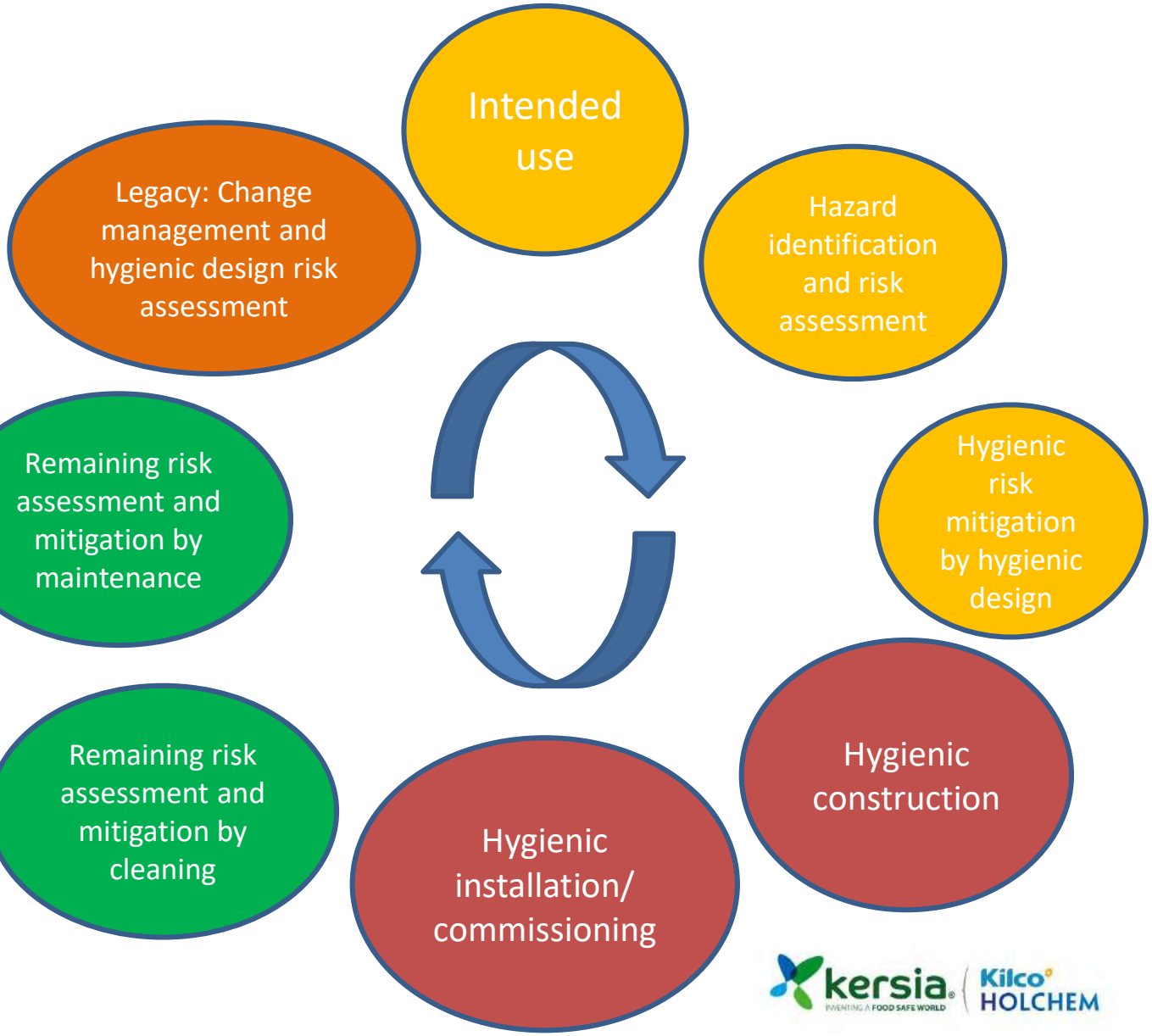
Hygienic design risk management cycle

HDRM WG

Conflicts of (EC) 853 vs ISO 12100



HDRM multidisciplinary team

Disciplines

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

Knowledge base

- The basics of hygienic design
- The principles of hazard analysis and risk assessment methods
- The basics of hygienic zoning
- Requirements and capabilities of the 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

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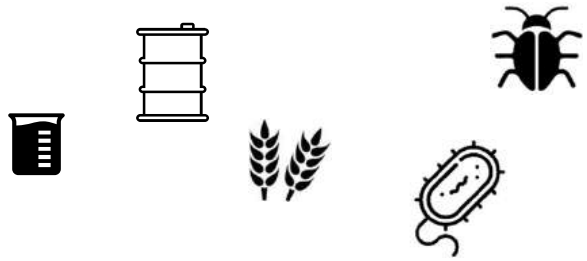
Intended use

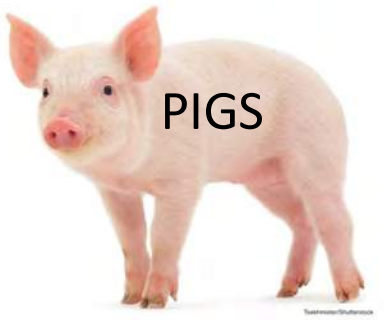
- Products
- Process
- Final consumer
- Cleaning conditions

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

Hazards



- Hazard definition
  - Could cause an adverse health effect to the consumer;
  - could be introduced to the building or equipment;
  - could accumulate or grow in 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



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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

- Amount of protein detected by PCR (10^{-12}g) to breach a defined limit of absence
- 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

Size is important!

REGULATORY ACTION GUIDANCE:

The following represent the criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and direct reference import detention to the appropriate Field Offices within the Human and Animal Food Program*.

a. The product contains a hard or sharp foreign object that measures 7 mm to 25 mm, in length.

HDRA

- 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;

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

		Likelihood of occurrence of hazard in the building or equipment at the point of processing		
		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 at point of consumption	Hazard would not be removed	Low risk	Medium risk	High risk
	May be present but infrequently	Low risk	Medium risk	High risk
	Hazard subsequently removed	Low risk	Low risk	Medium risk

Contamination mechanisms: Food is contaminated via building or equipment		Food Safety Hazards and Processing Issues												
		Chemical				Biological		Physical				Quality		
		Cleaning agents	Lubricants	Allergens	Material migration	Pathogens	Insects / Pest	Metal	Rubber	Plastic	Glass	Processing	Organolepttic residue	Brand protection residue
Size of hazard relative to quality or safety of subsequent products		MRL	g		mg			7mm	7mm	7mm	7mm			<kg
Ingress in the building or equipment	Entry from outside (including during equipment manufacture and subsequent food production	X					X							
	Generation within inside		X		X			X	X	X				X
Accumulation during processing or from cleaning residues														
Growth														

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 meat mincer												
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													

Contamination mechanisms: Food is contaminated via building or equipment		Food Safety Hazards and Processing Issues												
		Chemical				Biological		Physical				Quality		
		Cleaning agents	Lubricants	Allergens	Material migration	Pathogens	Insects / Pest	Metal	Rubber	Plastic	Glass	Processing	Organolepttic residue	Brand protection residue
Size of hazard relative to quality or safety of subsequent products		MRL	g		mg	A few pathogen cells		7mm	7mm	7mm	7mm			>kg
Ingress in the building or equipment	Entry from outside (including during equipment manufacture and subsequent food production	X					X							
	Generation within inside		X		X	X		X	X	X				X
Accumulation during processing or from cleaning residues														X
Growth						X								

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

	Cooked meat slicer												
Hazards	Cleaning agents	Lubricants	Allergens	Material migration	Pathogens (spoilage microorganisms)	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													

Risk mitigation via hygienic design: New opportunity

EN 1672-2

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

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

Assigned and unassigned equipment

User Requirement Specification

(EC) 853 - HACCP led

- Intended use
- HDRA
- Hazard control requirements
- Engineering requirements - Software language, parts compatibility, available space/building load capacity, available services.....

Supplier Specification

ISO 12100 -Machinery Safety led

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

Assigned – joint consultation

Unassigned - Compare URS with physical examination and Technical file to ensure all hazards identified in the URS are mitigated (confirmation of specification)

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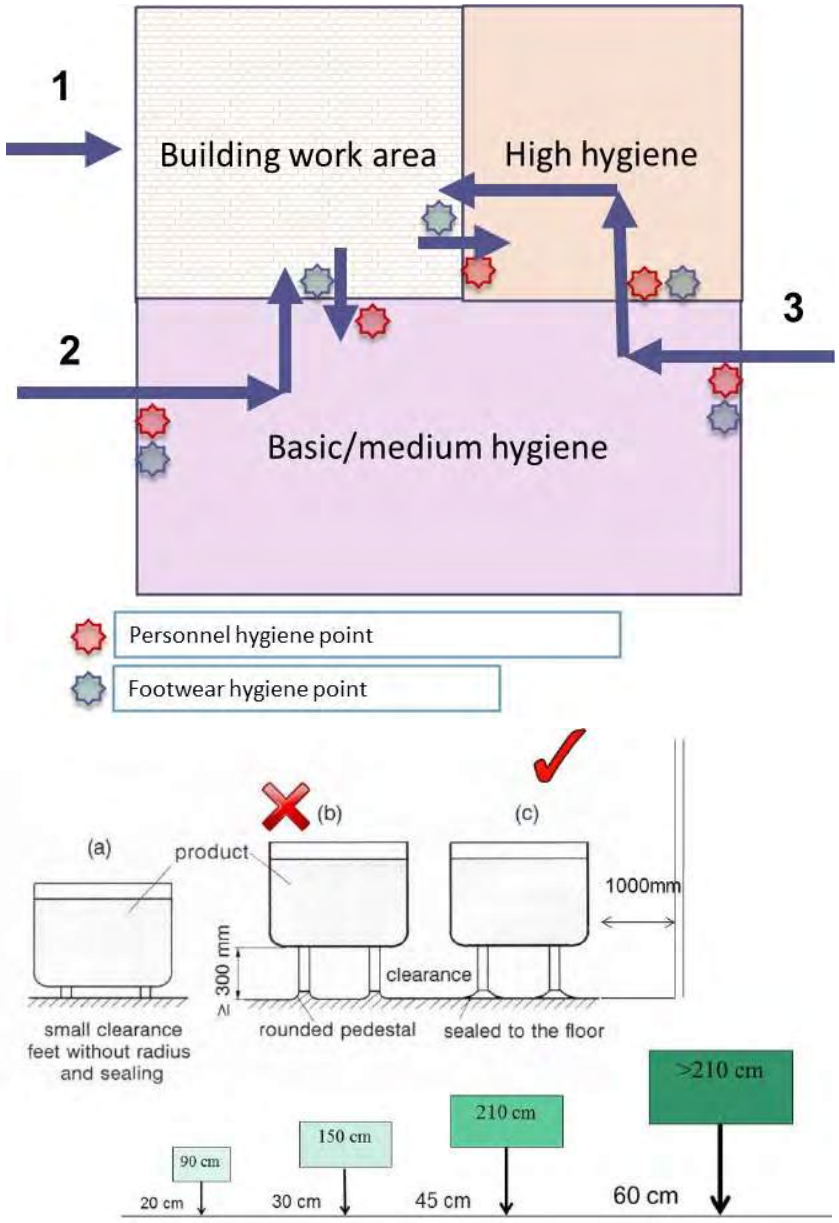
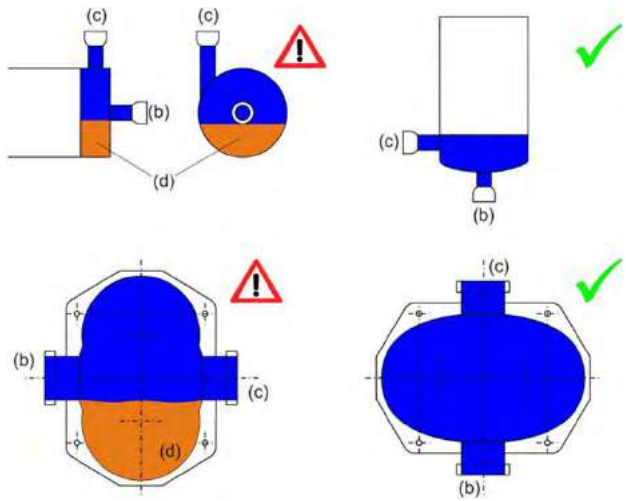
Hygienic construction and installation

- 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

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

Edvard Munch – The Scream

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: • any relevant legislation • where applicable, requirements for food contact surfaces to meet legal requirements • details of intended use of the equipment and the type of materials it will be handling. 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.

Implications for food service?

- Multidisciplinary team – group level?
- Purchase specification
  - Intended use
  - Risk assessed
  - URS/SS comparison – more generic – OEM lead?
- Hygienic installation/commissioning
  - Risk assessment
  - Clean up/Inspection – less disruptive/out of hours
- PRPs (residual risks)
  - Cleaning, maintenance
  - QA system update - easy

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John.Holah@kersia-group.com