



Hygienic Design of open processes: challenges in fulfilling normative and EHEDG requirements

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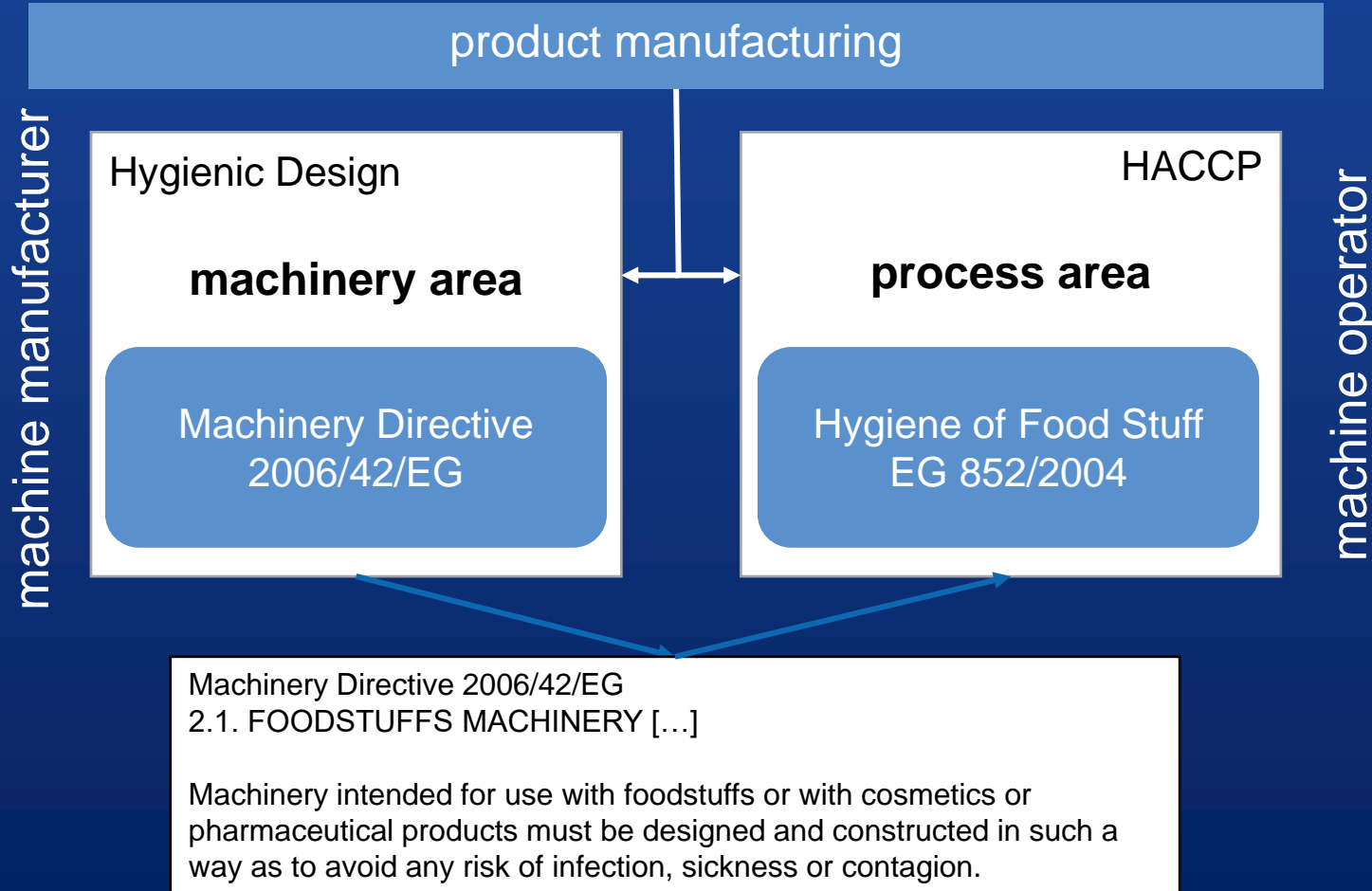






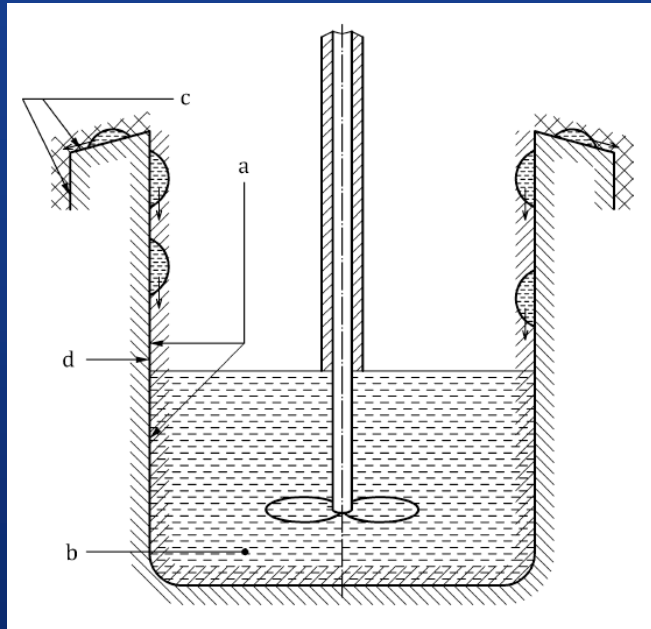






Responsibilities



Areas of equipment

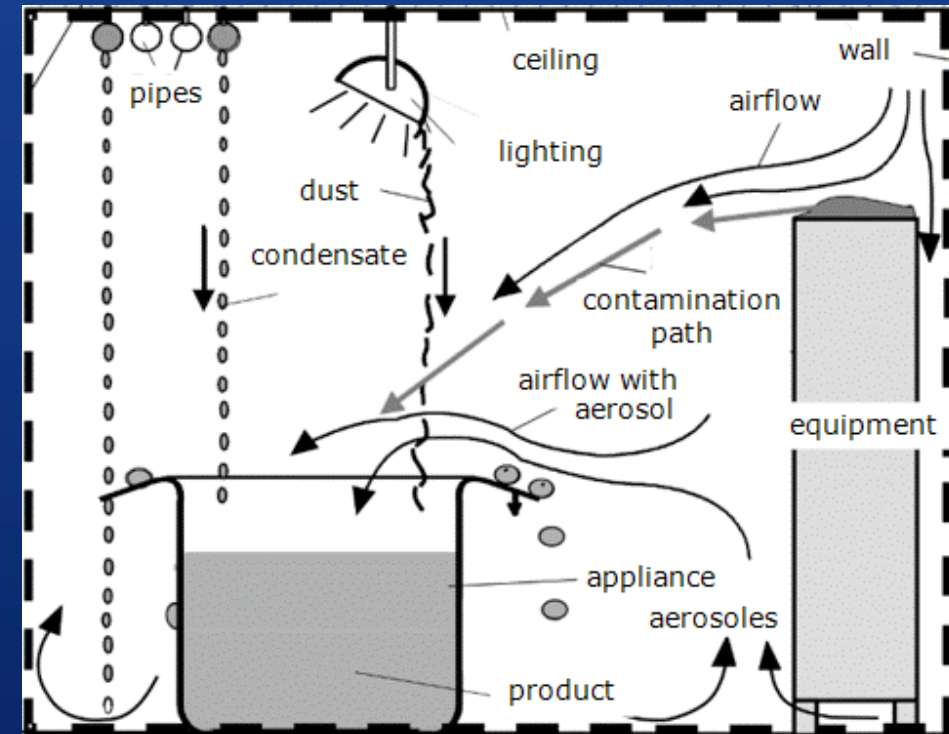
machine manufacturer



-  a food area
-  b food
-  c splash area
-  d non-food area

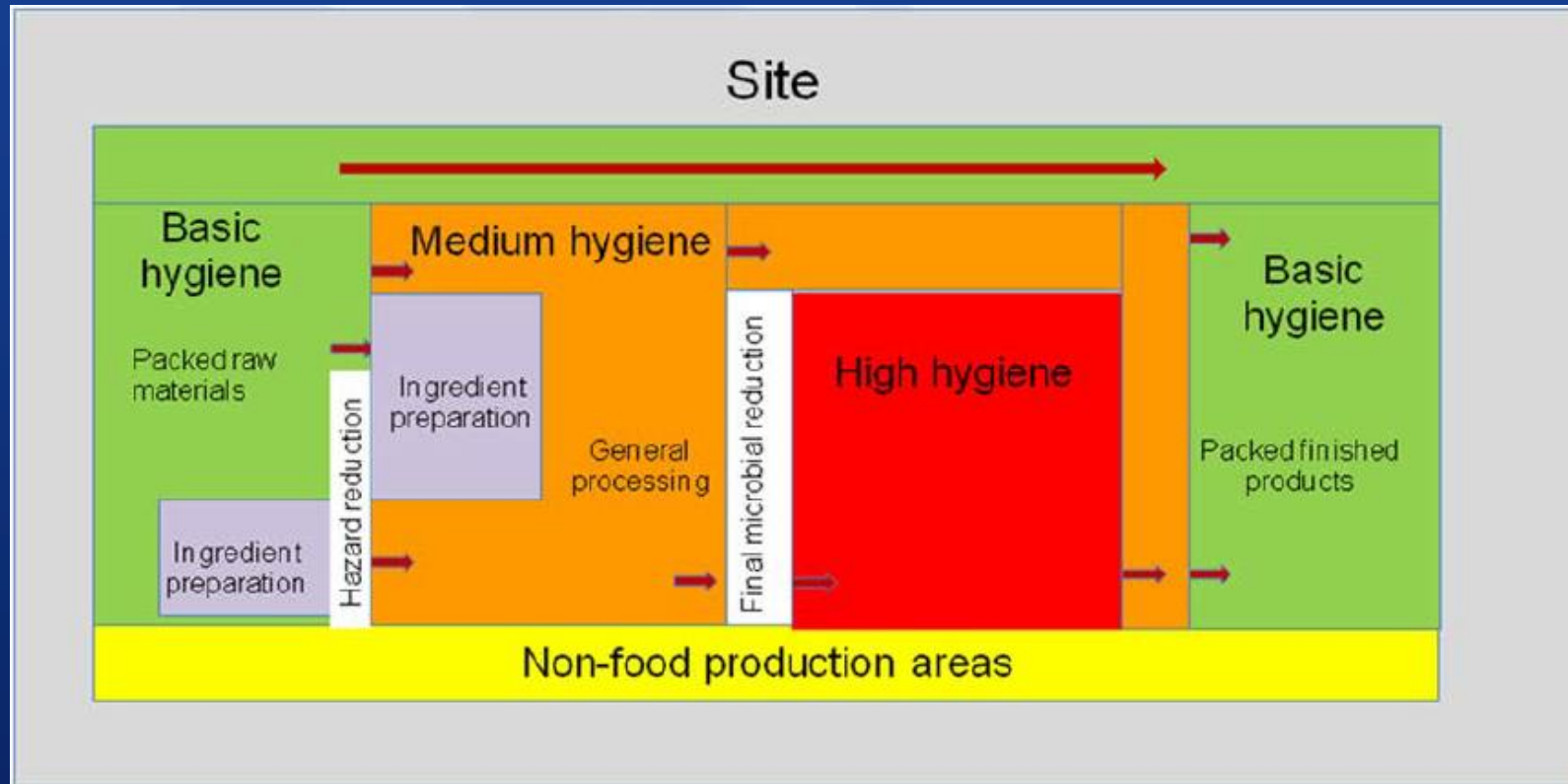
(EN 1672:2020)

machine operator

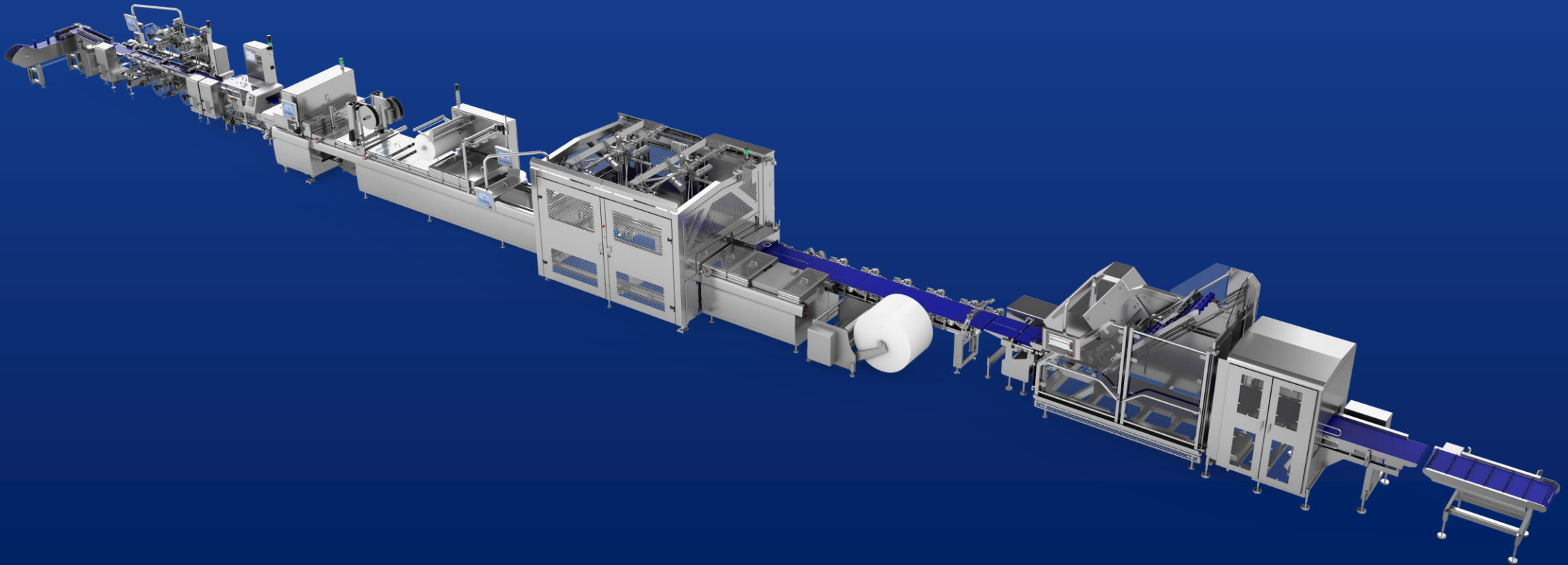


(Hauser, 2008)

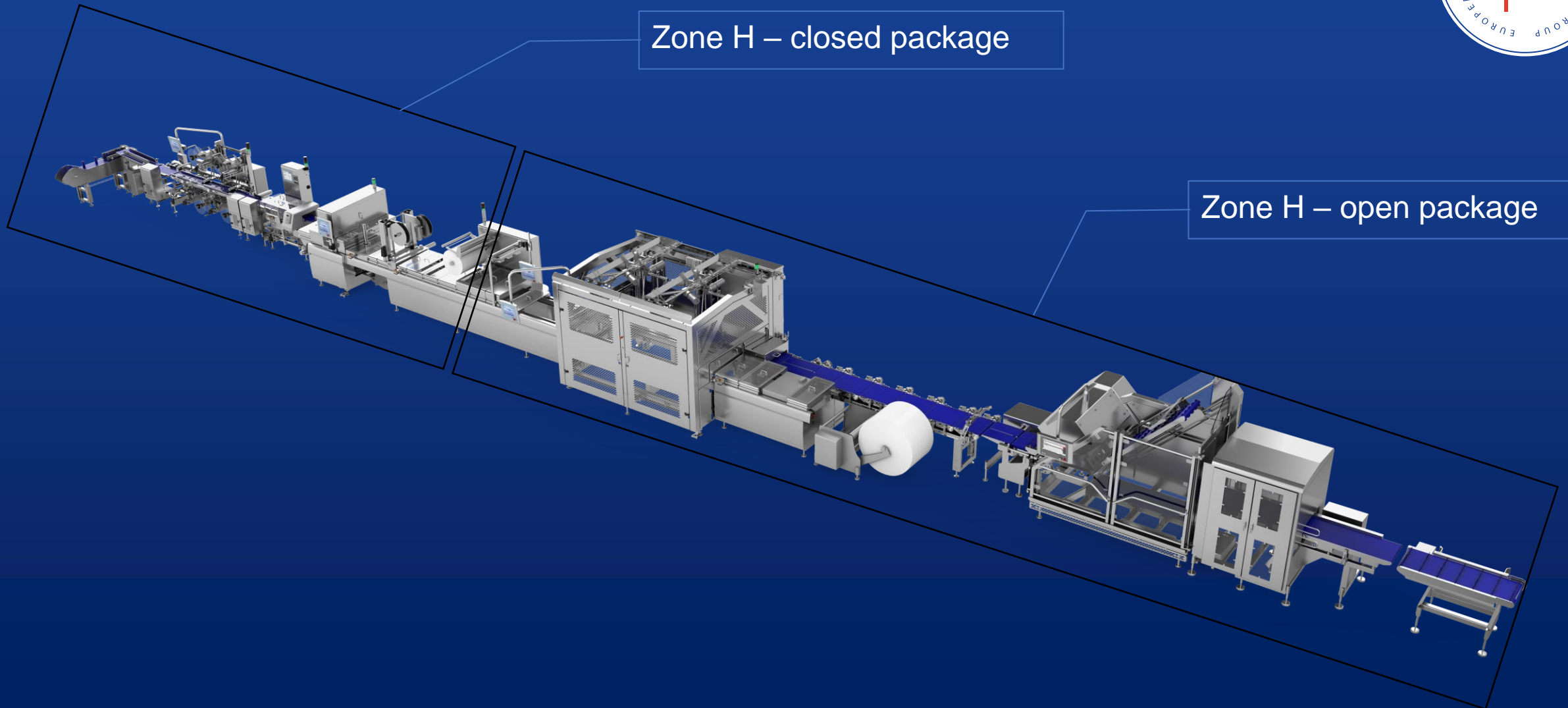
EHEDG Guideline 44: Hygiene Design principles for Food Factories



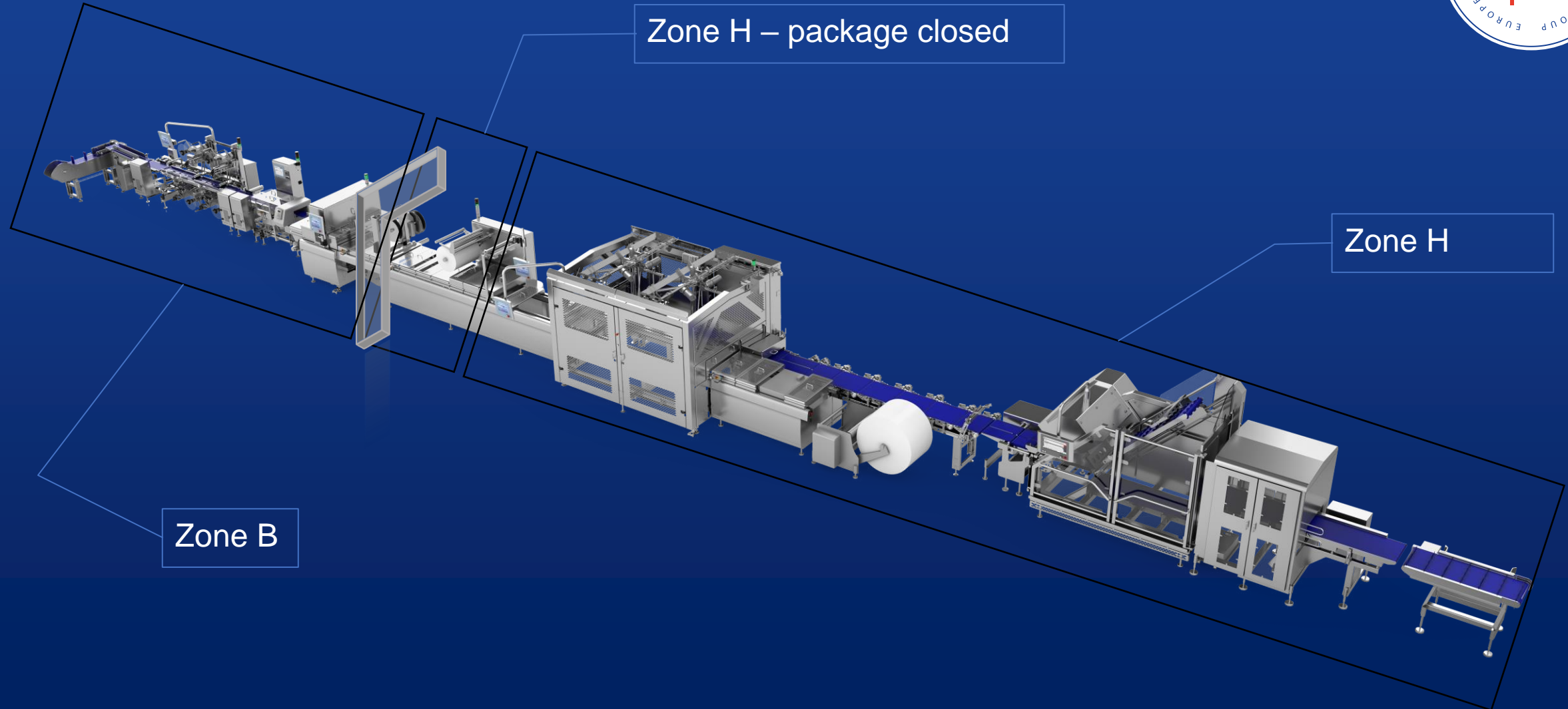
Processing lines - example



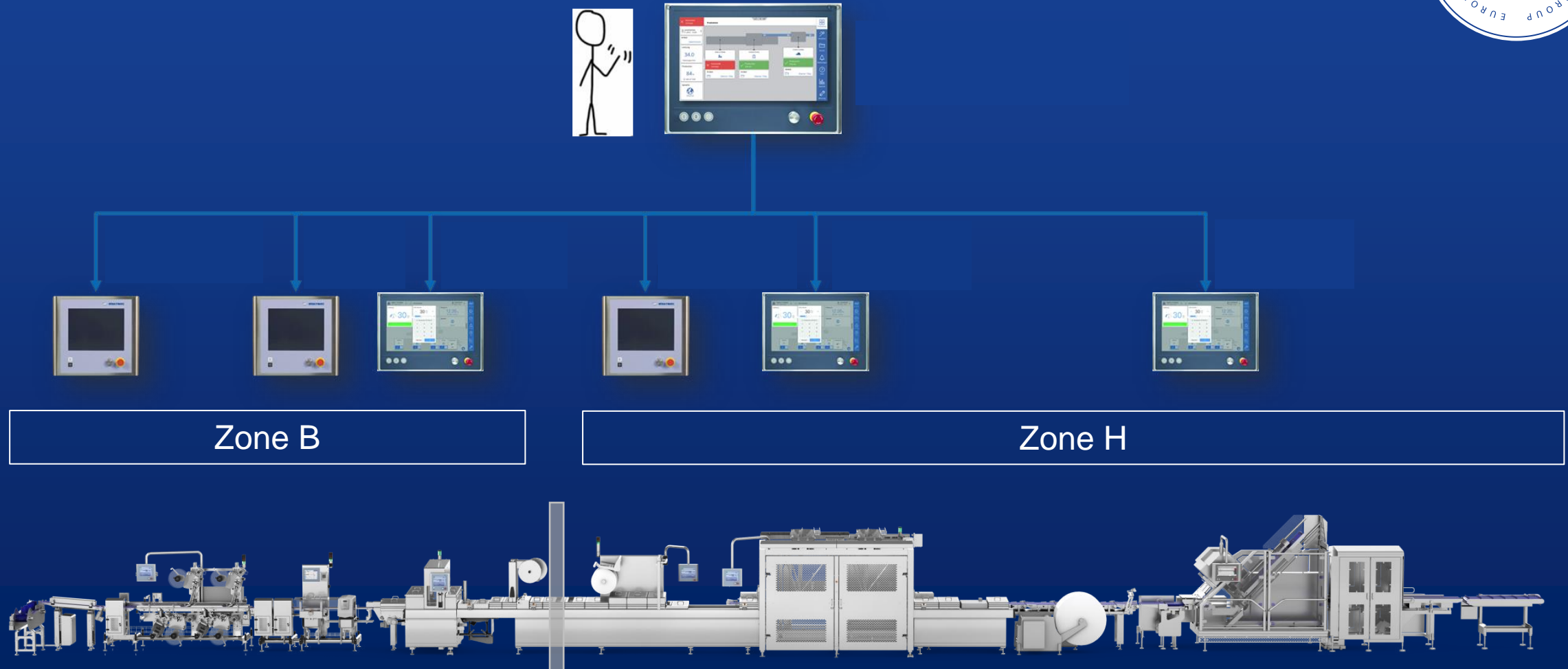
Processing lines - definition of areas



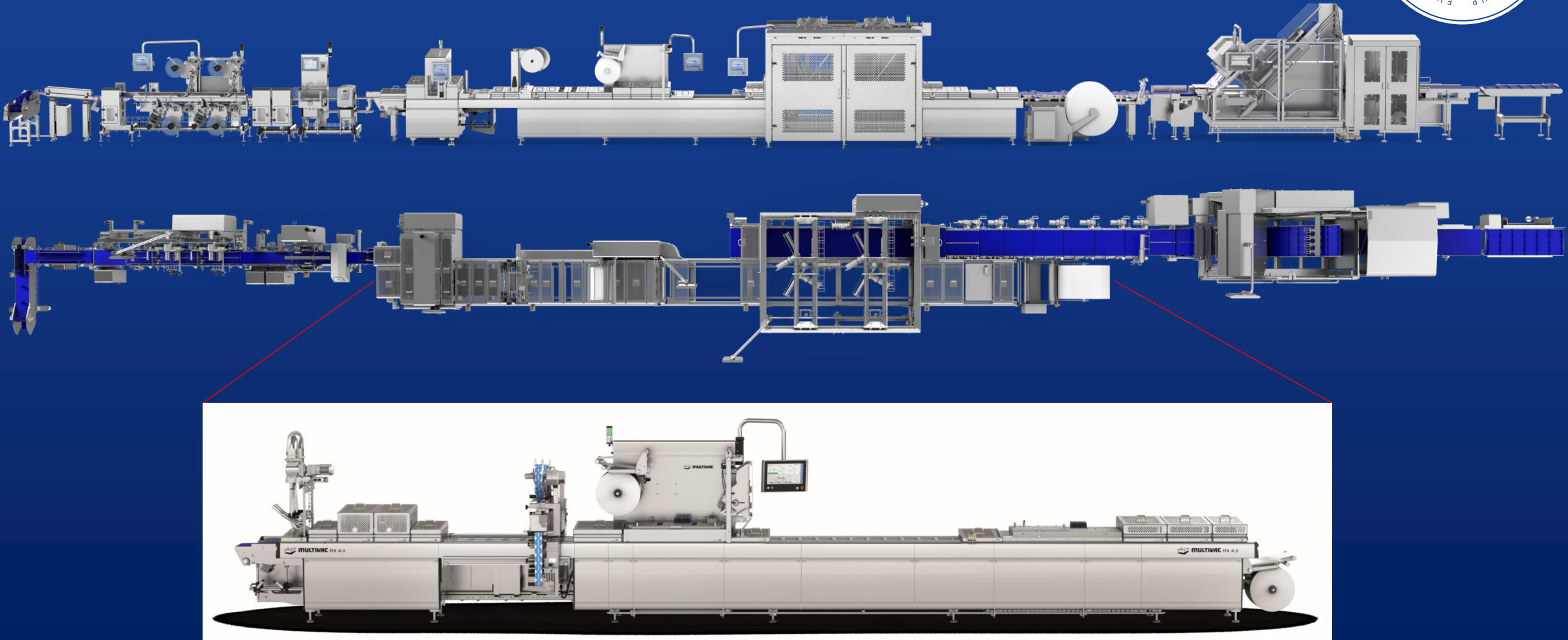
Processing lines - definition of areas



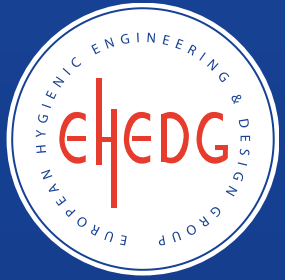
Processing lines



Material compliance



Material compliance - Food area



Article 1

Purpose and subject matter

[...] materials and articles intended to come into contact **directly or indirectly** with food [...]

Material compliance – Food area



EHEDG Doc. 8

[...] The designer must ensure that materials, under the intended conditions of use, in **direct or indirect contact** with the food do not release any substances in amounts that would be harmful to the consumer [...]

EN 1672-2:2020

Material of constructions – Food area

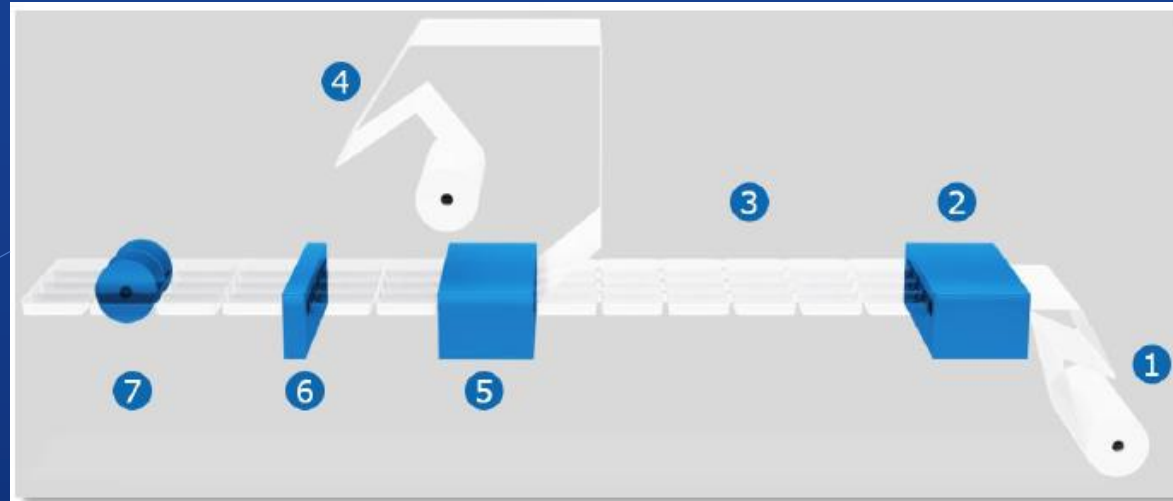
The materials shall

- not transfer undesirable colours or taint to the food
- neither contribute to the contamination of food nor have any adverse influence on the food [...]

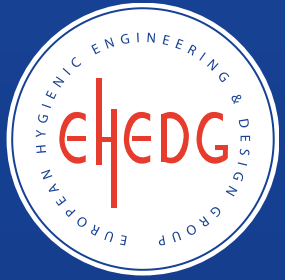


CE 1935/2004

TFP - food contact materials



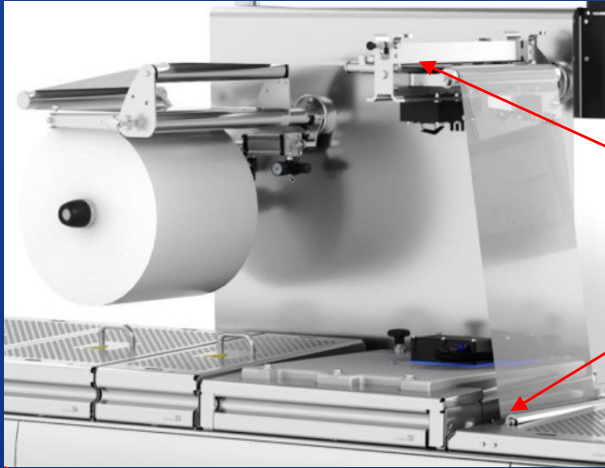
TFP - food contact materials



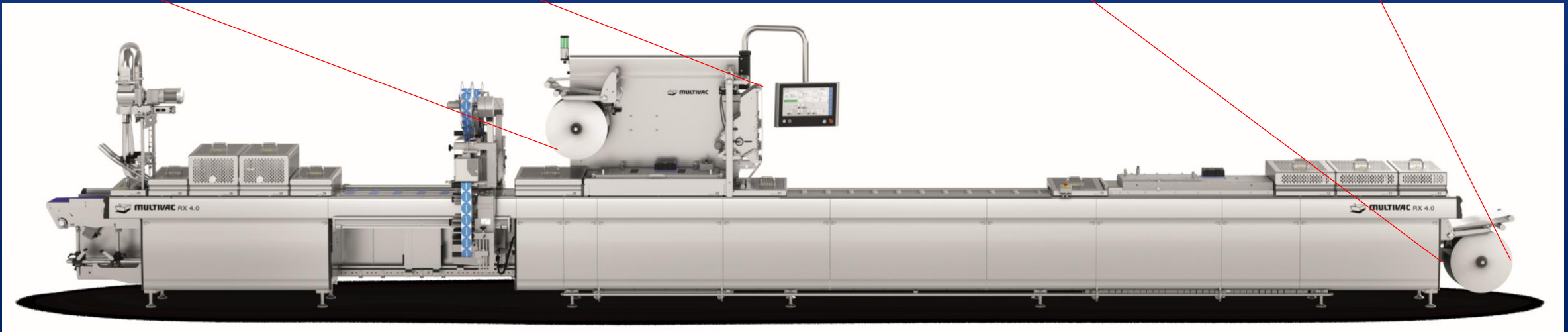
Indirect contact via the
product side of the film



TFP - food contact materials



1. Film unwinder



TFP - food contact materials

Material compliance

1. Film unwinder

2. Safety guards

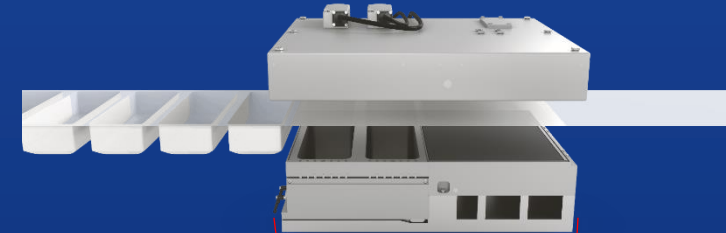


TFP - food contact materials

Material compliance

1. Film unwinder
2. Safety guard

3. Forming die

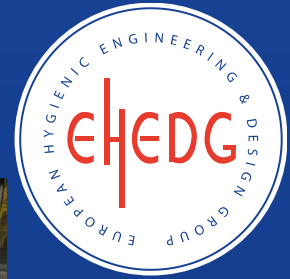


TFP - food contact materials

Material compliance

1. Film unwinder
2. Safety guard
3. Forming die

4. Loading area



TFP - food contact materials

Material compliance

1. Film unwinder
2. Safety guard
3. Forming die
4. Loading area

5. Sealing die



TFP - food contact materials

Material compliance

1. Film unwinder
2. Safety guard
3. Forming die
4. Loading area
5. Sealing die

6. Entire machine: Operating elements



TFP - food contact materials

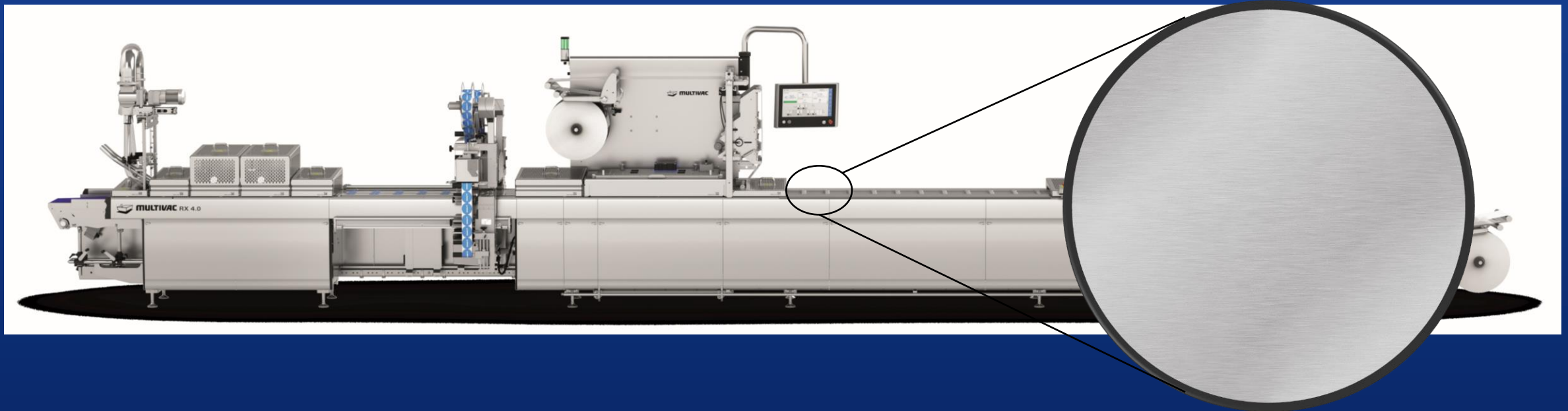
Material compliance

1. Film unwinder
2. Safety guard
3. Forming die
4. Loading area
5. Sealing die
6. Operating elements

7. Transport chain



Materials and Surfaces for food area



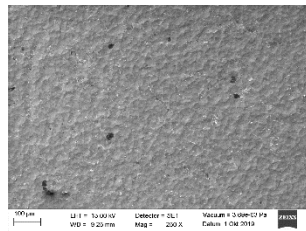
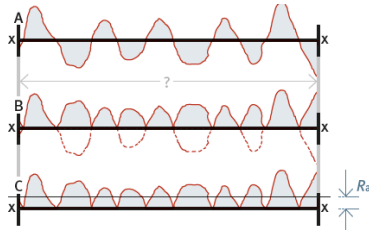
Materials – General requirements

EN 1672-2:2020 : All materials must be suitable for intended use. [...]
They should be ...

...without breaks, resistant
to cracking, chipping, flaking
and abrasion



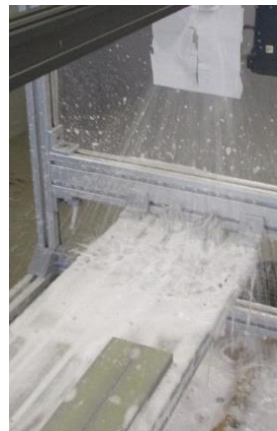
Ra-Value (DIN EN ISO
4287) Microscopic images



...cleanable and where
required capable of being
disinfected



Cleaning test



...corrosion-resistant

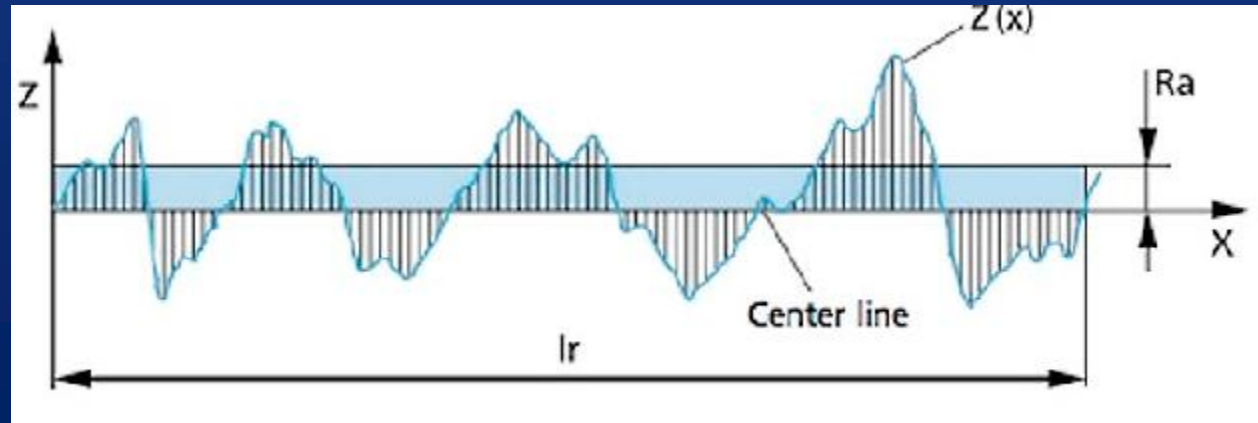


i.a. Salt spray test
ISO 9227

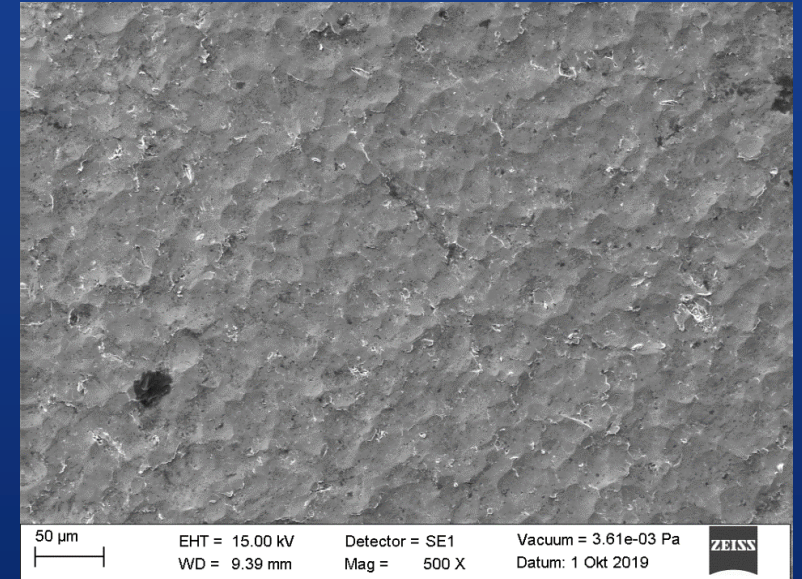
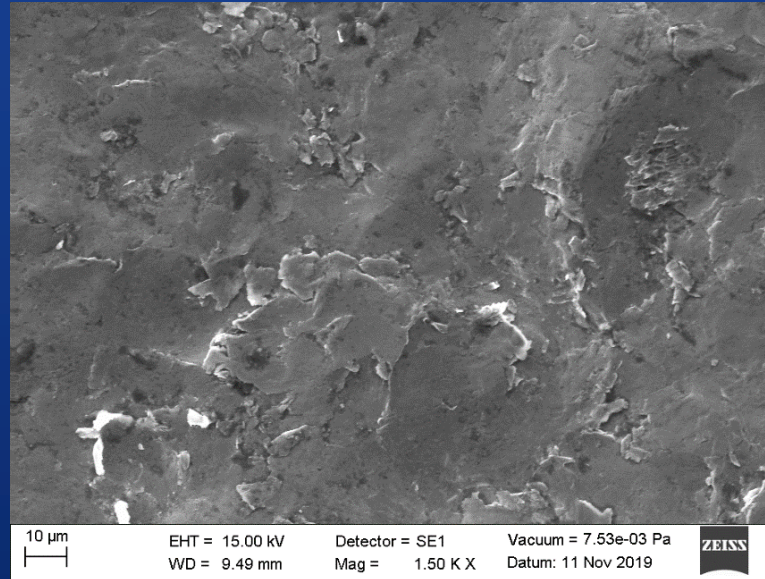
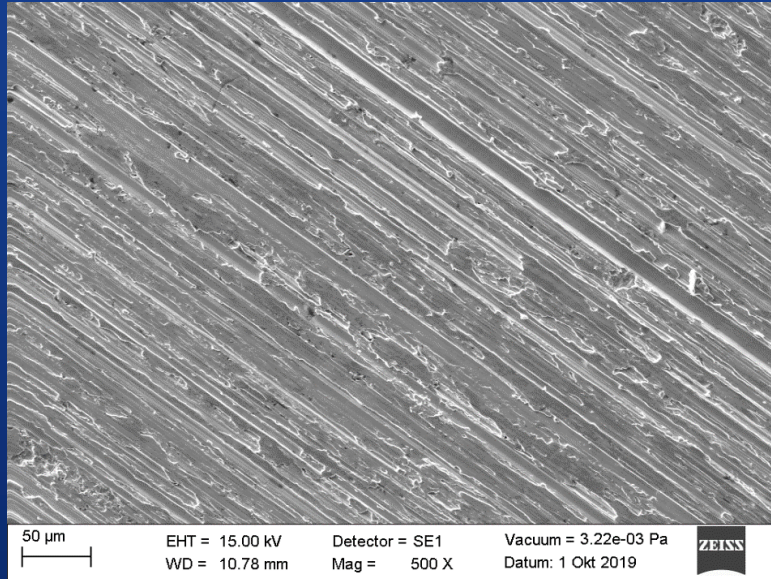
Surfaces for food area

DIN EN 1672-2:2020 – 5.3.2.1 Surfaces for food area

[...] As usually specified (e.g. EHEDG Doc 8), food contact surfaces shall have a surface finish R_a of $0,8 \mu\text{m}$ or lower, although the cleanability strongly depends on **the applied surface finishing technology**, as this can affect the surface topography. A roughness of $R_a > 0,8 \mu\text{m}$ is acceptable if the required cleanability according to the **iterative hygiene risk reduction process is achieved**.

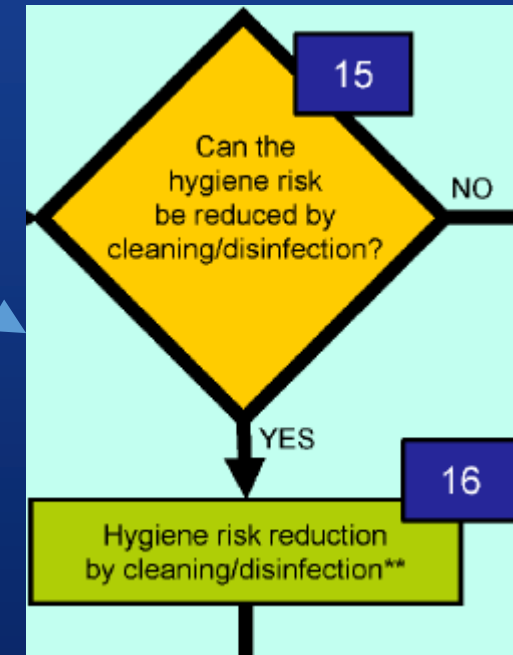
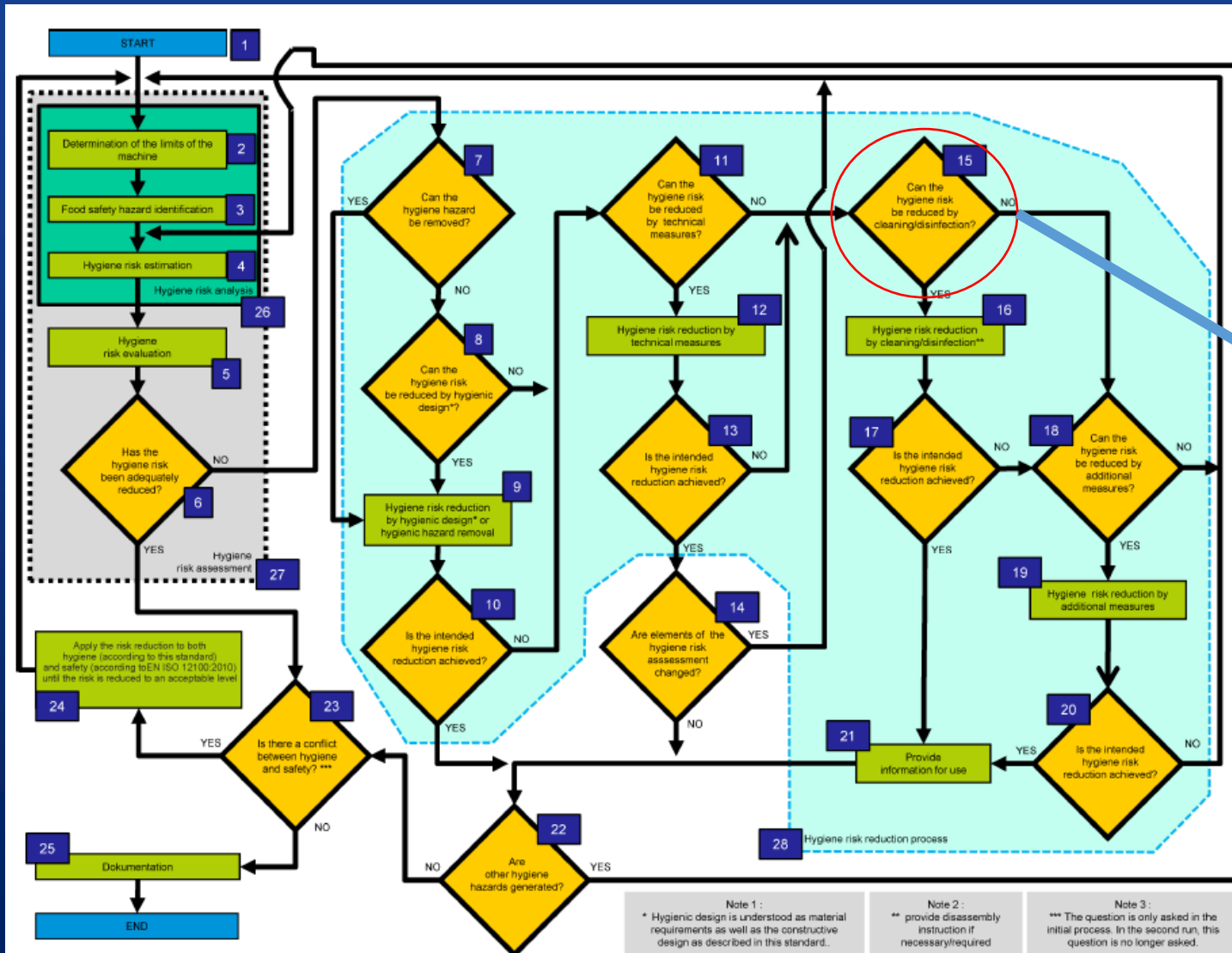


Surfaces for food area

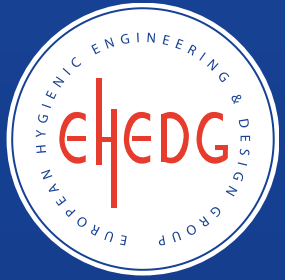





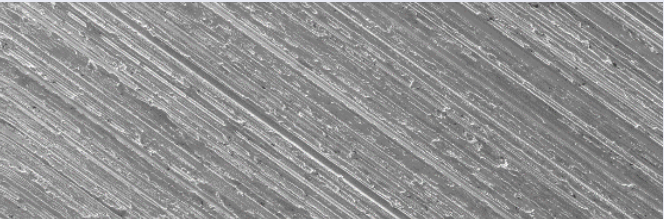
...an approach

Surfaces for food area



Cleaning Test of different surface qualities



Surface quality	Picture	Ra-Value	Microscope
Pickled (2B)		0,19	
Brushed (2J)		0,98	

Cleaning Test of different surface qualities



Contamination detectable via an ATP test:

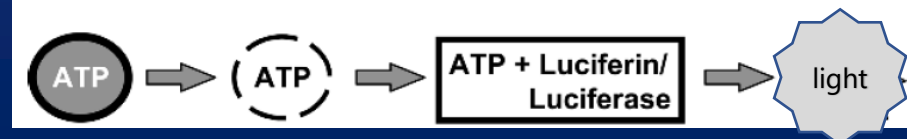
Surface evaluation (RLU = relative lights units)	
Very good:	avg < 500 RLU
tolerable:	500 < avg < 1.000 RLU
bad:	avg > 1.000 RLU
(Hauser, Hygienegerechte Apparate und Anlagen, 2008)	

avg: average

ATP = Adenosintriphosphat = energy supplier

Occurrence:

Microorganisms, animal and plant cells.



Cleaning Test of different surface qualities

first step...



Surface evaluation

Very good: avg < 500 RLU

tolerable: 500 < avg < 1.000 RLU

bad: avg > 1.000 RLU

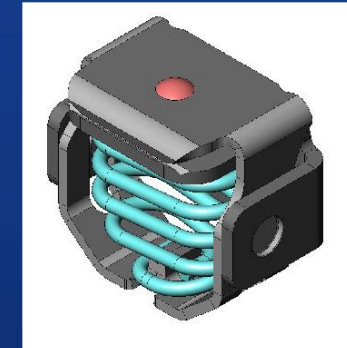
(Hauser, Hygienegerechte Apparate und Anlagen, 2008)

second step...

Confirmation by an external cleaning validation

<u>Surface quality</u>	<u>Picture</u>	<u>Ra-Value</u>	<u>Microscope</u>	
<u>Pickled (2B)</u>		0,19		<u>Cleanable</u>
<u>Brushed (2J)</u>		0,98		<u>Cleanable</u>

Hygienic Design – example (1)

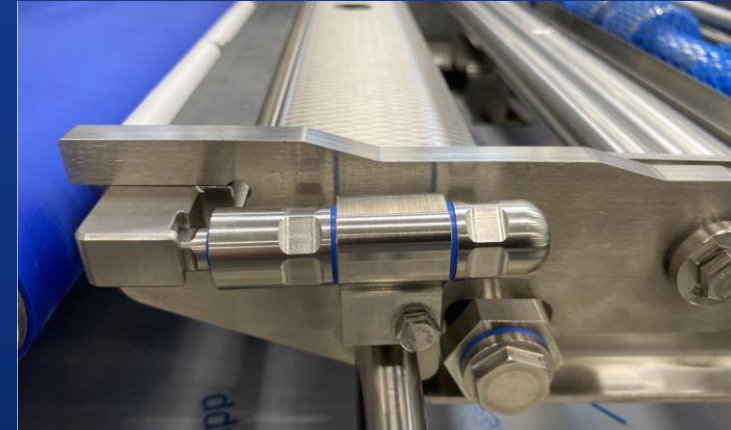


No distance between the windings	distance between the windings
Death spaces, not cleanable	cleanable

Hygienic Design – example (2)



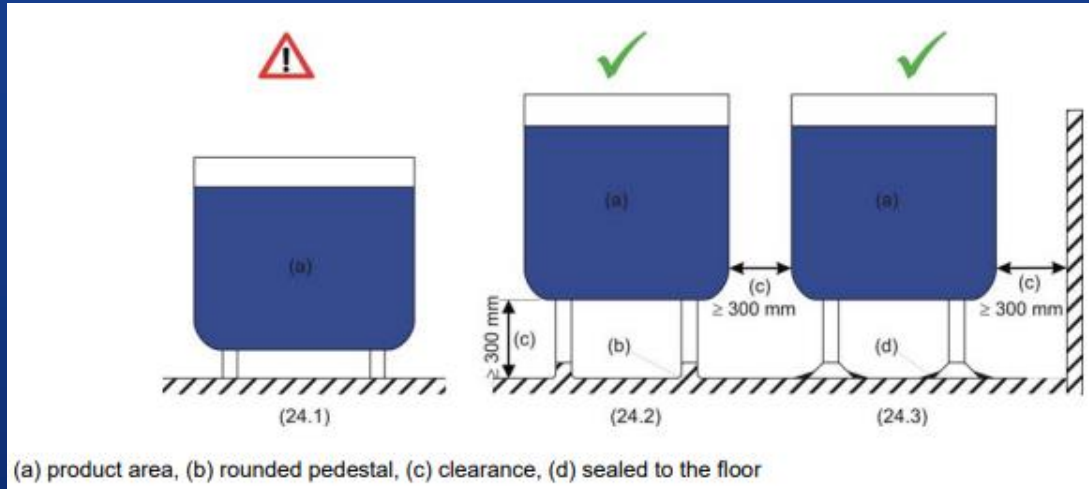
Open threads



Hygienic Design – example (3)

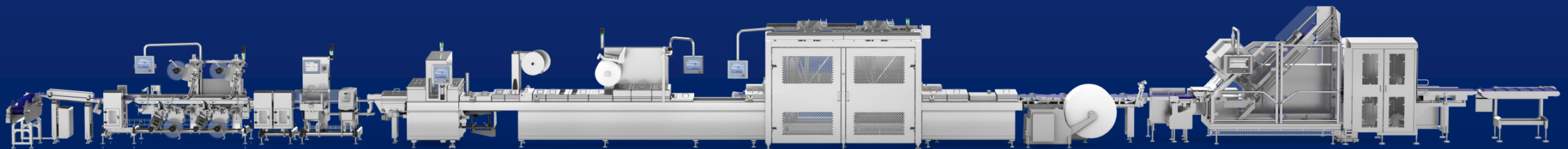
EHEDG

EN 1672-2



$P \leq 150 \text{ mm}$	$H \geq 100 \text{ mm}$
$P > 150 \text{ mm}$	$H \geq 150 \text{ mm}$

Dimensions for clearance underneath (H)
and access distance (P)



Thank you for your attention.