Prinzipien der Reinigungsvalidierung

und ihre Umsetzung in einem Lebensmittelbetrieb

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Thematische Übersicht

- ✓ **Lebensmittelsicherheit**
  - ➢ Sicherheitskonzepte – HACCP-Pläne – PRP
    - ➢ Vermeiden von Kontaminationen
      - ➢ Hygienic Design
        - ➢ **Cleaning Validation**

Food Safety wird erreicht durch

- Erfüllen der Guten Hygienepraxis (PRP)
- Beherrschen der kritischen Verarbeitungsschritte (CCP, oPRP)
  - Gefahren eliminieren oder auf das akzeptable Maß reduzieren
  - Wachstum oder Toxinbildung von Pathogenen verhindern
  - Rekontamination ausschließen (**Reinigung**)

PRP

oPRP

CCP

Zur wirksamen Reinigung gehören

- **Hygieneanforderungen an Maschinen**
  - Maschinenrichtlinie, Anhang I (Maschinenhersteller)
  - so konstruiert, dass leicht zu reinigen und zu desinfizieren

CERTIFIED HYGIENIC ENGINEERING & DESIGN GROUP EUROPEAN EHEDG
TYPE EL - CLASS I
JANUARY 2010


CERTIFICATE OF COMPLIANCE

EHEDG HYGIENIC ENGINEERING & DESIGN GROUP EUROPEAN

TYPE EL - CLASS I

Name of Institute
hereby declares that the product

equipment name and type
with sealing material

from

company name, town, country

Has been evaluated for compliance with the Hygienic Equipment Design Criteria of the EHEDG, by:

Name of Institute
and meets the criteria of this document as demonstrated by:

Evaluation Report No. xy

Signed _____ *Date 22. January 2011*
Evaluation Officer

Signed _____ *Date 22. January 2011*
Head of Department

Certificate No. xy

Logo of
Test Institute

Name and address of Institute

Categories

EL Class I
Closed, CIP cleaned

EL Class II
Closed, semi-open, wet cleaned

EL Aseptic Class I
Closed, CIP, sterilisable, bacteria tight

EL Aseptic Class II
Closed, dismanteled, sterilisable, bacteria tight after reassemly

ED
Closed or semi-open, dry cleaned

Zur wirksamen Reinigung gehören

- **Hygieneanforderungen an Maschinen**
  - Maschinenrichtlinie (Maschinenhersteller)
  - so konstruiert, dass leicht zu reinigen und zu desinfizieren
- **Verwendung empfohlener Reinigungs- und Desinfektionsmittel**
  - nach EN geprüft und zugelassen
  - Praxistest besonders wichtig
- **Reinigungs- und Desinfektionsmethoden**
  - situationsbedingt festlegen
  - Zusammenarbeit zwischen Maschinenhersteller, DM-Produzent, LM-Betrieb

Wann wird die Reinigung validiert?

Neue Linien

prospektive Validierung

→ vor dem Verkauf der ersten Produktions-Chargen

Bestehende Linien

retrospektive Validierung

→ Auswertung bestehender Reinigungsmethoden unter der Bedingung, dass Produkte, Verfahren und Ausrüstung unverändert bleiben

→ bei Abweichungen von den festgelegten Kriterien insbesondere hinsichtlich der Lebensmittelsicherheit muss eine Validierung durchgeführt werden

Cleaning Validation

Definition

Obtaining the documented evidence that cleaning and/or disinfection processes, if properly implemented, are consistently effective at reaching a predefined level of hygiene on equipment and environmental surfaces.

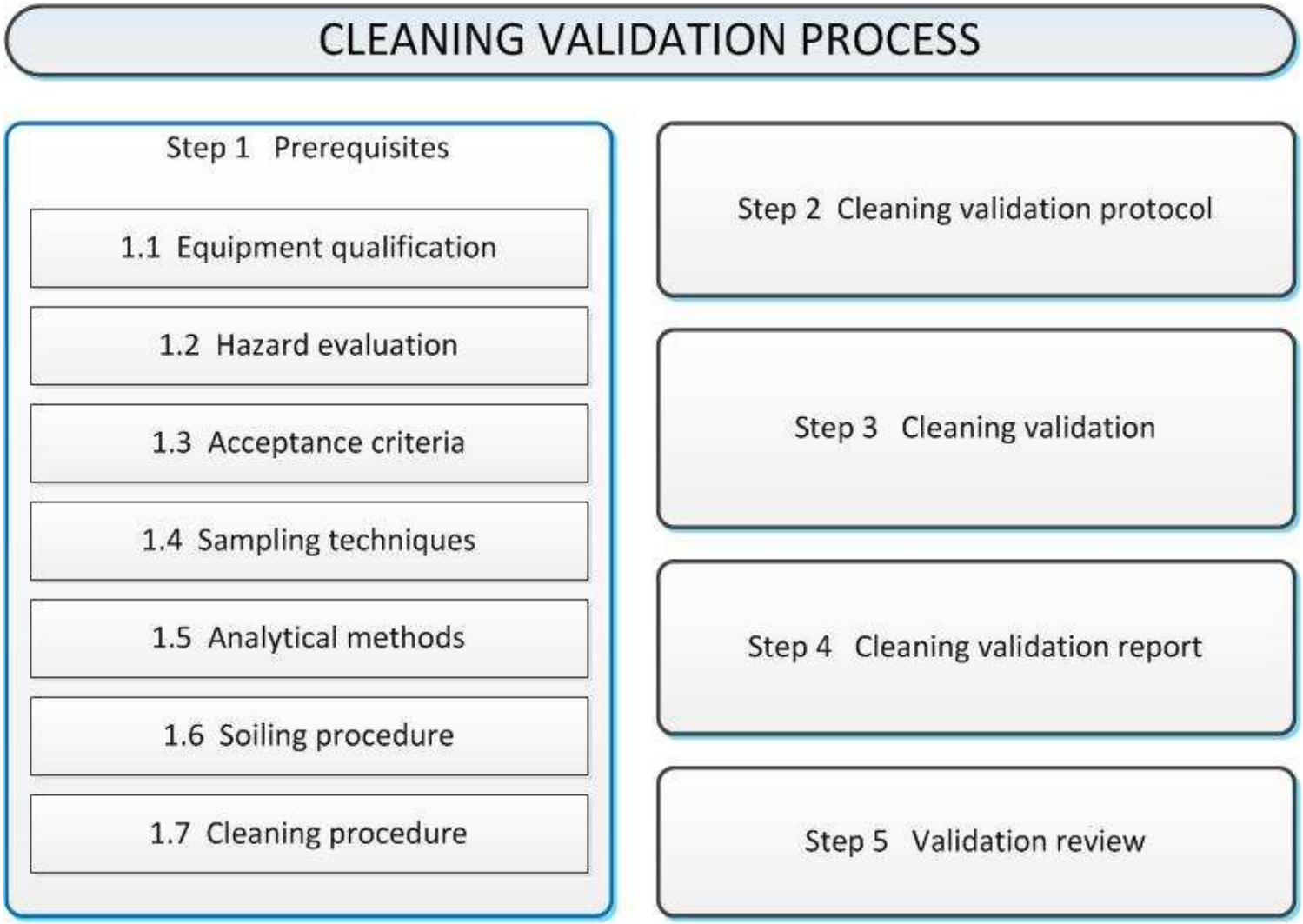
EHEDG-Guideline 45 (Dez. 2014)

Reinigungsvalidierung

- **Wer ?**
  - Lebensmittelhersteller
  - an der *full scale* Anlage
    - in Zusammenarbeit mit dem Hersteller der Reinigungsmittel
    - unter Berücksichtigung der Vorgaben der Maschinenhersteller

Reinigungsvalidierung

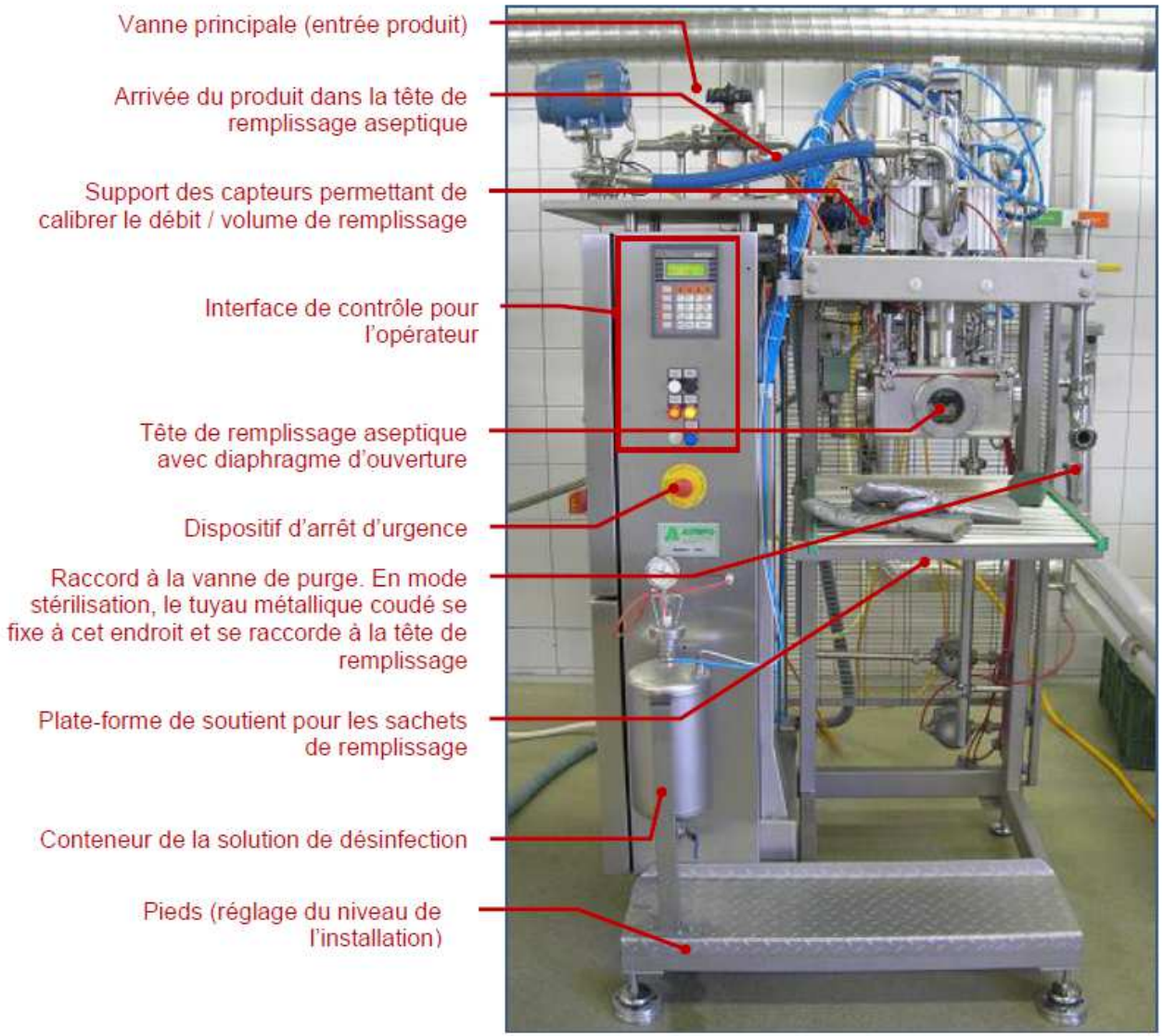
- **Wie ?**



STEP 1 Prerequisites

- **Equipment qualification**
  - Qualification is the formal process of obtaining the documented evidence that the equipment and utilities are fit for their intended use.
  - **Hygienic Design** Qualification
  - **Installation** and interface with other equipment
  - Check for cleaning instructions (dismantling, protection of sensors…)
  - Assess accessibility for cleaning & inspection and identify areas difficult to clean

Anlagenqualifizierung



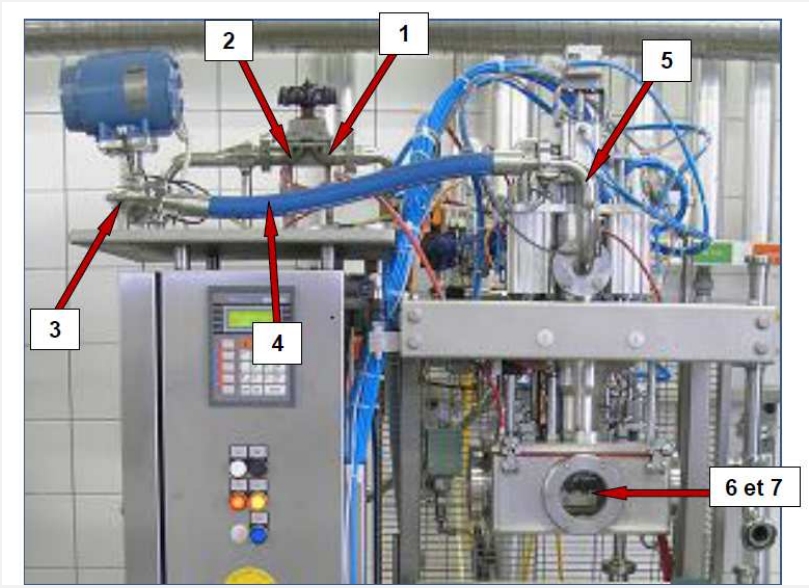
Visual inspection

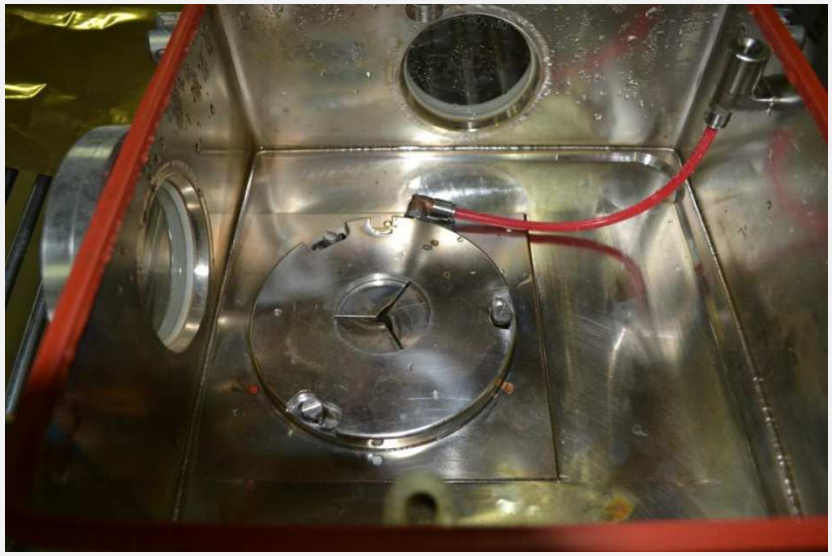
- Hygienic design?
- Installation?
- Dismantling?
- Accessibility?
- Food contact surfaces?

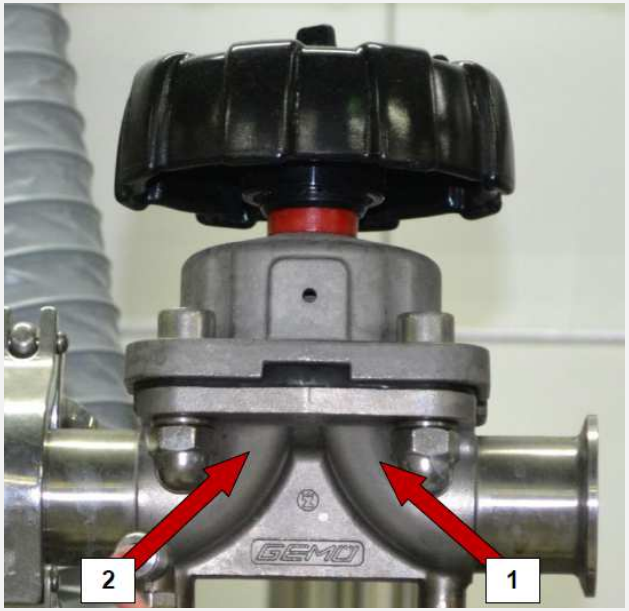
STEP 1 Prerequisites

- **Hazard evaluation**
  - Documenting the evaluation of the **difficult-to-clean** parts
  - Careful examination of the **position of the equipment in the whole processing line**, connection to other equipment and considering the direct and indirect food contact surfaces
  - Criticality of the food process, i.e. the requested cleanliness in regard to the **food safety level** expected in the end product
  - Physicochemical and microbiological **properties of the food**
  - Period and conditions for **storage of unclean equipment** before cleaning, and the time between cleaning and equipment reuse

schwierig zu reinigende Stellen







STEP 1 Prerequisites

- **Acceptance criteria**
  - The **cleanliness criteria** that have to be achieved for the surfaces and / or the end product
  - Should be based on the **food safety policy** of the manufacturer and the hazard evaluation
  - The approach can be product-specific or products can be grouped into families

Gefahrenbewertung und Akzeptanzkriterien

- Situation: → Produktion von Milchpulver
  → neue Abfüllanlage: Risiko der Rekontamination
  → Trockenreinigung
- Relevante Gefahren: *Cronobacter* sp. und Allergene
  → 24 Probenahmestellen wurden festgelegt
- Akzeptanzkriterien
  → Abwesenheit bei alle Probenahme stellen

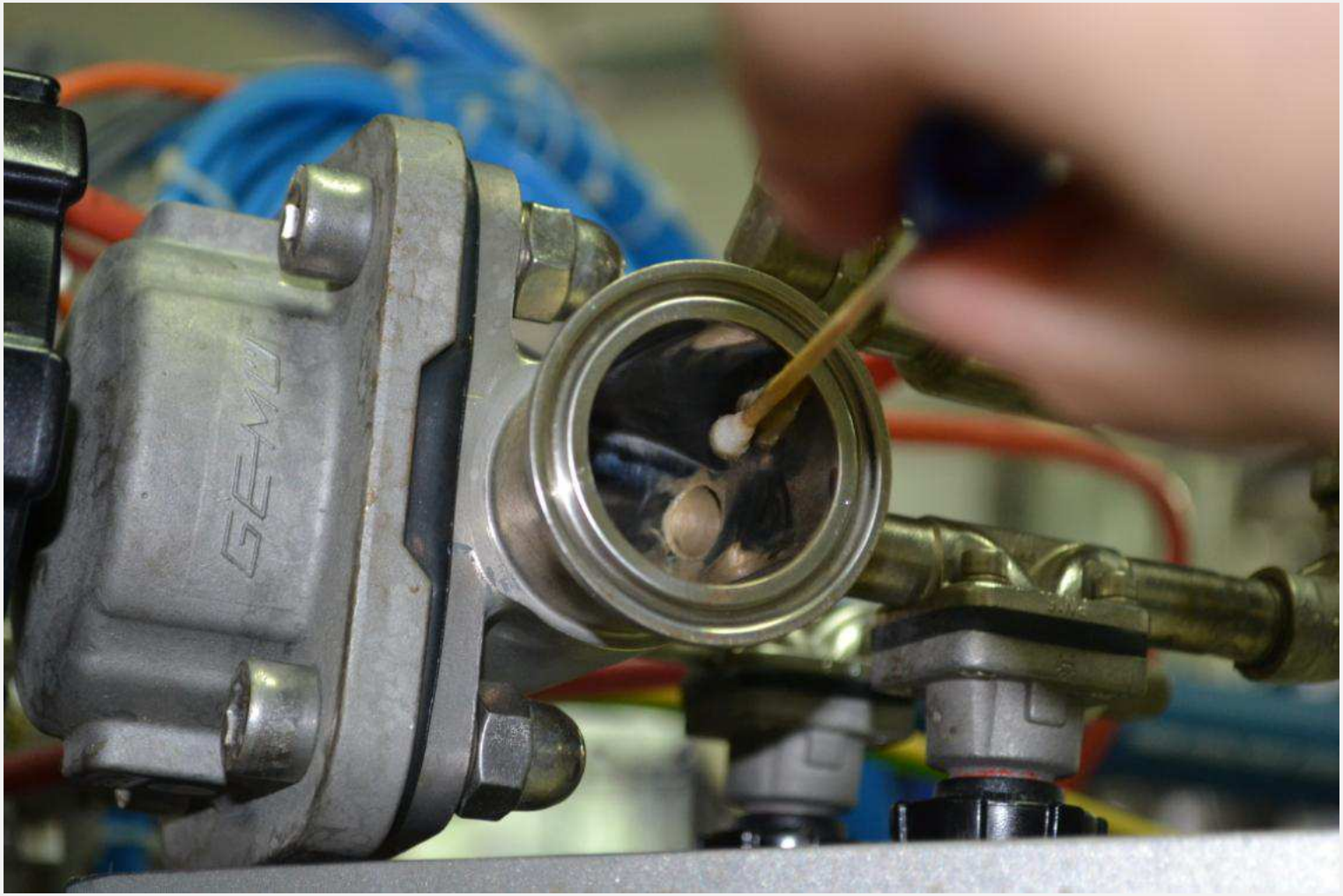
STEP 1 Prerequisites

- **Sampling and analytical methods**
  - The first and foremost criterion is the **visual** cleanliness
  - Two methods of sampling are acceptable: direct **surface** and **rinse** sample
  - Places that should be sampled are the difficult-to-clean ones determined during the hazard evaluation
  - **Analytical methods** should be specific for the contaminant to be analysed
  - The method should be **validated** and the limits of detection or quantification must be known
  - A **neutralization** step is needed before a microbiological analysis is done

Visuelle Inspektion

Figure 1: Inspection visuelle de l'entrée section « tête aseptique »

Tupfermethode (ISO 18593)



Details der Probenahme

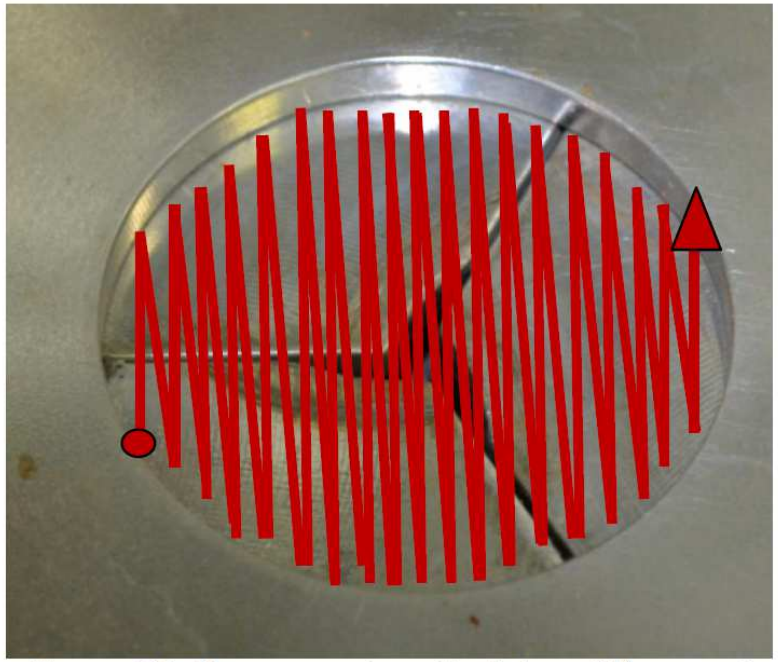


Figure 26: Mouvement vertical de prélèvement

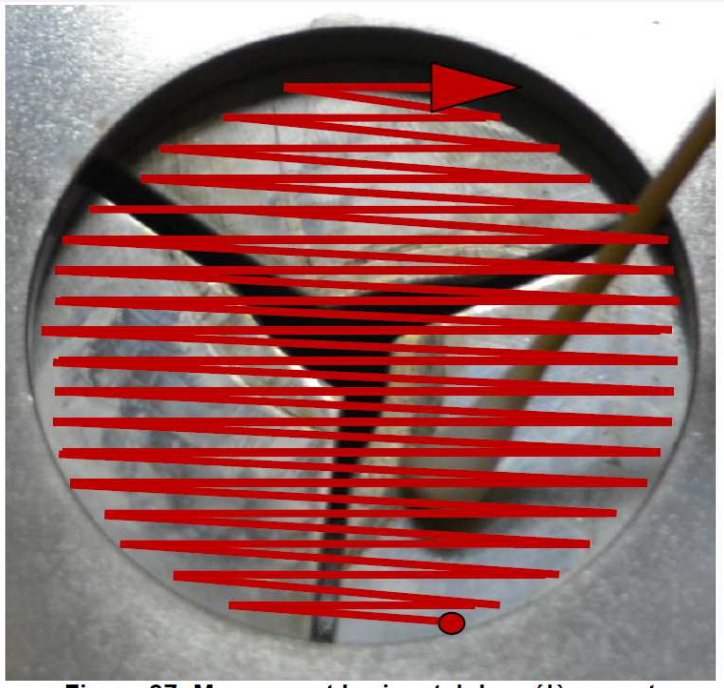


Figure 27: Mouvement horizontal de prélèvement

ATP-Messung

- Quantitativer Nachweis des gesamten ATPs durch eine Biolumineszenz-Reaktion
- Unterschiedlicher Gehalt an ATP in verschiedenen Geweben
- Nachweisgrenzen:

  1000 – 10´000 Bakterien

  30 Hefen
- Eigene Grenzwerte bestimmen durch 40 – 50 Messungen an derselben, gereinigten Stelle

Der Praxistest

Kinetische Studie: dickflüssiges Produkt

STEP 1 Prerequisites

- **Soiling procedure**
  - Soiling technique to **mimic normal / extreme situation**
  - Soiling should be identical to the chosen worst-case scenario
  - Identification and validation of **surrogates**, if necessary

    e.g. *Enterococcus faecium* NRRL B-2354

    Bacillus subtilis DSM 347

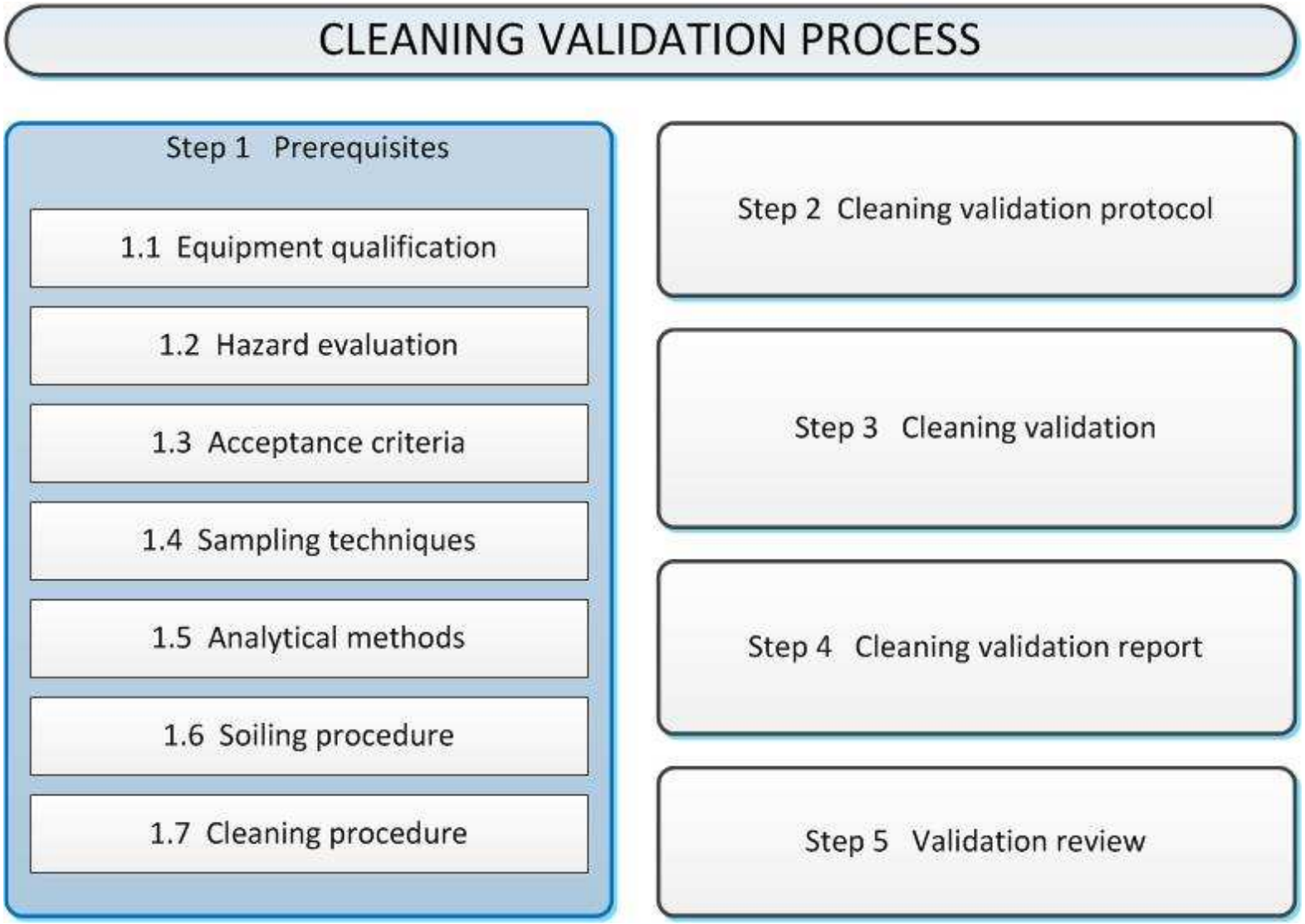
STEP 1 Prerequisites

- **Cleaning procedure**

  Approved **Standard Operation Procedure** (SOP) giving details about

  - Water quality
  - Cleaning and disinfecting agents
  - Cleaning process parameters
  - Responsibilities and qualification of the persons involved
  - Monitoring including calibration of the sensors

Reinigungsvalidierung



STEP 2 Cleaning validation protocol

- covers in detail the complete process of validation
- summarizes all reflections made
- allows verifying if all prerequisites are in place

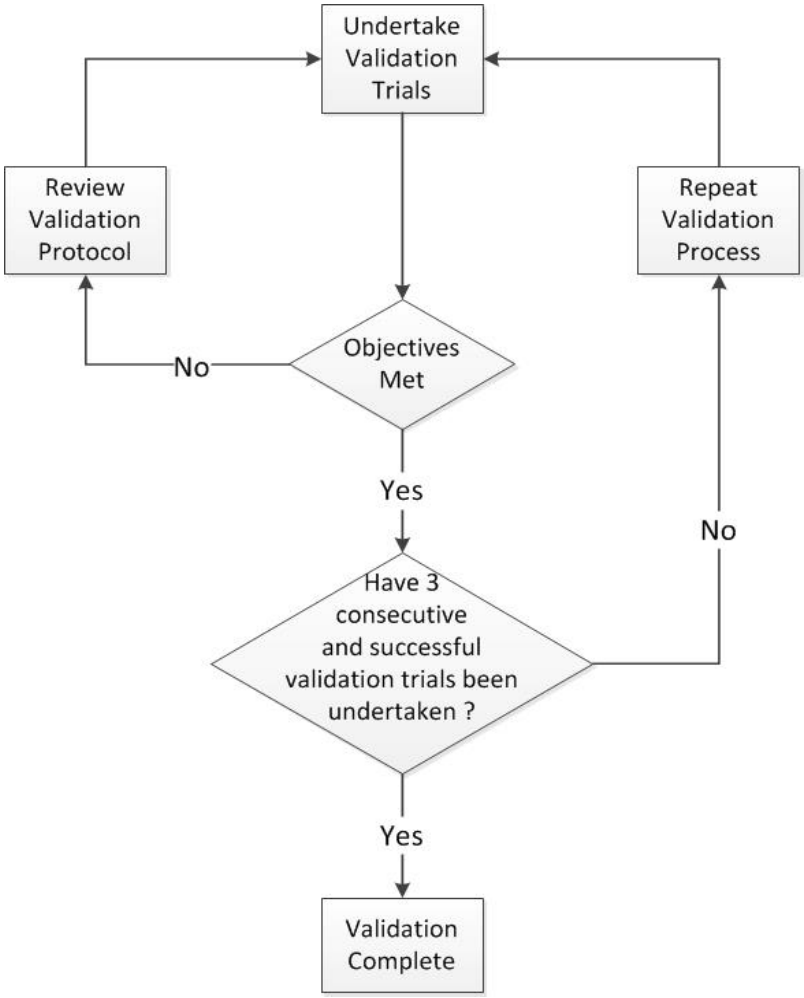
- Objective
- Groups of products
- Responsibility
- Qualification of equipment
- Acceptance criteria
- Worst case scenario
- Soiling

- Cleaning SOP
- Consecutive cycles
- Sampling
- Test methodds
- Corrective actions
- References
- Form for documentation

STEP 3 Cleaning validation process

- Minimum **3** consecutive trials
- **All** meet the validation objectives
- Analytical services can be outsourced
- **Subcontractors** must be involved into the validation process

STEP 3 Cleaning validation process



STEP 4 Cleaning Validation Report

- stating the outcome and conclusions
- retaining the relevant cleaning records
- signed by the operator and reviewed by quality assurance

- short summary about objective
- evaluation of the results
- description of deviations from the protocol
- general conclusion
- attachments
- approval of the validation
- determination of critical points for monitoring and verification

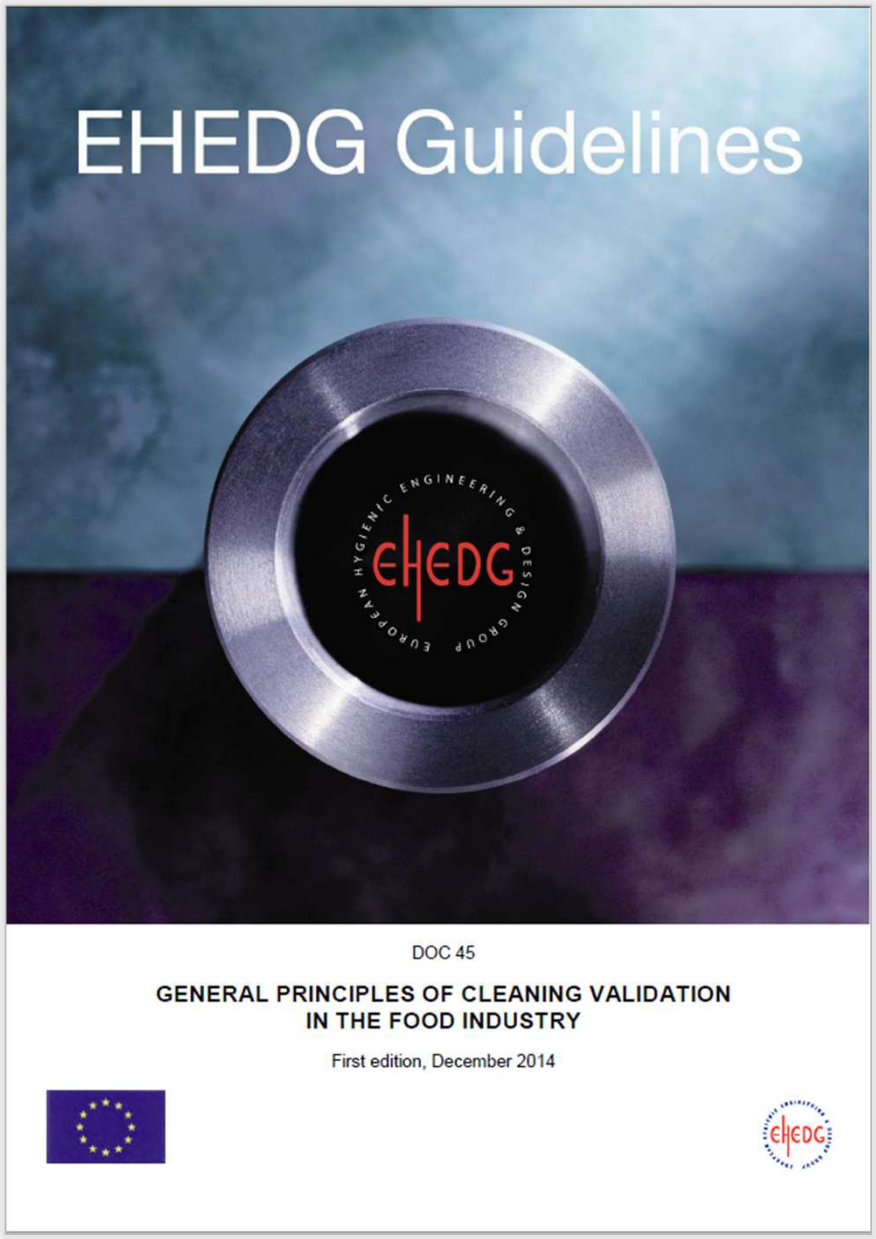
STEP 5 Validation Review

- There should be **periodic revalidation** as well as **revalidation after changes**.
- **Periodic revalidation** should be performed to assess process changes that may occur gradually over a period of time.
- **Changes requiring revalidation** should be defined in the validation protocol and may include changes in the equipment, changes in the raw material, the process or manufacturing area, appearance of negative safety trends or new findings.

Reinigungsvalidierung

- **Zusammenfassung**
  - Grenzen der Hygienic Design – Zertifizierung:
    - Brandneu – gebraucht
    - Installation
    - Übertragung auf andere Bauteile
  - Ausrüstung an Ort und Stelle installiert
  - Berücksichtigung eigener Gegebenheiten
    - Produkt
    - Reinigung
    - Personal
  - Ganze Linien können erfasst werden

Merci !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EHEDG
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IN THE FOOD INDUSTRY
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