Why is Hygienic Design Important?

FOOD SAFETY

Prevents Ingress

Prevents Growth

Prevents Accumulation

Easier to Clean

Less Downtime

Operational Costs

Sustainability

Quality

Efficiency

Compliance

The ‘Influencer’ PRP?

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Hygienic Design

Equipment / Buildings

- Cleaning / Hygiene
- Allergen Management
- PPM
- Pest Control
- GMP
- Waste Control
- Process Controls

Legislation, Guidelines & Standards

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Legislation

2006/42/EC New Machinery Directive
852/2004/EC Annex II Chapter 5 Hygiene of Food Stuffs
1935/2004 Material and Articles intended to be in contact with food

Industry Standards

ISO 14159:2002 – Safety of Machinery — Hygiene Requirements for the Design of Machinery
EN 1672-2:2009 – Food Processing Machinery – Basic Concepts – Hygiene and Cleanability Requirements

Cost of Poor Hygienic Design

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- Entire crop of cantaloupes recalled (300,000)
- 147 cases – 33 deaths
- *L.monocytogenes* found on equipment and in water
- Contaminated in the farms pack house
- Dirty water and old, hard to clean equipment that was designed and had previous use for potato peeling. Unfit for melons – consumed raw
- No antibacterial agent in the wash

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Colorado cantaloupe farmers charged in listeria outbreak

27 September 2013

Jensen Farms co-owner Eric Jensen was seen examining his cantaloupe crop in September 2011

The owners of a Colorado cantaloupe farm linked to a 2011 food poisoning outbreak which killed 33 people and sickened 147 have been arrested and charged with selling contaminated food.

Eric and Ryan Jensen face up to six years in prison and up to $1.5m (£936,856) in fines.

The brothers did not adequately wash the melons before selling them, US officials say.

The Jensens called the outbreak a "terrible accident".

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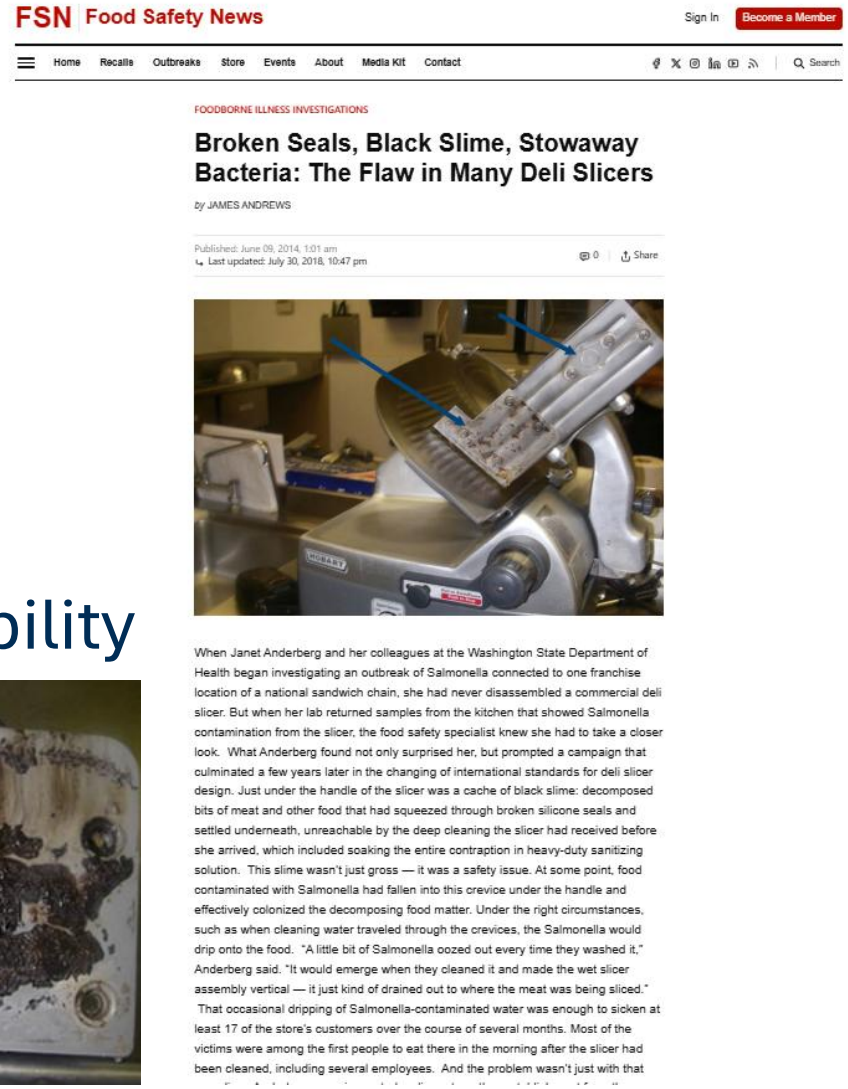
Cost of Poor Hygienic Design

- Maple Leaf – Deli Meats 2008 Canada
- 220 cooked products contaminated
- 57 confirmed cases- 23 deaths
- Poor HD of sliced machines - lack of cleanability
- $20M Recall Cost / $27M lawsuit



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FOODBORNE ILLNESS INVESTIGATIONS

Broken Seals, Black Slime, Stowaway Bacteria: The Flaw in Many Deli Slicers

by JAMES ANDREWS

Published: June 09, 2014, 1:01 am
Last updated: July 30, 2018, 10:47 pm

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When Janet Anderberg and her colleagues at the Washington State Department of Health began investigating an outbreak of Salmonella connected to one franchise location of a national sandwich chain, she had never disassembled a commercial deli slicer. But when her lab returned samples from the kitchen that showed Salmonella contamination from the slicer, the food safety specialist knew she had to take a closer look. What Anderberg found not only surprised her, but prompted a campaign that culminated a few years later in the changing of international standards for deli slicer design. Just under the handle of the slicer was a cache of black slime: decomposed bits of meat and other food that had squeezed through broken silicone seals and settled underneath, unreachable by the deep cleaning the slicer had received before she arrived, which included soaking the entire contraption in heavy-duty sanitizing solution. This slime wasn't just gross — it was a safety issue. At some point, food contaminated with Salmonella had fallen into this crevice under the handle and effectively colonized the decomposing food matter. Under the right circumstances, such as when cleaning water traveled through the crevices, the Salmonella would drip onto the food. "A little bit of Salmonella oozed out every time they washed it," Anderberg said. "It would emerge when they cleaned it and made the wet slicer assembly vertical — it just kind of drained out to where the meat was being sliced." That occasional dripping of Salmonella-contaminated water was enough to sicken at least 17 of the store's customers over the course of several months. Most of the victims were among the first people to eat there in the morning after the slicer had been cleaned, including several employees. And the problem wasn't just with that

Cost of Poor Hygienic Design

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ZERO2FIVE research

Change overs would..
'...typically, now take 30 minutes ... historically, they could have taken 2 hours.'

Second hand equipment could account for between 50-80% of the equipment they purchase

Capital Cost V's Total Cost of Ownership?

Purchase Price
Delivery
Installation & Training

Downtime
Maintenance
Cleaning
Chemicals
Power
Water
Parts
Modifications
Compliance / quality
End of life costs

GFSI JI and JII

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- Driving forward improvements in CPO standards
- Voluntary
- JI – Supplier
- JII - User
- **No CPO scheme has taken up JI** no standard
- The Future

GFSI
Global Food Safety Initiative

BRCGS Non-Conformances

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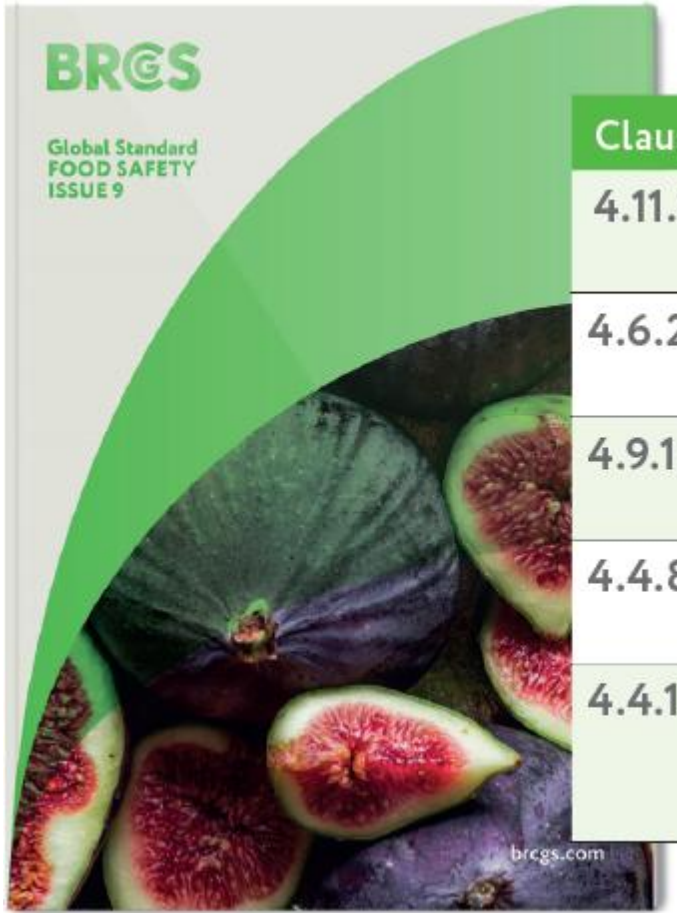

Clause	Description	NCs raised
4.11.1	The premises and equipment shall be maintained in a clean and hygienic condition.	4,715
4.6.2	The design and construction of equipment shall be based on risk, to prevent product contamination.	3,322
4.9.1.1	Processes shall be in place to manage the use, storage and handling of chemicals to prevent chemical contamination.	3,284
4.4.8	Doors (both internal and external) shall be maintained in good condition.	3,007
4.4.1	Walls shall be finished and maintained to prevent the accumulation of dirt, minimise condensation and mould growth, and facilitate cleaning.	2,933

BRCGS Global Food Standard Food Safety Issue 9 ***– Top 5 non conformances 2024-2025*** *– BRCGS Annual Report 2024-25*

Hygienic Design Risk Assessment

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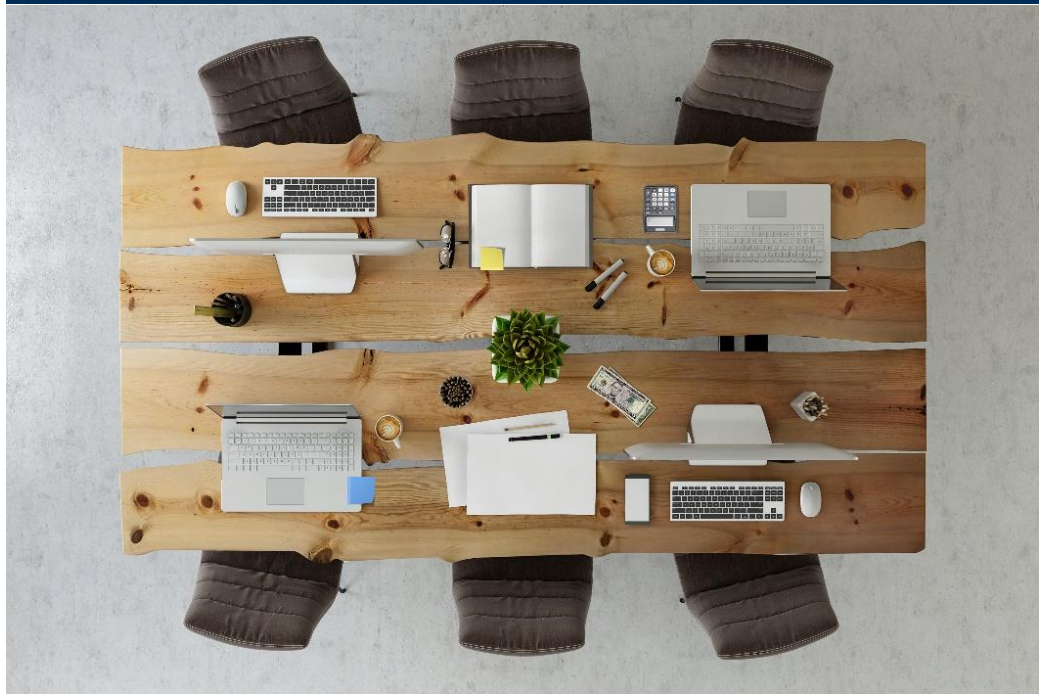
The HD Team



- Design / Architecture
- Finance
- Food Technology, Quality and Safety
- Engineering
- Hygiene
- Operations / Production

Hygienic Design Risk Assessment HDRA

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Intended use information

Consider the hazards by type

What part of process and subsequent steps

Consider the likelihood of occurrence at time of processing

Consider the likelihood of occurrence at time of final consumption

Determine the overall risk

Intended Use

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- Products and characteristics
- Processes
- Final consumer
- Cleaning conditions
- Purpose
- Operating environment
- Legal, industry, customer requirements
- Current / Future / Past

Types of Hazards

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Chemical	Biological
• Cleaning chemicals • Lubricants • Allergens • Material migration	• Pathogens • Parasites • Insects / pests
Physical	**Quality**
• Metal • Glass • Rubber • Plastic	• Processing • Organoleptic issues • Brand protection

Hygienic Design Risk Assessment HDRA

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		Potential Negative Impact of Contamination		
Likelihood of occurrence on ingress, accumulation or growth		Low (1)	Medium (2)	High (3)
	High (3)	Medium (3)	High (6)	High (9)
	Medium (2)	Low (2)	Medium (4)	High (6)
	Low (1)	Low (1)	Medium (3)	Medium(3)

Likelihood of occurrence	
3	Hazard likely to be present, accumulate or grow and be transferred to food
2	Hazard likely to be present, introduced or harboured
1	Hazard not likely to be present in equipment building or environment

Potential Negative Impact	
3	Presence of significant hazards identified by the HACCP plan which are not controlled by a later process step or segregation
2	Presence of a hazard recognised by the HACCP plan, quality or brand protection issue which is not controlled by a later process step or segregation
1	Presence of Hazard irrelevant or controlled by a later process step

HDRA
Intended Use: Cooked Meat Slicer

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Hazard	Likelihood	Negative Impact	Overall Risk
Cleaning Chemicals	1	1	1
Lubricants	2	2	4
Material Migration	2	2	4
Allergens	1	1	1
Pathogens	2	3	6
Pests	1	1	2
Metal	3	1	3
Rubber	2	2	4
Glass	1	1	1
Plastic	2	2	4
Organoleptic	1	1	1
Species	1	1	1
Processing	1	1	1

User Requirement Specification

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Information required:

- Engineering requirements
- H&S
- **Intended Use**
- **HDRA**
- **Any hazard control requirements**

- Compare the supplier's specification against the URS (off the shelf)
- Supply URS to supplier for them to review (bespoke)

Supplier Specification

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

- Assess SS and equipment and ensure all hazards in URS are mitigated

- If they can not PRP / OPRP will need to manage

Hazard Mitigation

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Foreseen hazards from risk assessment

Hazards identified by comparing URS and SS

Hazards created during installation

Hazard Mitigation

Apply Hygienic Design principles

- Compatibility of materials
- Ability to clean
- Ability to access
- Ability to drain
- Ability to segregate
- Surfaces and geometry

Free to download

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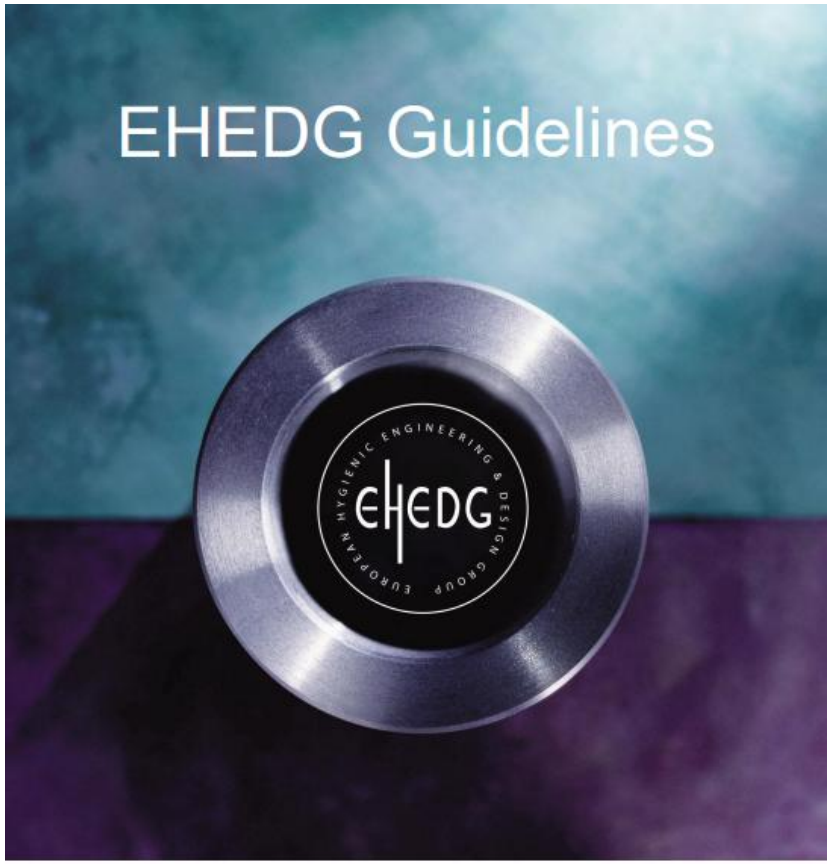

Guideline 8
HYGIENIC DESIGN PRINCIPLES
4th Edition, December 2025

Cooked Meats Slicer HDRA

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- Lubricants **must** be segregated from the products - Use food safe lubricants
- Food contact surface **must** be made from food grade material
- HD mitigation is required for the use of rubber and plastic - eliminate or specify based on cleaning chemicals / products/ usage
- HD mitigation required for pathogens:
  - regular quick removal of blade guard and the prevention of any ingress and accumulation

Hazard	Likelihood	Negative Impact	Overall Risk
Cleaning Chemicals	1	1	1
Lubricants	2	2	4
Material Migration	2	2	4
Allergens	1	1	1
Pathogens	2	3	6
Pests	1	1	2
Metal	3	1	3
Rubber	2	2	4
Glass	1	1	1
Plastic	2	2	4
Organoleptic	1	1	1
Species	1	1	1
Processing	1	1	1

Installation

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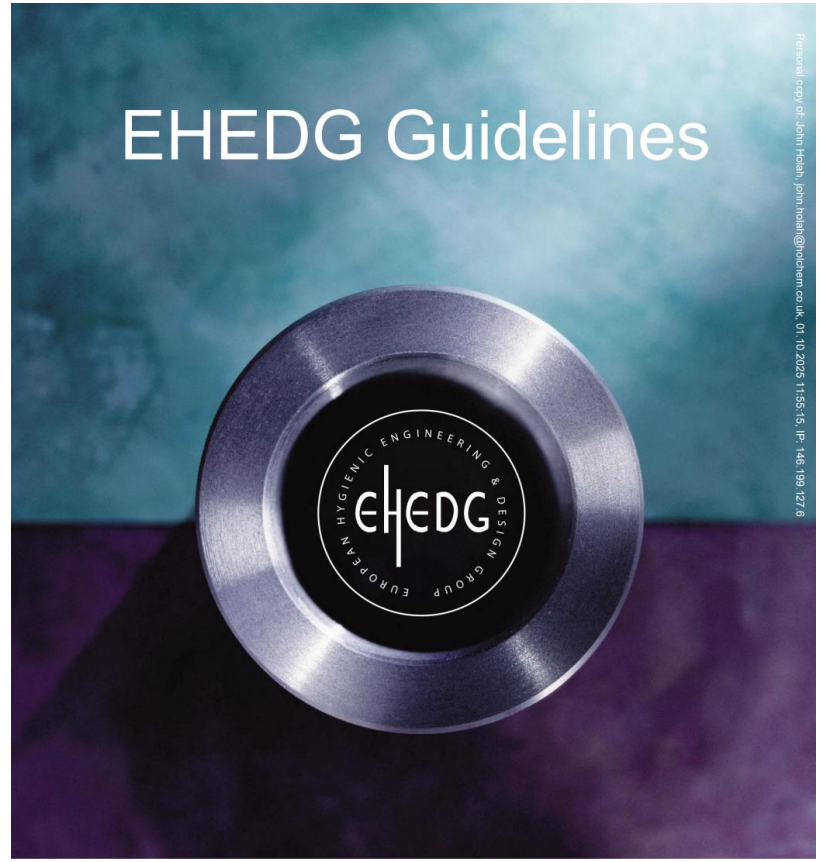
Common risk factors for persistence are inadequate zoning and hygiene barriers; lack of hygienic design of equipment and machines; and inadequate cleaning and disinfection



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Persistence of microbiological hazards in food and feed production and processing environments

EFSA Panel on Biological Hazards (BIOHAZ), Konstantinos Koutsoumanis, Ana Allende, Declan Bolton, Sara Bover-Cid, Marianne Chemaly, Alessandra De Cesare, Lieve Herman ... See all authors

First published: 19 January 2024 | https://doi.org/10.2903/j.efsa.2024.8521 | VIEW METRICS

Adopted: 6 December 2023
Amended: 18 June 2024

Guideline 44 Part 2

MANAGING BUILDING WORK AND EQUIPMENT INSTALLATION/REMOVAL DURING FOOD PRODUCTION

July 2025

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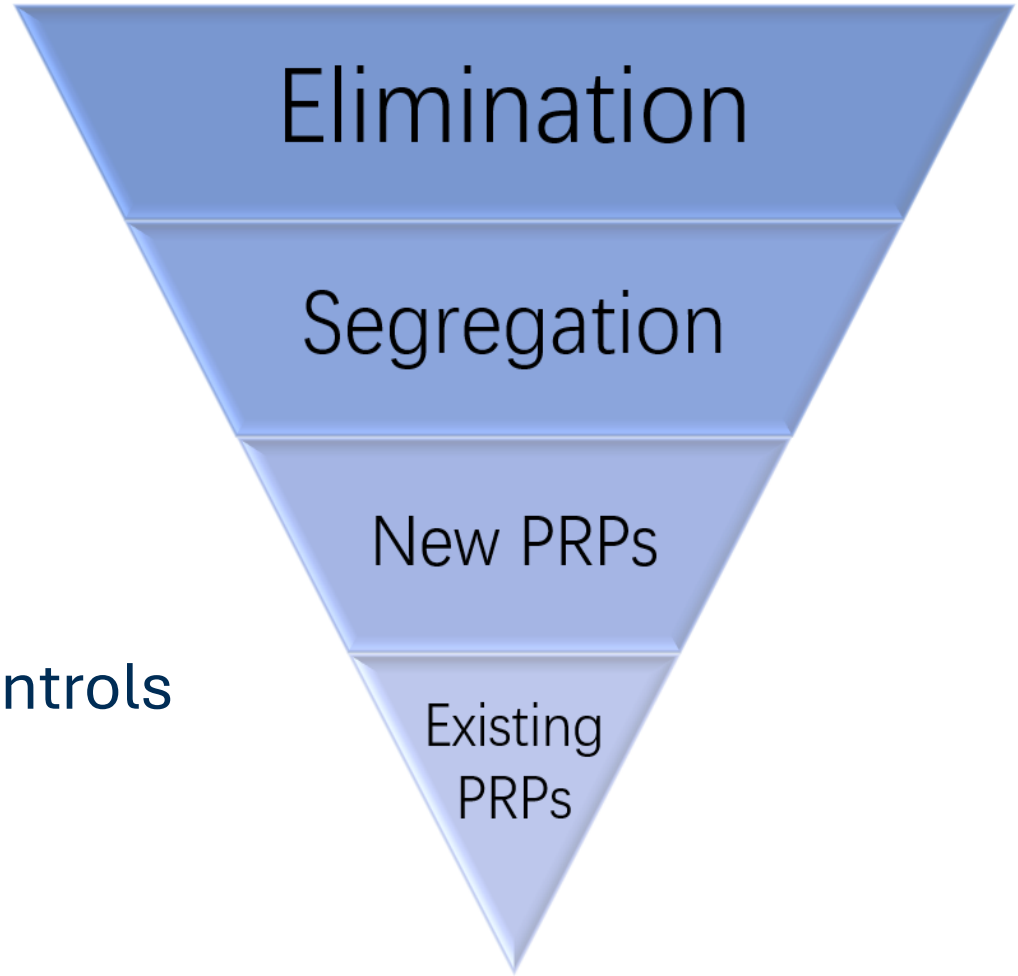
Installation

- Risk based – Team – another risk assessment!
- Which part of the factory?
- Production continuing?
- Hazards introduced: contractors / pests / building work etc
- Management of contractors / additional controls
- Documentation



Post Installation

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- Cleaned
- Inspected
- Tested
- Authorised person(s)
- Document / Records

- Enhanced Controls
- Environmental Swabbing
- FB Detection
- Product testing
- Update paperwork / systems

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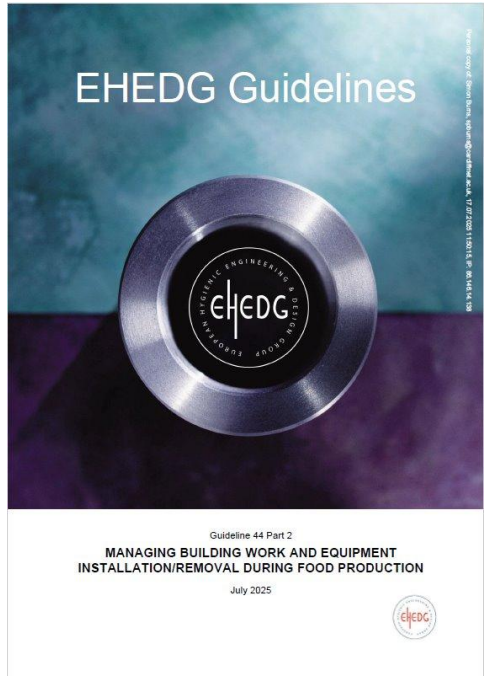
- Formed in 1989 by a handful of European-based organisations
- Various member types concerned with HD
- Over 50 guidance documents
- Equipment certification and training
- Webinars and world congress
- Guidance documents



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