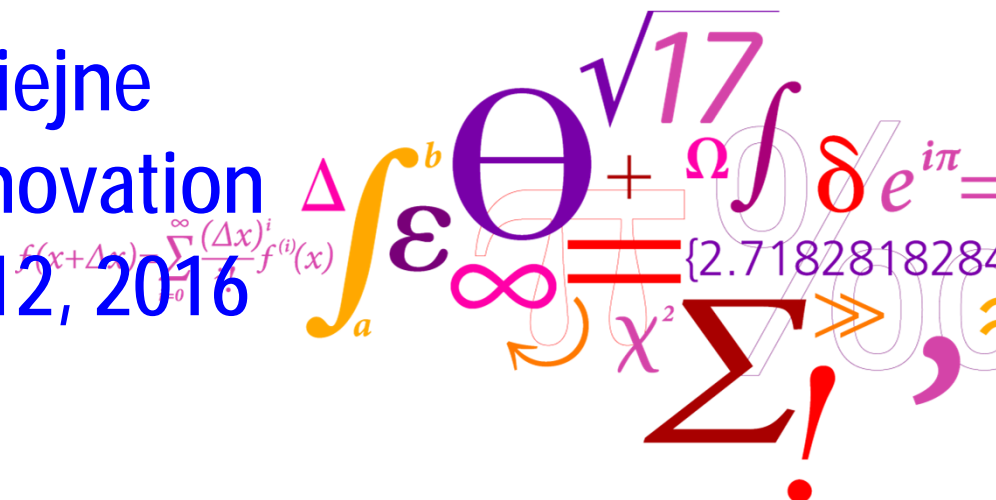# INTRODUCTION TO THE
SEMINAR ON DESIGN & ARCHITECTURE

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Rådet for Bedre Hygiejne
Temadag Hygiejne & Innovation
DTU, Lyngby, January 12, 2016

DTU Food
National Food Institute
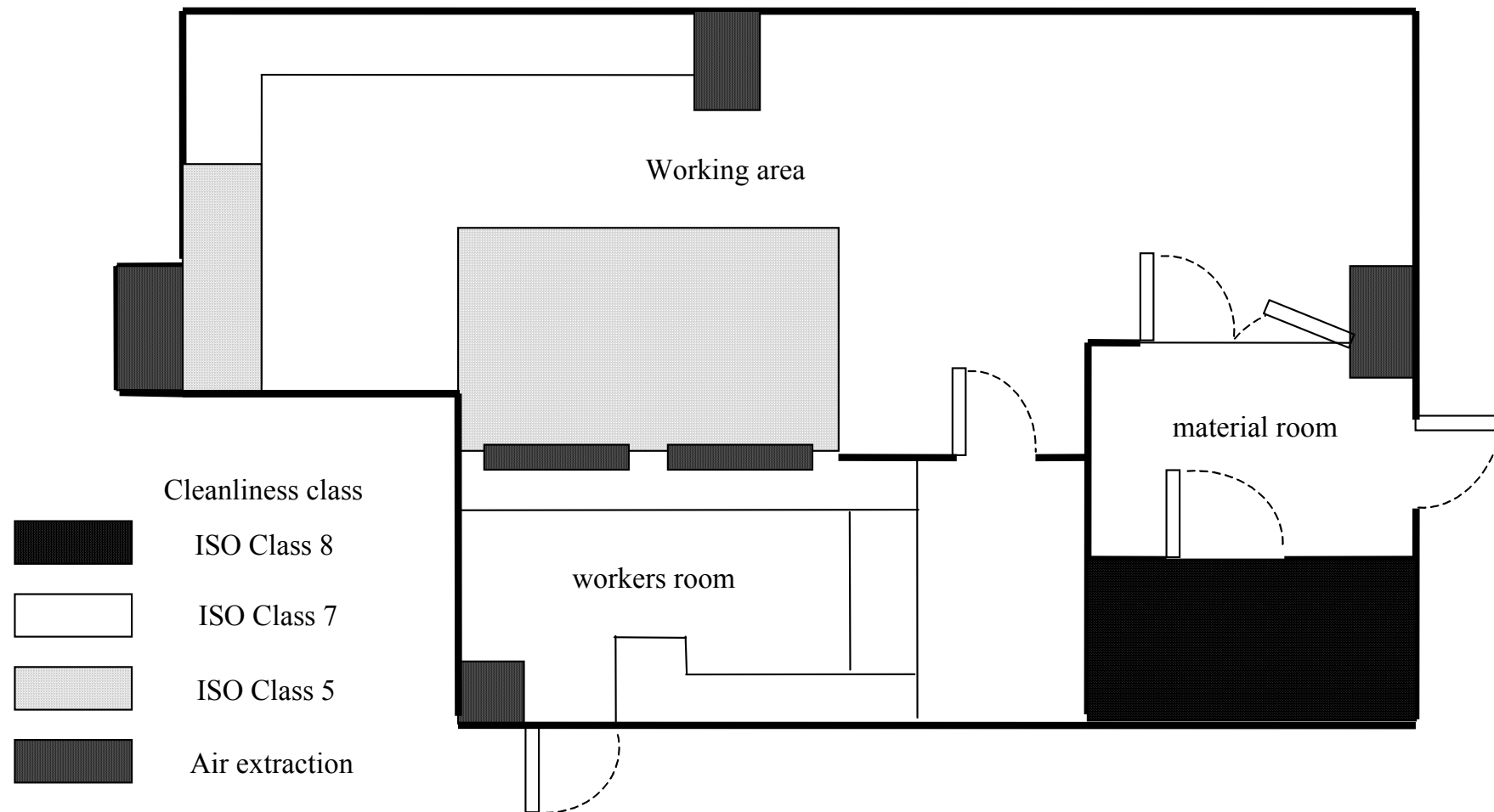
CLEANROOM TECHNOLOGY IS USED IN

- **ULTRA CLEAN AREAS**
  e.g. in production of intravenous solutions

- **CONTROLLED PROCESSES**
  e.g. in operation theatres

Example of Cleanroom Plan

Working area

material room

workers room

Cleanliness class

ISO Class 8

ISO Class 7

ISO Class 5

Air extraction

DEFINITION OF CLEANROOM

- **The aim of cleanroom is to protect processes (or products) from air contaminants**

- **The cleanroom class should be chosen according to the activity**

- **Important factors are air related e.g. air distribution, air flow & pressure differences**

Important in Cleanroom Design

- **Choosing materials of ceiling, walls and floors**

- **Places of doors**

- **Places of equipment**

- **Material flows**

- **Maintenance routes**

- **Places for changing clothes**

- **Routes for personnel**
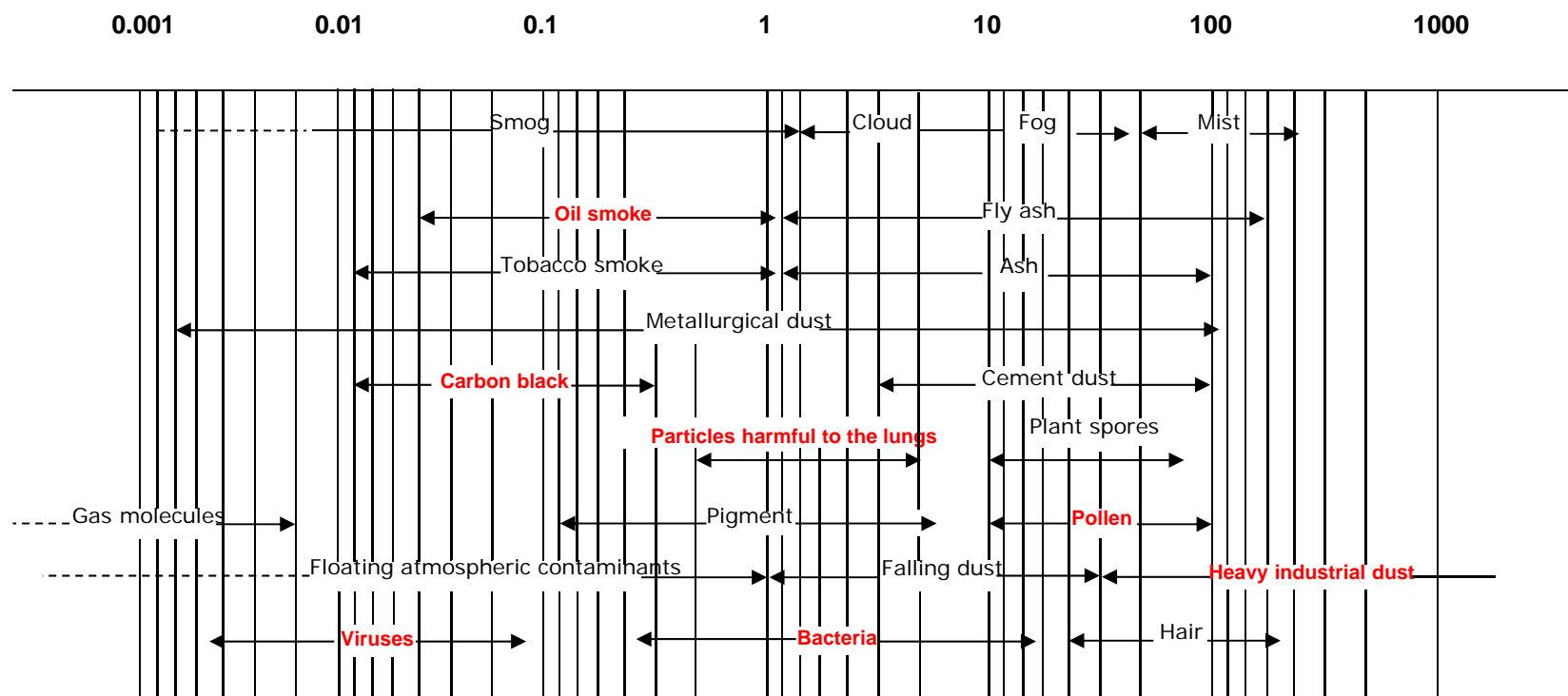
DEFINITION OF CLEANROOM

- **Standard ISO 14644-1:1999 "Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness" defines cleanroom as a room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room, and in which other relevant parameters e.g. temperature, humidity, and pressure, are controlled as necessary.**

DISTURBANCES AFFECTING THE AIR FLOW

- **Disturbances affect laminar air flow much, because contaminants tend to accumulate in swirls.**

- **The air flow can be disturbed by**
    - **physical barriers and moving objects**
    - **persons**
    - **other air flows**

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Particle sizes (μm)

| | 0.001 | 0.01 | 0.1 | 1 | 10 | 100 | 1000 |

Smog · Cloud · Fog · Mist

Oil smoke · Fly ash

Tobacco smoke · Ash

Metallurgical dust

Carbon black · Cement dust

Plant spores

Particles harmful to the lungs

Gas molecules · Pigment · **Pollen**

Floating atmospheric contaminants · Falling dust · **Heavy industrial dust**

Viruses · **Bacteria** · Hair

MOVEMENTS OF PARTICLES IN AIR

Sedimentation of particles in still air / 1 meter

Diameter of particle μm	Sedimentation time min
2	130
4	33
8	8
16	2

Cleanroom classes according to standard ISO 14644-1:1999

ISO classification	Maximum concentration limits (particles/m^3 of air) for particles equal to and larger than the sizes shown below					
	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 µm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1 000	237	102	35	8	
ISO Class 4	10 000	2 370	1 020	352	83	
ISO Class 5	100 000	23 700	10 200	3 520	832	29
ISO Class 6	1 000 000	237 000	102 000	35 200	8 320	293
ISO Class 7				352 000	83 200	2 930
ISO Class 8				3 520 000	832 000	29 300
ISO Class 9				35 200 000	8 320 000	293 000

A) **Particle limits in various cleanroom classes**

Grade	At rest		In operation	
	0.5 μm	5 μm	0.5 μm	5 μm
A	3 500	1	3 500	1
B	3 500	1	350 000	2 000
C	350 000	2 000	3 500 000	20 000
D	3 500 000	20 000	not defined	not defined

B) **Microbial limits in various cleanroom classes**

| Grade	Air samples cfu/m^3	Settle plates (9 cm) cfu/h	Contact plates (5.5 cm) cfu/plate	Glove print (5 fingers) cfu/glove
A	< 1	< 1	< 1	< 1
B	10	5	5	5
C	100	50	25	-
D	200	100	50	-

A = sterile production, B = background environment for Grade A

C = aseptic production & D = less critical stages in sterile production

Proper Behaviour in Cleanrooms

- **Calm, appropriate movements**

- **Proper clothing including protective accessories required in cleanroom class**

Number of particles generated per second and per person larger than size

(particles/second)

particle size (µm)
LASER COUNTER
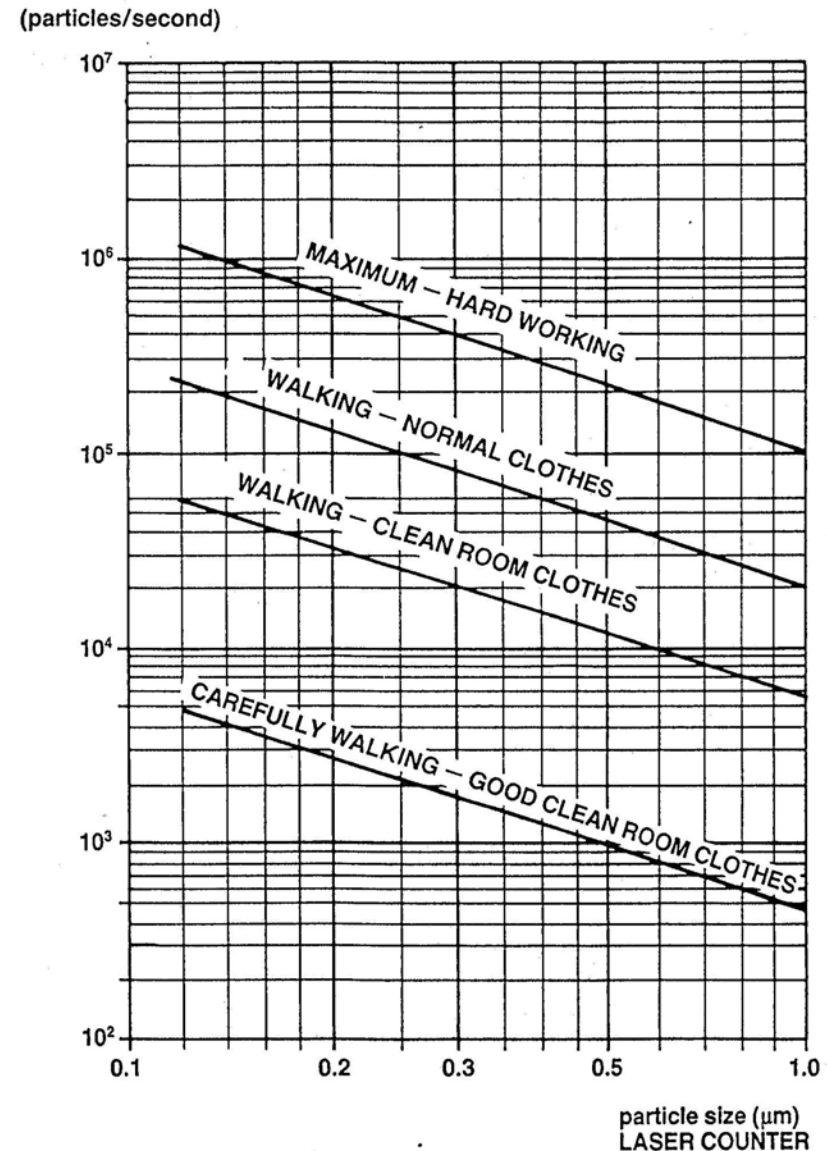
EHEDG Guideline Doc. 44 – Hygienic Design Principles for Food Factories Good Building Design:

- **protect against** physical (e.g. dust particles) , chemical (e.g. poisonous gases) and biological (e.g. insects) **contamination**

- **have as few** personnel entries and exterior **openings as possible**; security and fire escapes are still needed

- have solid doors with **self-closing mechanisms**

- **physical internal walls separating departments** from each other

- **reduce cross-contamination by segregation of various flows** e.g. products, personnel, equipment, waste and air

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For cleaning and maintenance purposes **a minimum clearance under and between equipment as well as from the wall** is suggested:

➢ 20 cm clearance for ≤ 90 cm sized equipment

➢ 30 cm clearance for 90 – 150 cm sized equipment

➢ 45 cm clearance for 150 – 210 cm sized equipment

➢ > 60 cm clearance for > 210 cm sized equipment
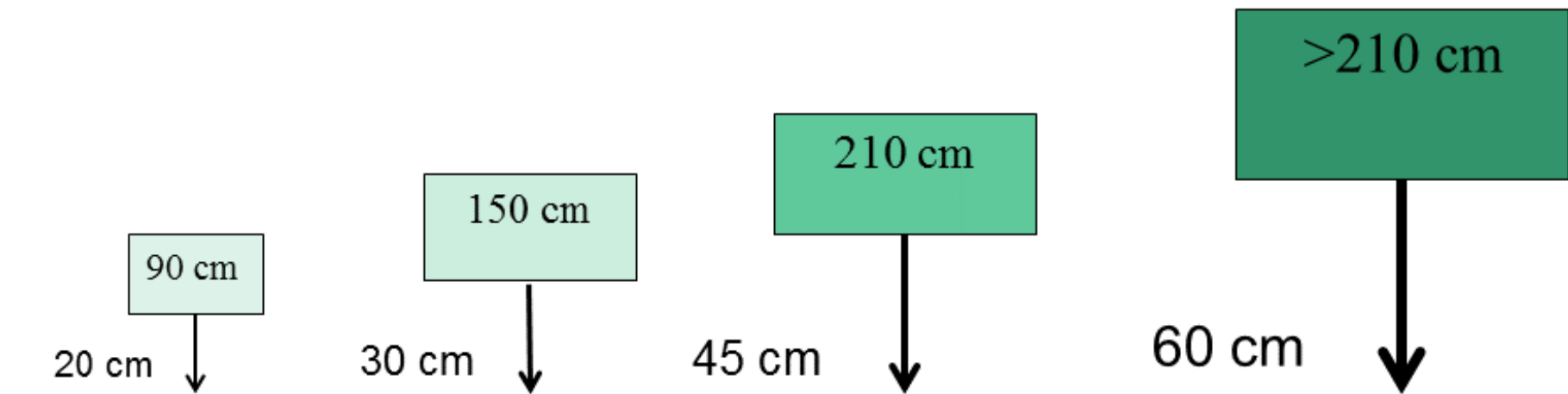
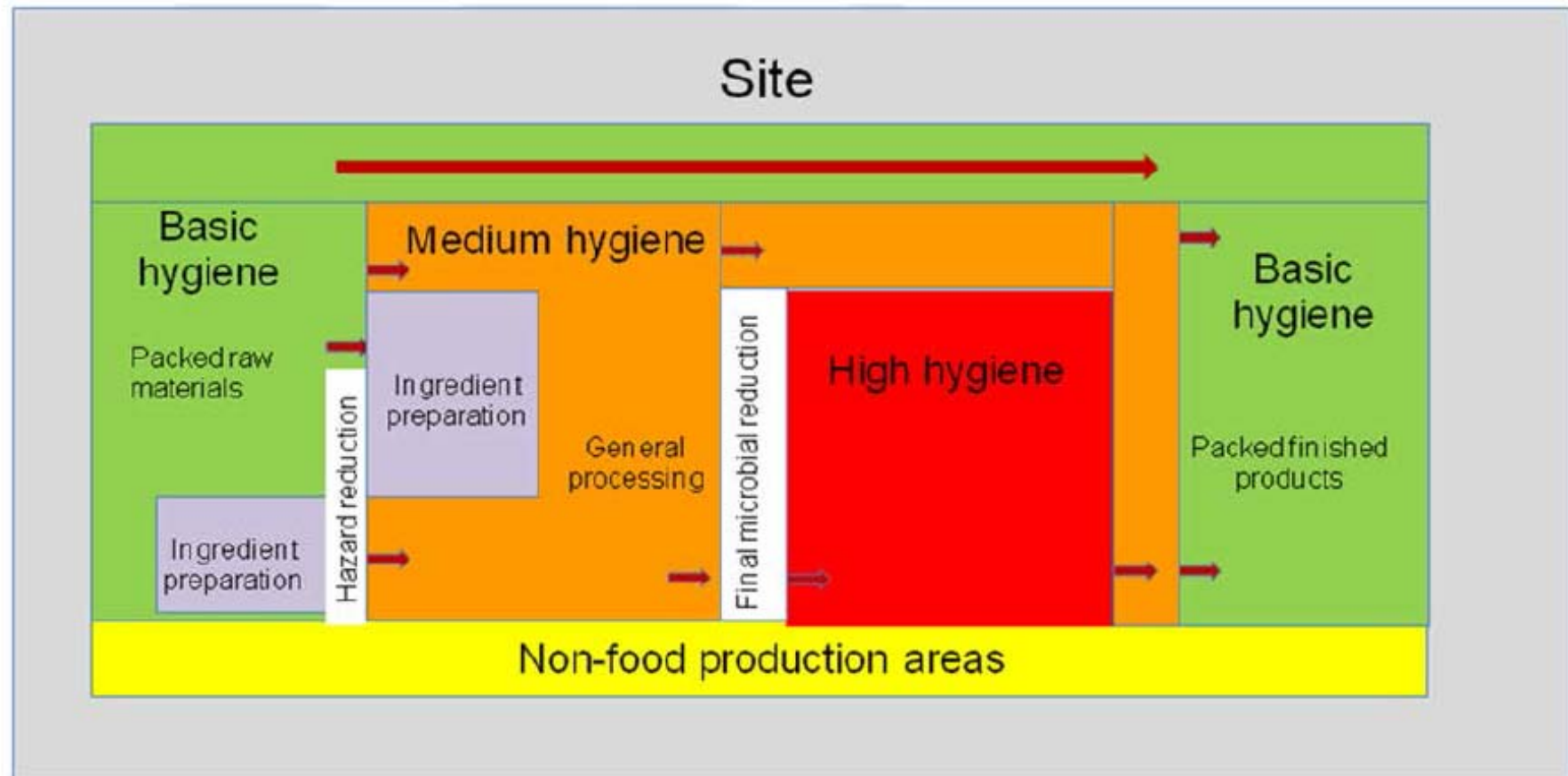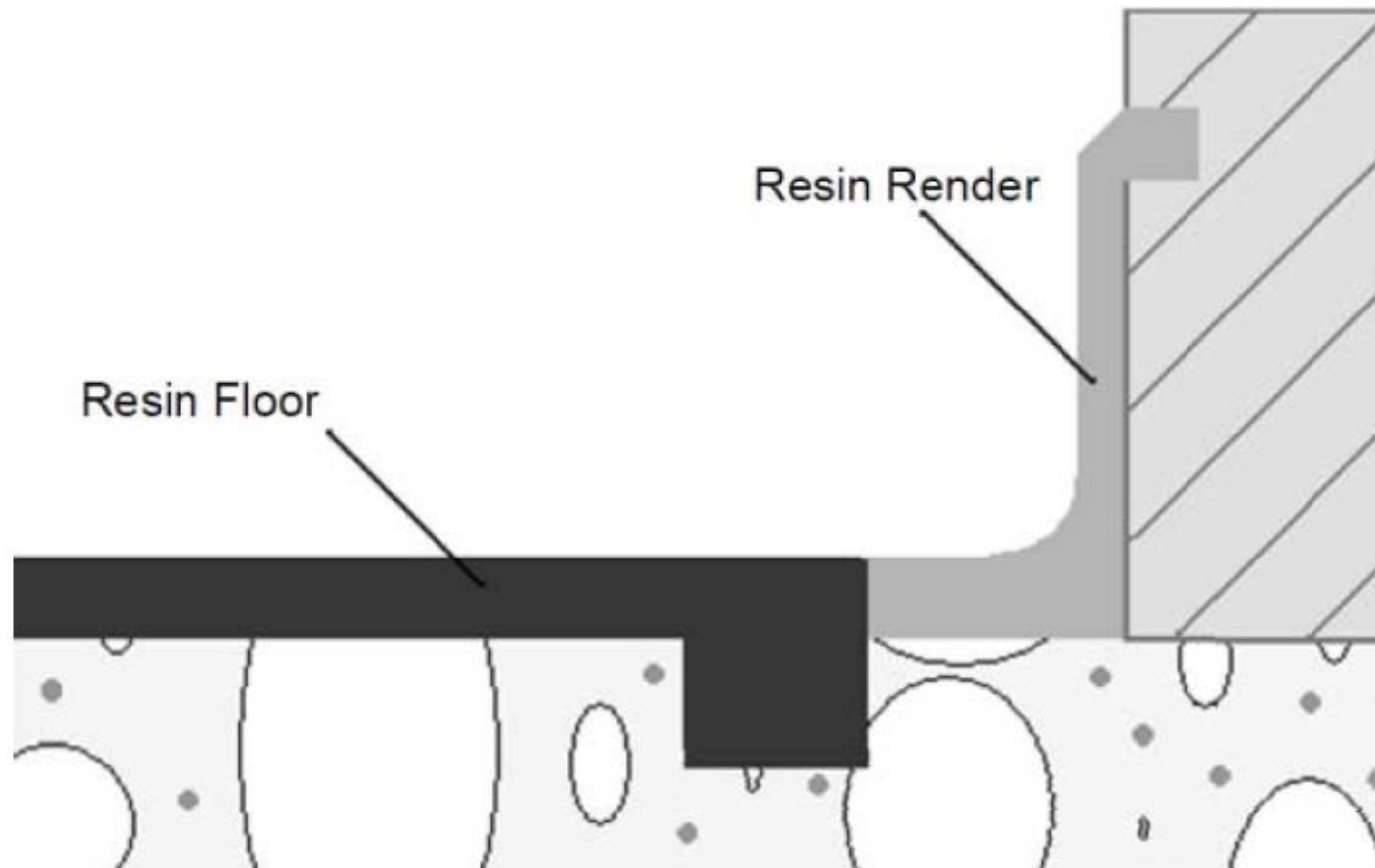# EHEDG Guideline Doc. 44 – Hygienic Design Principles for Food Factories

Figure 7.1.1 - Schematic representation of food manufacturing zones showing potential routes of product flow dependent on the product's need for microbiological protection from the manufacturing environment.

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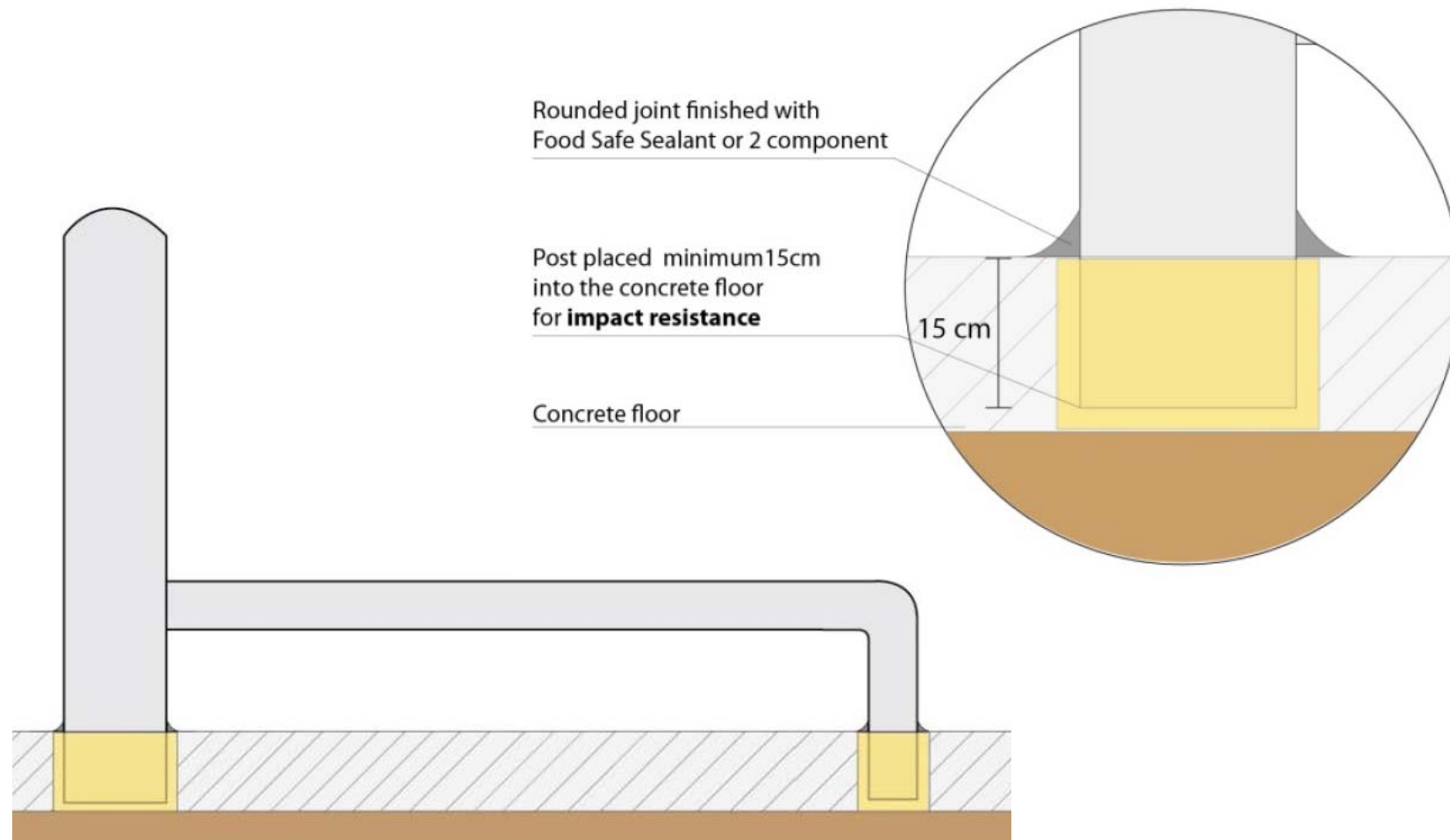# EHEDG Guideline Doc. 44 – Hygienic Design Principles for Food Factories

Material transport through hatches with two doors – one in the processing area and one in the hygienic area – which should be interlocked i.e. only one door can be opened at one time

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Resin Render

Resin Floor

Resin floor finish (above) - The resin render must be non-porous and of sufficient thickness to be impervious to water. This solution is widely used for solid walls and kerbs.

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Rounded joint finished with Food Safe Sealant or 2 component

Post placed minimum 15cm into the concrete floor for **impact resistance**

15 cm

Concrete floor

Insertion of a crash bar into the floor structure with detailed insertion using 2-component epoxy fixation.

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The joints between the crash bar and the floor must be rounded out and sealed with a food safe sealant.

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coved base skirting, laying

bonding layer / tile adhesive

Argelith tile

expansion joint

wall

screed

styrene strip

PE foil

water proofing layer

expansion cord

concrete basement
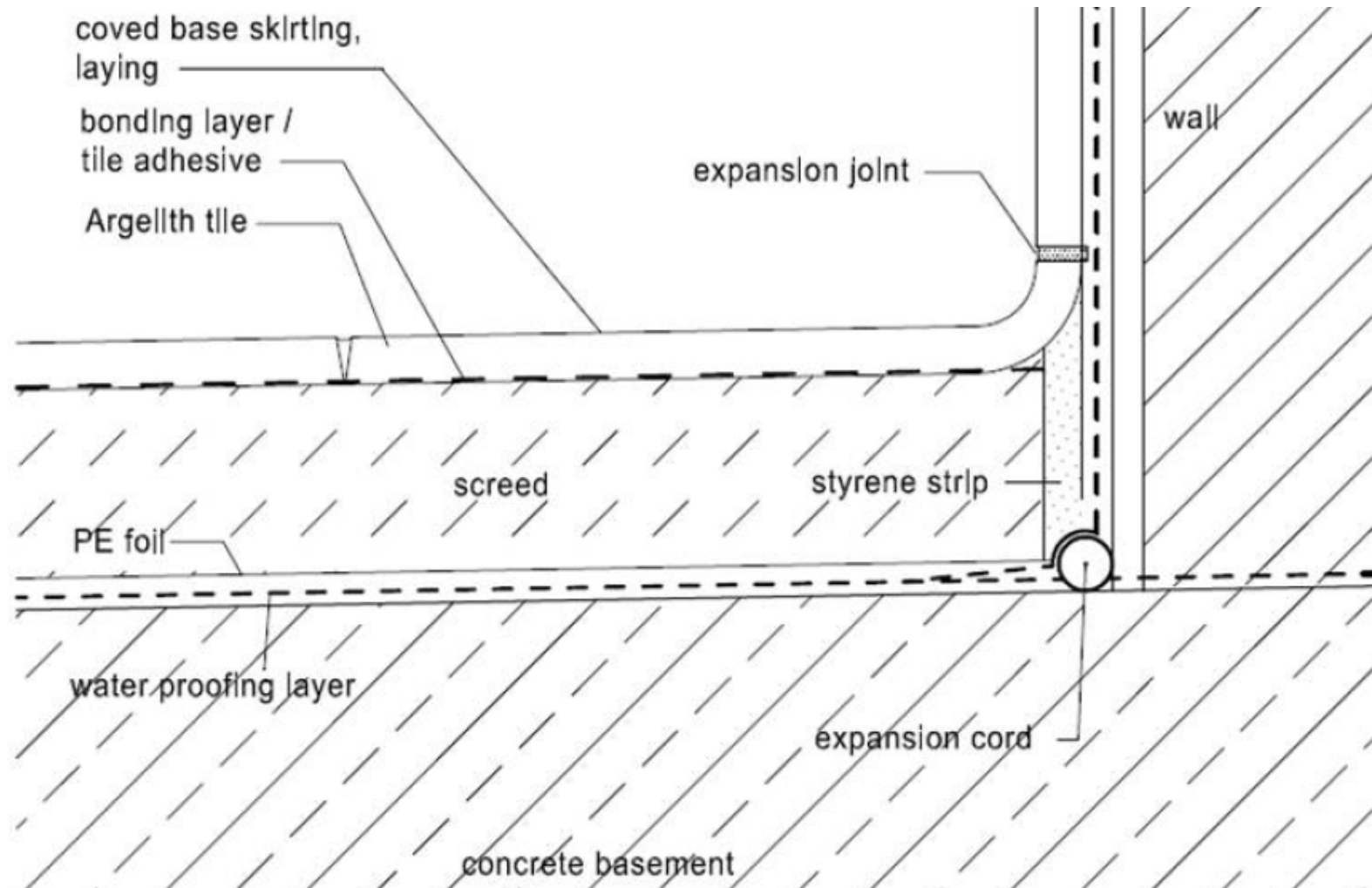
Tiled cove detail completed with tiled floor and wall

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Coving tiles completed with tiled floor and wall

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Food processing machinery

Line discharging pipe

Safe air gap:
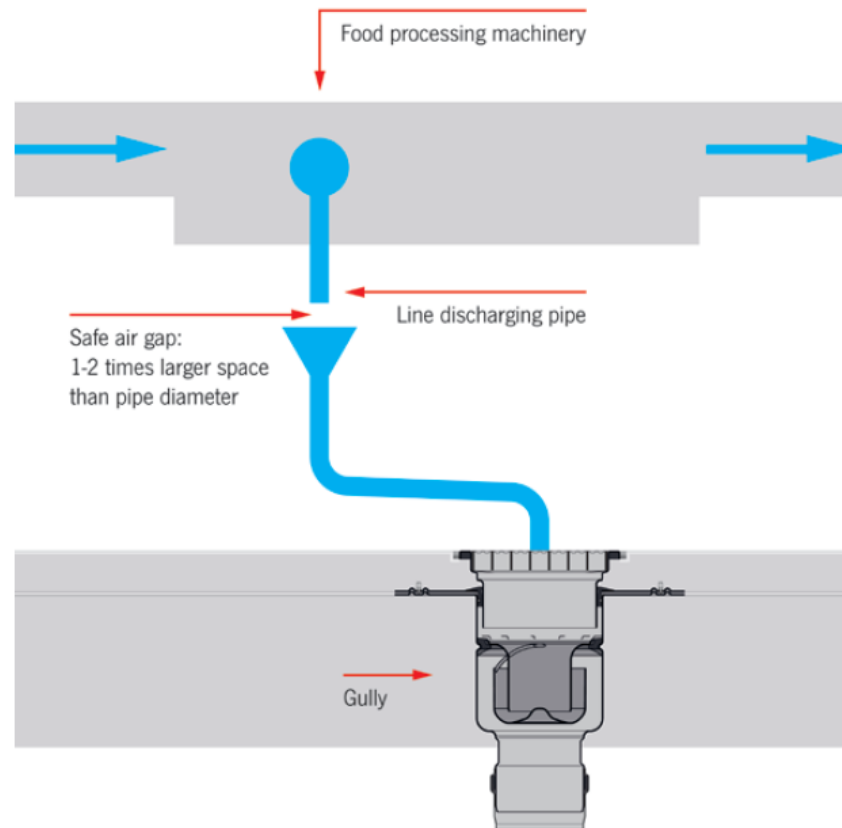1-2 times larger space
than pipe diameter

Gully

Figure 8.7.1 - Tundish or funnel directly connected to drain gully grating

The gap is essential to avoid cross contamination and backflow from the drainage to the machine. To be fully accessible for cleaning and inspection, drains should not ne positioned under the machinery.

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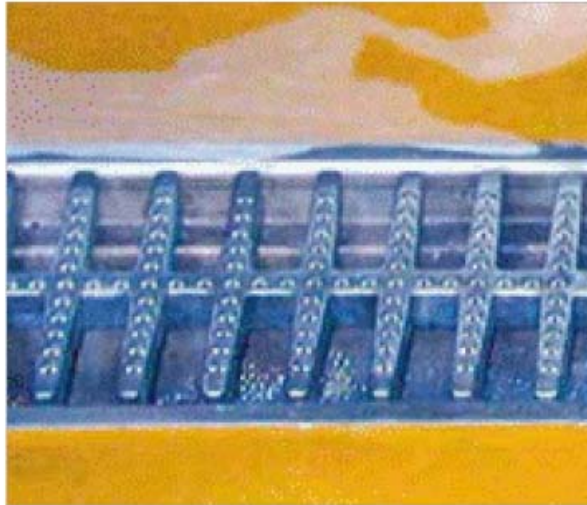# EHEDG Guideline Doc. 44 – Hygienic Design Principles for Food Factories

Figure 8.7.4 - Example of channel with gratings having open sides allowing solid waste into the drain

The size and slope of the drainage channel should be increased to support transport of solid waste. The waste should have unrestricted access to the drainage system (see above).

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No edge in-fill

Metal to metal contact / crevices

Sharp inside corners

Fixed water trap

Figure 8.7.5 - Gully of poor design

Edge in-fill

Radiused inside corners

Weldings without crevices

Removable water trap

Drainable body
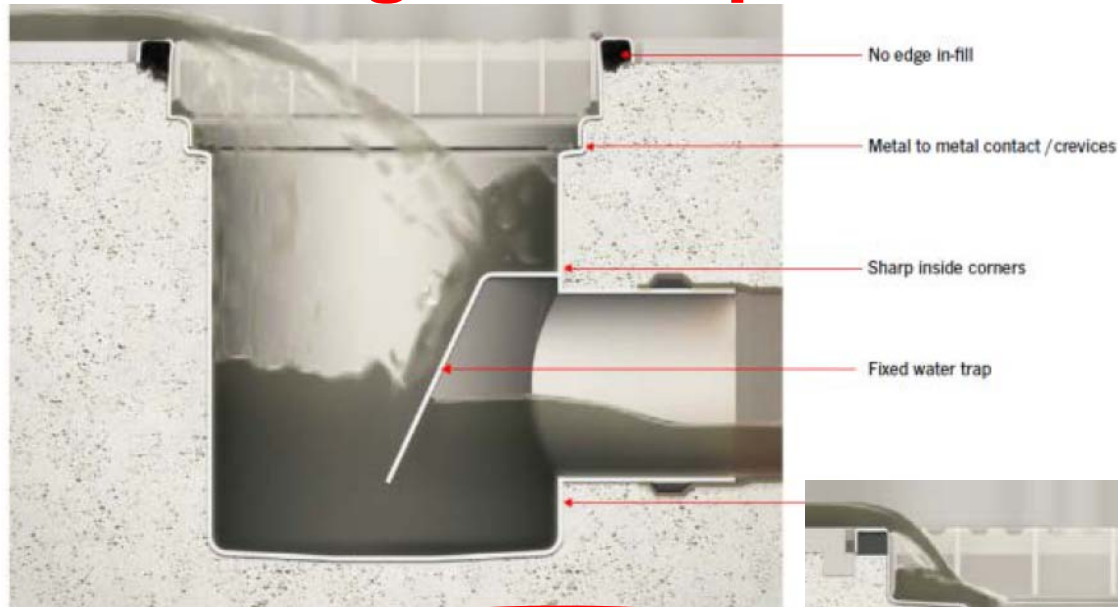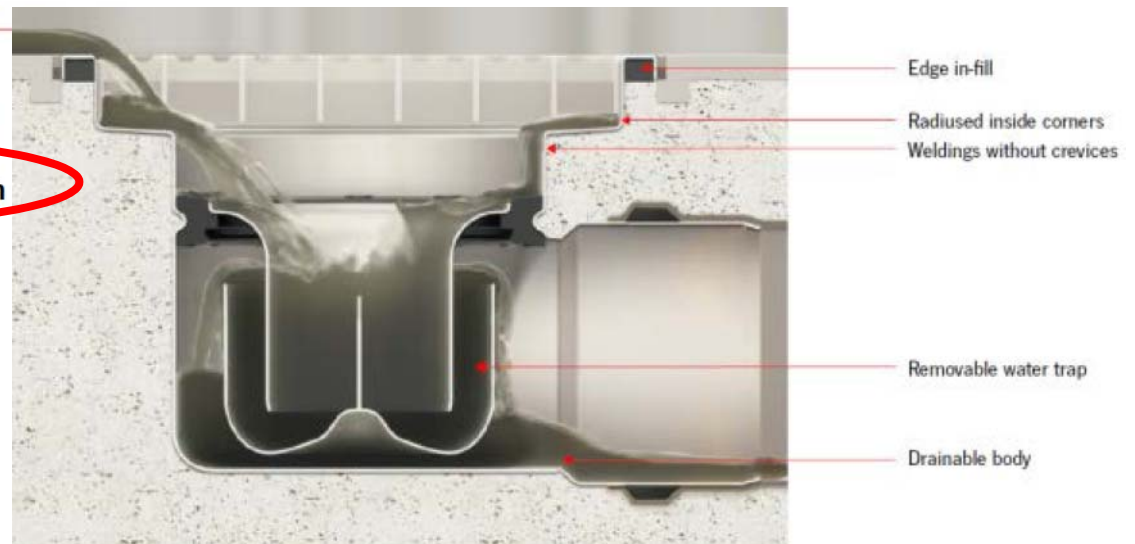
Figure 8.7.6 - Gully of preferred design

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➢ **Premises and equipment must be designed, fabricated, constructed and installed according to sound hygienic desing principles**

➢ **Hygienic design provides defence against**

  ➢ **internal factory hazards e.g. easy to clean and no harbourage sites**

  ➢ **external factory hazards e.g. deliberate contamination**

➢ **Hygienic design provides hygienic conditions via best practices and structure rigidity**

EHEDG Guideline Doc. 44 –The Site:
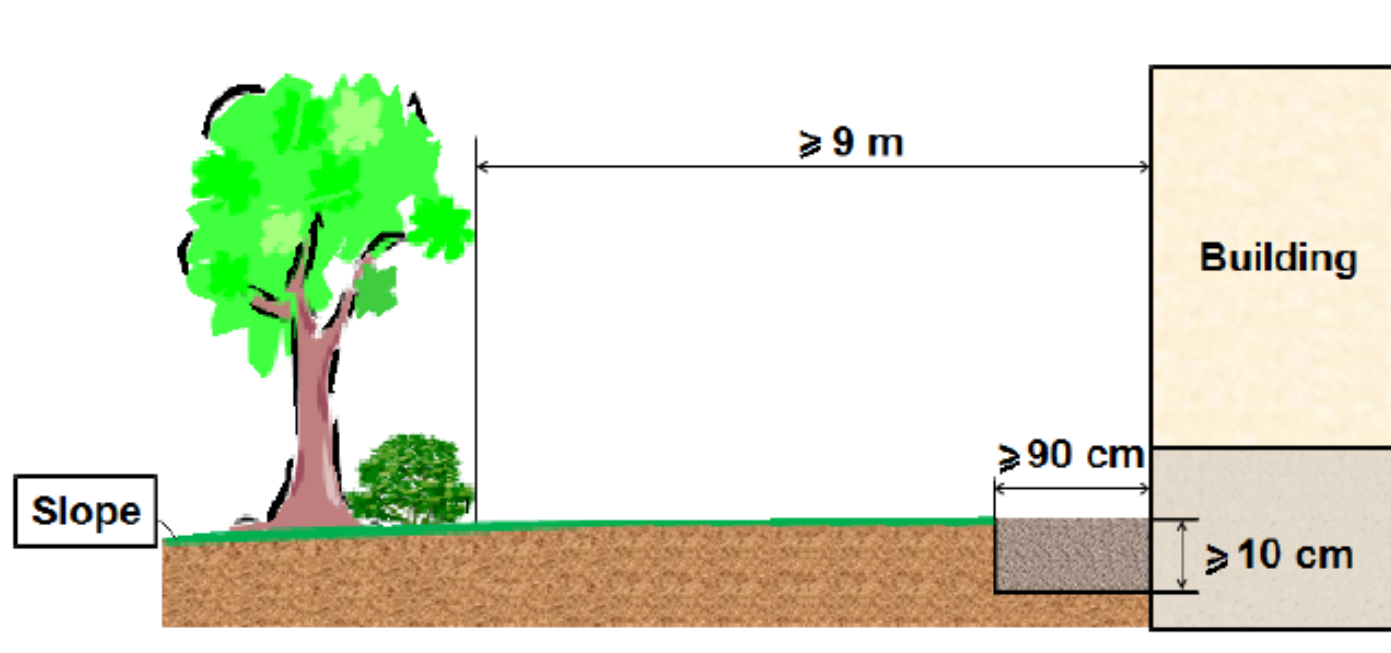
5.3.1 - The site should have a path or pebbled gravel strip around the factory that is at least 90 cm wide and 10 cm deep, and trees should be located at least 9 m from buildings.

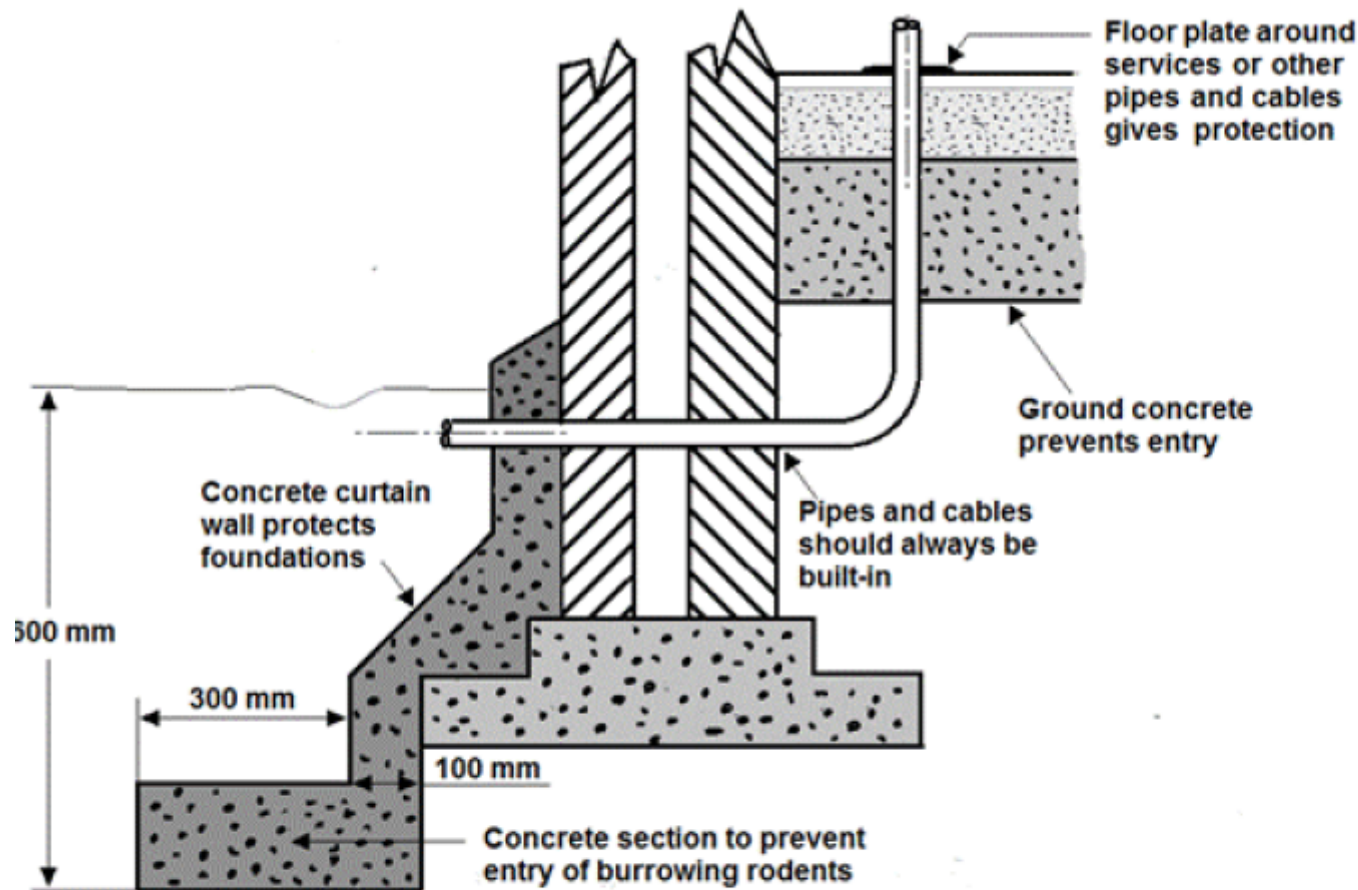# EHEDG Guideline Doc. 44 – Hygienic Design Principles for Food Factories

Floor plate around services or other pipes and cables gives protection

Ground concrete prevents entry

Concrete curtain wall protects foundations

Pipes and cables should always be built-in

500 mm

300 mm

100 mm

Concrete section to prevent entry of burrowing rodents

Figure 8.1.1 - Pest proofing measure to prevent entry through foundations

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EXTERIOR WALLS should have no horizontal surfaces (gradient $\geq 45°$) to be insect and rodent proof