



# CLEANING/DISINFECTION

## Jaap Koster

# AGENDA

- Definition
- Types of Desinfectants
- Basic Principles of Cleaning/Desinfection
- Cleaning/Desinfection in Practice
- Monitoring
- Validation



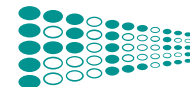
# DEFINITIONS



# THE IDEAL DISINFECTANT

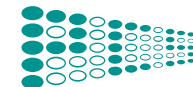
- Effective against all micro-organisms
- Works at every temperature, pH etc.
- Works on every surface
- Does not corrode the surface
- Does not expire
- Not toxic to humans
- No residues
- Cheap

**But unfortunately,  
it does not exist!**



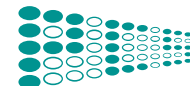
# DEFINITIONS

- Bacteriostatic (not for disinfectants but for antibiotics)
  - Slows bacteria down
- Bactericide
  - Kills bacteria (not their spores)
- Virucide
  - Kills viruses
- Fungicide
  - Kills moulds and yeasts
- Germicide
  - Kills all micro-organisms
- Sporicide
  - Kills all spores



# CLEANING AND DISINFECTION (1)

- Cleaning
  1. Removing (chemical) materials, dust (then)
  2. Vacuuming / Soap / Water
- Disinfecting
  - Reducing the number of micro-organisms
  - Only if sterilization is not possible, or when it is less important
- Sterilizing
  - Killing “all” micro-organisms (max. 1 per 1,000,000 is left alive)

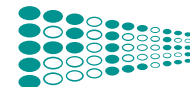


## CLEANING AND DISINFECTION (2)

- What will be cleaned?
- What will be disinfected?
- What will be sterilized?



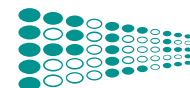
# TYPES OF DISINFECTION





# DISINFECTANTS AND HOW THEY FUNCTION

- **Quaternary ammonium compounds** change the surface tension so that structures (pili) on the cell wall are removed
- **Aldehydes** damage the protein structure
- **Halogens** (chlorine, iodine) and **Peroxides** oxidate organic materials
- **Alcohol** coagulate proteins
- **Peracetic Acid, Peroxides** oxidizes the outer cell-membranes of the micro-organism





# DISINFECTANTS AND HOW THEY FUNCTION

desinfectant	bactericidal	fungicidal	virucidal	sporicidal
alcohols	+	+/-	+/-	-
aldehydes	+	+	+	+
chlorine	+	+	+	+
hypochloriet	+	+	+/-	+/-
waterstofperoxide/perazijnzuur	+	+	+	+
fendol-producten	+	+	+/-	-
quat. Ammonium producten	+	+	+/-	-



# SENSITIVITY TO DISINFECTANTS

Vegetative Cells

**Easy**

Enveloped  
virus

Mould Spores

Non-enveloped  
virus

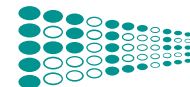
Bacteria Spores

**Hard**



# TYPES OF DISINFECTANTS

- What will be used?
- Is there circulation?
  - Why?
- Combination cleaning/disinfectants

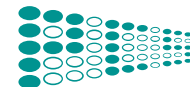


# BASIC PRINCIPLES CLEANING/DISINFECTION



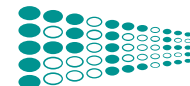
# WHAT CAN INFLUENCE THE DISINFECTION

- Contamination
- Contact (surface and fumigation)
- Exposure Time
- Types of Micro-Organisms
- Disinfectant
  - Concentration
  - Material
  - Solvent
- Surface material
- Temperature



# THE USE OF CLEANING

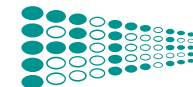
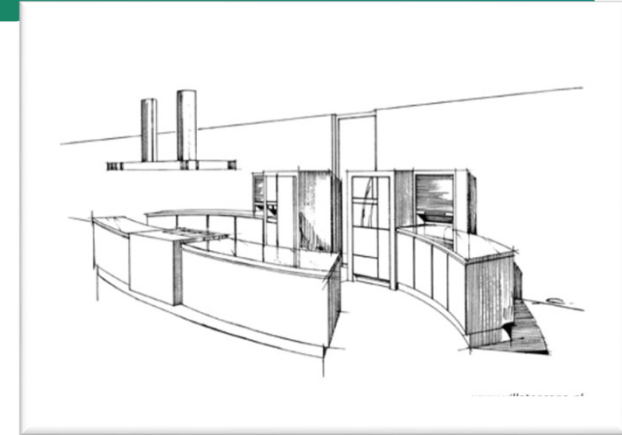
- Removing visible contamination, because contamination
  - Reacts with disinfectants
  - Shield bacteria
  - Are a source of nutrition
- With vaccine- or bio-technological production:
  - Disinfection (killing a specific organism)
  - Cleaning
  - Disinfection
  - Washing





# PRINCIPLES; DESIGN

- Smooth surfaces, not porous
- No edges
- No corners, smooth surface
- Use materials that can handle disinfectants
- No non-essential materials in the clean room
- No shelves, ridges, etc.
- Sanitary Design



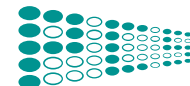
## PRINCIPLES; USE

- Make sure that as little as possible is present in the clean room
- A clean room is not a storage room
- Clean everything up first
- Make sure everything is accessible
- Leave no materials behind
- Store materials (where?)



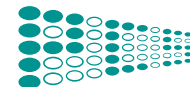
## PRINCIPLES: CLEANING/DISINFECTION

- Work from high to low
- Work from clean to dirty
- Work from back to front (or to the door)
- Make sure that cleaning/disinfection is not spreading contamination
  - Ensure the use of sterile solvents (where needed)
  - Ensure clean/sterile aids
- Keep cleaning materials away from production
- Cleaning- and disinfectants may (usually) leave no residues (wash afterwards)



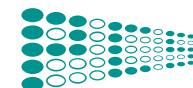
# TYPES OF CONTAMINATION

- Depends on the process
- Glas
- Product
- Metal (aluminium)
- Skin, hairs
- Micro-organisms



# PRINCIPLES: CLEANING

- Proper exposure time
- Proper concentration
- Correct scheduling
- Right type of cleaning agent/disinfectant
- Keep to all the behavioral rules



# CLEANING/DISINFECTION IN PRACTICE

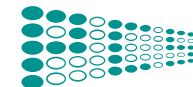


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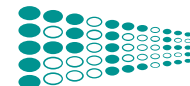


**I'm fed up with cleaning your room!  
From now on, wipe your feet!**



# CLEANING AND DISINFECTION IN PRACTICE

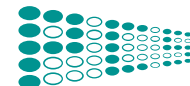
- Procedure
  - Frequency (how long will a room remain clean?)
  - Roulation regime
    - Is this always necessary? It is, according to the new guidelines!
  - Concentration
  - Making the agents, expiration dates
  - Exposure times
  - Follow-up





# CLEANING AND DISINFECTION IN PRACTICE

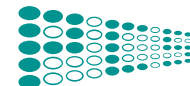
- Procedure
  - What rooms, spaces?
    - All positions always or changing schedule
  - Will cleaning agents/disinfectants be qualified, if so which tests?
  - Cleanroom disinfectants will have to be sterile before use (Class A/B)
  - During the infeeding of materials into the cleanroom, a sporicide is advised to be used (PIC/s)



# CLEANING AND DISINFECTION IN PRACTICE

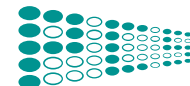
## Reporting:

- Used materials
- Creating materials
- What materials have been used?
- Cleaner/operator
- Date/time
- Specifics
- Signing off by supervisor and customer?
- Logs



# CLEANING AND DISINFECTION IN PRACTICE

- Training
  - Training in GMP
    - Personal Hygiene
    - Basic principles microbiology/desinfection
    - Dress qualification
    - Practical training cleaning en disinfection
    - Filling in logs
  - Who checks this and how?

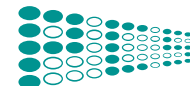


# VALIDATION



# VALIDATION DISINFECTANT

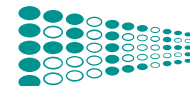
- 3 distinct phases
- **Phase 1** theoretical effectiveness:
  - Literature
  - 5 log reduction
  - 5-5-5 test (European Suspension Test)
    - 5 minutes
    - 5 log
    - 5 stams (gram +, gram -, mould, sporeformer, Pseudomonas)



# VALIDATION DISINFECTANT

## **Phase 2** effectiveness on surfaces

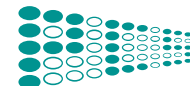
- Choose worst case surfaces
  - “Contaminate” surfaces with bacteria
  - Treat with disinfectants according to the procedure
  - Sample the surface
  - Determine reduction
- 
- A minimum of 3 log reduction is required
  - Choose standard panel + in house stems
- 
- Watch for the formation of residu



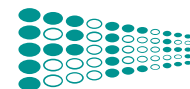
# VALIDATION DISINFECTANT

## Phase 3 effectiveness in practice

- Follow EM-results during certain period of time
- Disadvantage: not specific
- Sample before and after and examine reduction
- Disadvantage: low numbers don't say much
- Sample for the formation is residues



# MONITORING

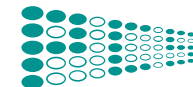
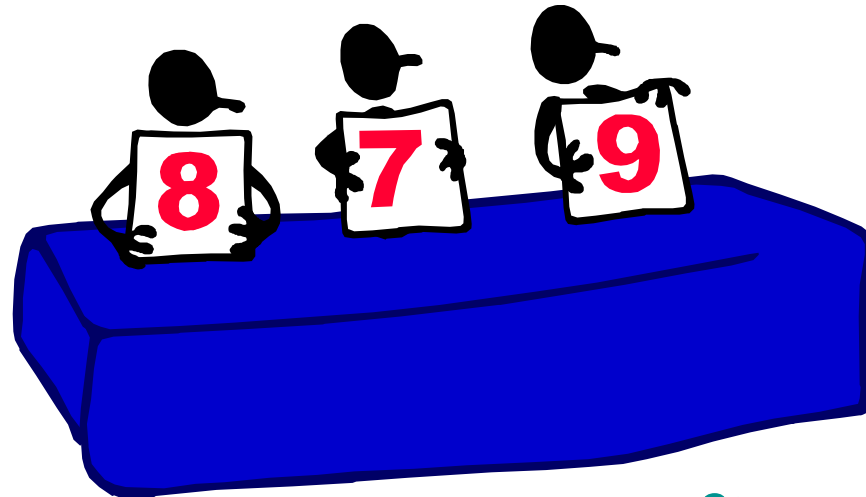




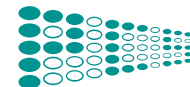
# MONITORING

- How can cleaning/desinfection be monitored?
  - Log
  - Visual checks
  - Presence during cleaning
  - EM-results

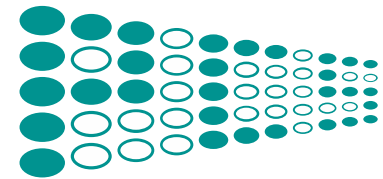
*House Flora shifts/drifts*



# QUESTIONS



**THANK YOU FOR  
YOUR ATTENTION**



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