DESIGN CRITERIA AND FACTORS IMPORTANT IN ACHIEVING OPTIMUM HYGIENIC **CIP** RESULTS

28 June 2023

Agenda

1. Foodborne disease – global perspective
2. Disease from dairy products
3. Recalls and related pathogens
4. Whole genome sequencing
5. Hygienic design criteria relevant to CIP
6. Micro-organisms relation to food contact surfaces
7. Interrelationship of validation, monitoring and verification in **CIP processes**
8. Hygienic Design criteria relevant to CIP – validation process

    - DQ: Design Qualification
    - IQ: Installation Qualification
    - OQ: Operational Qualification
    - PQ: Performance Qualification

Foodborne disease - Global perspective

- Each year worldwide, unsafe food causes 600 million cases of foodborne diseases and 420 000 deaths
- WHO estimated that 33 million years of healthy lives are lost due to eating unsafe food globally each year, and this number is likely an underestimation. (WHO, 2022)
- In Africa, it is estimated that 92 million people fall ill from consuming contaminated foods, resulting in 137 000 deaths each year (Bisholo, Ghuman and Haffejee, 2018)

Bisholo KZ, Ghuman S, Haffejee F. Food-borne disease prevalence in rural villages in the Eastern Cape, South Africa. Afr J Prim Health Care Fam Med. 2018 Sep 27;10(1):e1-e5. doi: 10.4102/phcfm.v10i1.1796. PMID: 30326722; PMCID: PMC6191658.

https://www.hsph.harvard.edu/news/hsph-in-the-news/foodborne-illness-africa/

https://https://www.who.int/activities/estimating-the-burden-of-foodborne-diseases

https://www.dailymaverick.co.za/article/2023-06-08-food-safety-day-reflection-sa-grapples-with-food-borne-disease-cholera-and-poor-service-delivery/

www.up.ac.za/news/post_2981218-up-expert-on-what-you-need-to-know-about-food-borne-risks

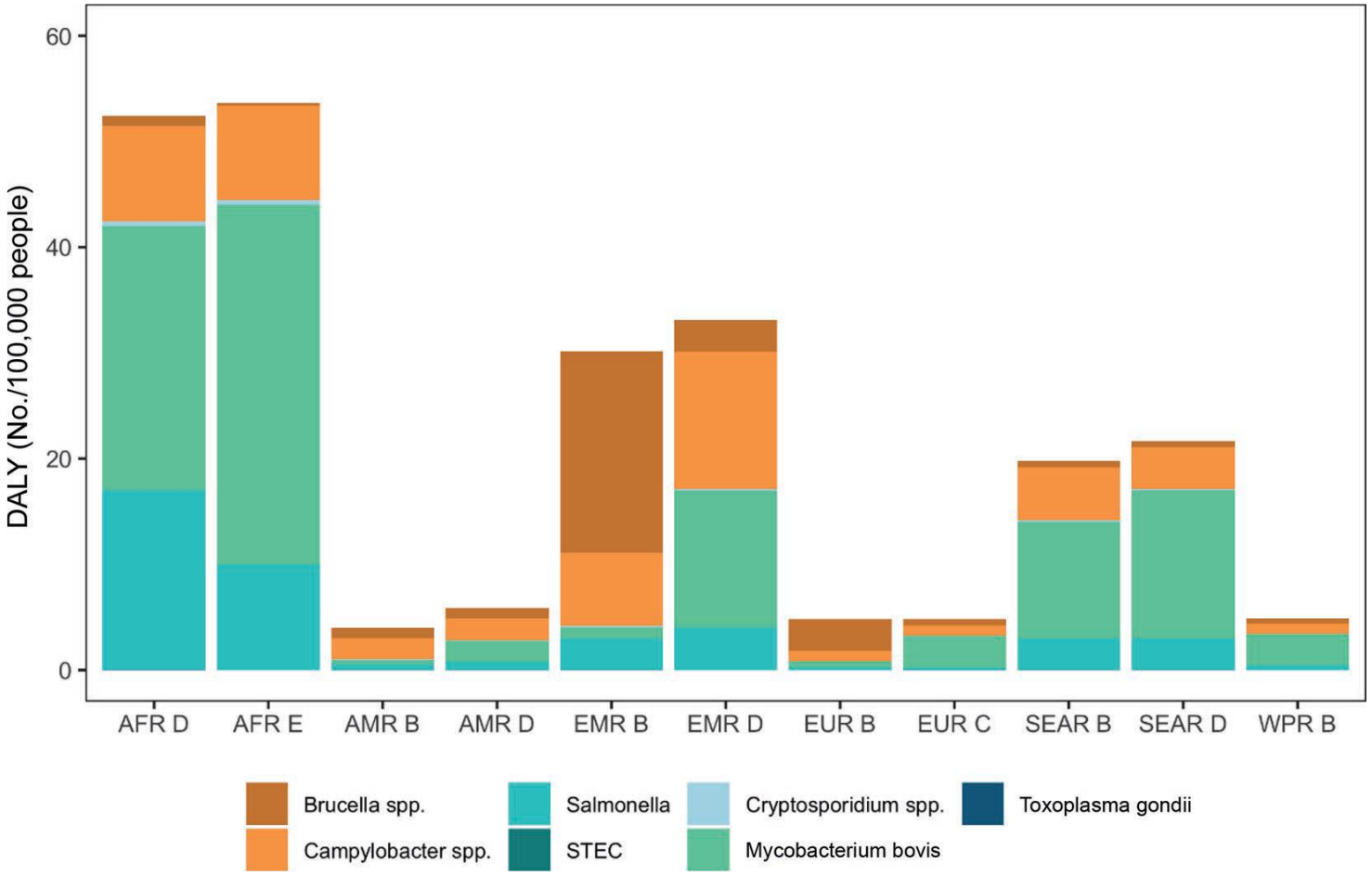

Figure 2. Global burden of disease from dairy products by region and some important hazards. **DALY = disability-adjusted life years**; STEC = Shiga toxin-producing *Escherichia coli*. The x-axis codes refer to WHO regions: AFR = Africa; AMR = the Americas; EMR = Eastern Mediterranean; EUR = Europe; SEAR = South-East Asia; and WPR = Western Pacific. Regions are further subdivided on the basis of mortality: **B = low child mortality and very low adult mortality; C = low child mortality and high adult mortality; D = high child and adult mortality; E = high child and very high adult mortality**. Grace et al., 2020 .

Milk-borne pathogenic bacteria

Milk-borne pathogenic bacteria pose a serious threat to human health, and constitute about 90% of all dairy- related diseases

- *Staphylococcus aureus*,
- *Salmonella spp.*,
- *Listeria monocytogenes*,
- *Escherichia coli* O157:H7
- *Campylobacter*

Berhe, G., Wasihun, A.G., Kassaye, E. *et al.* Milk-borne bacterial health hazards in milk produced for commercial purpose in Tigray, northern Ethiopia. *BMC Public Health* **20**, 894 (2020). https://doi.org/10.1186/s12889-020-09016-6

Claeys W, Cardoen S, Daube G, De Block J, Dewettinck K, Dierick K. Raw or heated cow milk consumption: Review of risks and benefits. Food Control. 2013;31:251e262.

Ryser ET. Public Health Concerns. In: Applied Diary Microbiology; Steele Edition. New York: Mercell Dekker, Inc; 1998. p. 263–404.

Tennessee *E. coli* outbreak linked to raw milk from multistate cow-share

Key takeaways:

•Five cases of *E. coli* — two in infants — were linked to raw milk distributed in a three-state cow-share arrangement.
•The direct sale of raw milk is illegal in some states, but people may acquire it in cow-shares.
An outbreak of Shiga toxin-producing *Escherichia coli* in Tennessee was caused by raw milk consumption among members of a cow-share, according to a study.
Two 10-month-old infants were hospitalized in August 2022 with confirmed Shiga toxin-producing *E. coli*, with one of the two developing hemolytic uremic syndrome (HUS) linked to raw milk distributed as part of a cow-share program that had more than 100 participants in Georgia, Tennessee and North Carolina.

https://www.healio.com/news/infectious-disease/20230510/tennessee-e-coli-outbreak-linked-to-raw-milk-from-multistate-cowshare

Six E. coli infections linked to fermented raw milk

- **Six E. coli infections linked to fermented raw milk**
- By Joe Whitworth on May 18, 2023
- Five people are sick in France, two seriously, and one in Belgium after drinking a brand of raw fermented milk.
- In France, four children and one adult have been infected by Shiga toxin-producing E. coli (STEC) O26:H11. They fell ill between the end of March and the beginning of April this year.
- Santé publique France has been investigating two cases of Hemolytic Uremic Syndrome (HUS) in the Hauts-de-France and Île-de France regions. The latter was in the context of a family outbreak. The suspected food was fermented raw milk. HUS is a severe complication associated with E. coli infections that causes kidney failure.
- "The sequencing of the strains isolated within these outbreaks confirmed the same genomic profile. Food investigations made it possible to identify, for the case in Hauts-de-France, the place of purchase and to sample milk on sale at the time of the inspections. It was fermented raw milk made in Belgium," agency officials told *Food Safety News*.

https://www.foodsafetynews.com/2023/05/six-e-coli-infections-linked-to-fermented-raw-milk/

Cricket Creek Farm Recalls Sophelise and Tobasi Cheeses Because of Potential *Listeria Monocytogenes* Contamination

- **Company Announcement**
- Cricket Creek Farm of Williamstown, MA is recalling 165 units of Sophelise cheese and 149 pounds of Tobasi cheese because it has the potential to be contaminated with *Listeria monocytogenes*, an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Although healthy individuals may suffer only short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain and diarrhea, *Listeria* infection can cause miscarriages and stillbirths among pregnant women.
- Sophelise and Tobasi were distributed in Massachusetts and New York through Wild Oats, Williamstown, MA; Provisions Williamstown, Williamstown, MA; McEnroe Organic Farm Market, Millerton, NY; New Lebanon Farmers Market; New Lebanon, NY, at restaurants, and farmers markets.
- Sophelise product code: 087055 is a washed, pasteurized milk cheese with a soft rind and pinkish hue; the circular cheese measures 4 inches in diameter and roughly 1 inch tall. It is sold in semi-transparent packaging with a round blue label. Sophelise was distributed between March 29, 2023 and May 26, 2023.
- Tobasi with a product label of 315, 341, 048 is a washed raw-milk cheese with an orange rind and creamy interior. When sold retail by Cricket Creek Farm, it is wrapped in clear packaging with a gray and orange label. When sold at retail stores, it is sold in small rectangular cuts. When sold wholesale, the cheese is a square format roughly 8”x8” and 1.25 inches tall. These batches of Tobasi were distributed between March 26, 2023, to May 26, 2023.
- One hospitalization due to *Listeria monocytogenes* has been reported to date. Following this customer notification of illness, products purchased by this individual were tested by Biotrax Testing Laboratory and the current batch of Sophelise was determined to be positive for *Listeria monocytogenes*. The three batches of Tobasi are being recalled due to their proximity during storage to the exposed product.

https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/cricket-creek-farm-recalls-sophelise-and-tobasi-cheeses-because-potential-listeria-monocytogenes?utm_medium=email&utm_source=rasa_io&utm_campaign=newsletter

The genus *Salmonella*

- Member of the Family Enterobacteriaceae
- Temperature: 7°-47°C
- pH: 4.0 -9.0 (optimum 7)
- Diarrhea, abdominal pain, fever, vomiting, nausea and death
- Survival for long periods will occur:
- chocolate stored for 18 months at ambient
- environment for >12 months
- Infectious dose
  - S. Typhimurium in chocolate 1 cell ingested
  - S. Heidelberg cheddar cheese 100-500 cells

The genus *Listeria*

- Ubiquitous environmental organism
- Facultative anaerobe
- Temp:--0.4°C to 43°C
- pH:-4.39 (30°C), 5.0 to 9.6 (5°C)
- NaCI:-grows to 10% (0.94aw), survives 25% (0.84aw)
- Healthy persons rarely infected: immunocompromised at risk
- Abortion and still births
- Various infections including: endocarditis, peritonitis, conjunctivitis, meningitis, septicemia
- Highest rate of mortality of all food pathogens ~25%
- Estimated that 10% of healthy adults carry in gut/(hands)

The genus *Escherichia*

- Min pH 3.8, temperature 7–45˚C
- Gastrointestinal tract of man and other animals
- Four groups associated with foodborne disease:
  - Enteropathogenic E. coli (EPEC)
  - Enterotoxigenic E. coli (ETEC)
  - EnteroinvasiveE. coli (EIEC)
  - Enterohaemorrhagic E. coli (STEC) O157:H7
- Collectively known as Verocytotoxin-producing E. coli (VTEC)
- Most E. coli are not pathogenic: very common gut bacteria

The genus *Bacillus cereus*

- Mesophilic, Gram +ve, spore former
- Wide presence in the environment
- Produces 2 toxins, emetic & diarrheal
- Emetic is pre-formed toxin and can present in 0.5 hours –nausea and vomiting
- Toxin requires >105cells and is heat resistant (120°C / 90 min)
- Diarrhea requires growth of the organism in the gut –watery diarrhea
- Associated with dried foods, particularly cooked rice with poor cooling

Microbial toxins

- Organism grows in food, produces toxin, toxin causes illness
- Poisoning can occur in absence of live organism as long as toxin is present
  - *Clostridium botulinum*
  - *Staphylococcus aureus*
  - *Bacillus cereus*
- Heat-stable toxins (Staphylococcus aureus)
- Limit the concentration –enterotoxins are only synthesized above around 105cells per ml
- Baby food: 30,000 cfu/ml S. aureus starts to form heat-stable toxin

Spoilage microorganisms

Growth in food can change the organoleptic properties such that it is no longer wholesome (it may still be safe, however)

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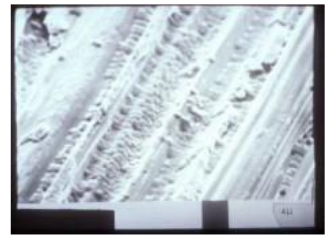
- Pseudomonads
- Gram –ve, obligate aerobic rods
- Most common Gram-ve spoilage organism in factories
- Minimum growth temperature -1.5°C
- Break down amino acids to ‘putrid’ sulphides, esters and amines
- Clostridium estertheticum
- Gram +ve, anaerobic spore-former, which can grow at 0°C
- Spoils vacuum-packed chilled red meat (beef, lamb and venison).

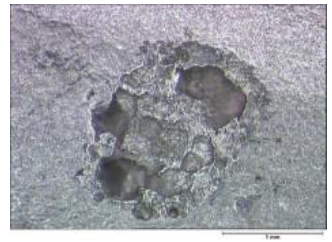
Whole Genome Sequencing -WGS

- Will revolutionize microbiological source attribution of foodborne illness outbreaks
- Expanding our knowledge of the epidemiology of different infectious diseases
- High precision of WGS enables matching of isolates from different sources and different outbreaks
- The technology is now much cheaper and simpler to apply for food producers and regulators with advances continuously being made

Microorganisms and food contacts surfaces



- Natural microbial growth and survival mode
- From adhered single cells to biofilms dependent on moisture and nutrient levels (few µm to mm thick)
- Processing equipment has many surfaces suitable for colonisation –SS, plastics, rubber, even PTFE
- If surfaces are exposed to (frequent) cleaning, microbial adhesion can be controlled
- Surface attached microorganisms have enhanced resistance to chemical disinfection
- Some microorganisms may cause corrosion



Key Hygienic Design Areas

Hygienic Building Design	• Hygienic Floors, Walls, Ceilings, Drains, Zoning • Food Defense, e.g. site security, fencing • HVAC, Cabling, ducts, cabinets
Hygienic Utilities	• Water, Steam • Air
Hygienic Equipment and Process Design	• Materials of construction • Hygienic Welding • Maintenance • Cleanability and Drainability
Cleaning and Sanitation (Disinfection)	• Cleaning In Place (CIP) Design • Dry cleaning, Cleaning out Place, Open Plant Cleaning • Cleaning Procedures • Cleaning Validation • Cleaning and Sanitation chemicals
Personnel Hygiene	• Gowning, e.g. Hand/Shoe cleaning devices • Culture • Practices

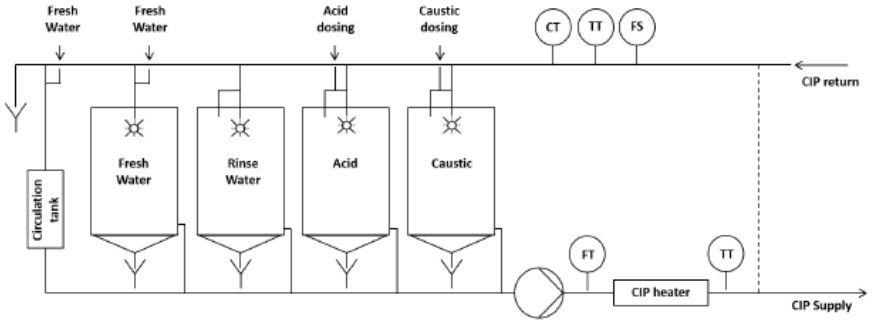
Hygienic Design criteria relevant to CIP

1. Hygienic Design criteria for CIP Installations
2. Design of closed equipment for processing of liquid food products
3. Design of valves, pumps and pipe couplings.
4. Treatment of Stainless Steel Surfaces
5. Design and construction of materials for equipment in contact with food

7. CIP process validation

Other factors

1. Soiling and soil composition
2. Microbiological fouling
3. Detergent chemistry



Overview of objects to be cleaned						
Object	Name	Retained volume (l)		Required flow (m³/h)		Estimated rinse time (min)
		In pipe	In vessel	For pipe	For spray device	
1	Storage tank	36	140	-	18	5
2	Transfer pipe DN50	290	-	11		3
3	Buffertank 1	60	12	-	6	8
4	Dosing station 1	65	-	4		10
5	Buffertank 2	84	15	-	6	8
6	Filler 1	89		8		10

The interrelationship of validation, monitoring and verification in **CIP processes**

Validation - Does it work?

Demonstrates that a cleaning procedure (Standard Operating Procedure, SOP) is effective in achieving the predetermined required level of cleanliness, whilst applying expected worst-case conditions.

Once a cleaning procedure has been validated, then it is routinely applied and the process should be monitored and verified.

Revalidation may be required following changes to the equipment, manufacturing process or cleaning procedure.

Cleaning validation can be performed in three different ways: **prospective**, **concurrent** and **retrospective**

Prospective cleaning validation is a methodical approach that assesses the cleaning programme under **worst case scenarios** (e.g. most difficult to clean area of the equipment, most strongly adhered soil and minimal acceptable cleaning parameters).

Concurrent cleaning validation is applied, if it is impractical to complete a cleaning validation before finished product that is intended for sale will be produced for a new or modified process, or if validation is being undertaken on an existing process that has not historically been validated.

Retrospective cleaning validation is based on the analysis of historical data to provide documentary evidence that the cleaning protocol is effective**. It refers to a cleaning programme that has been implemented for some time.**

Verification – Has it worked?

Determines that the control parameters have been implemented as intended.

Occurs during or after the cleaning procedure through a variety of activities, including observation of monitoring activities and review of records.

Monitoring – Is it working?
Monitoring cleaning effectiveness is performed during every cleaning procedure. It includes a **planned sequence of observations, measurements, records and documentation of control parameters,** to assess whether the cleaning procedure is performing within specifications.

Monitoring activities are typically **“real-time” measurements** during cleaning.

Hygienic Design criteria relevant to CIP – validation process

CIP programmes or protocols consist of a sequence of different cleaning steps depending on:

- The object which needs to be cleaned (physical layout, size, number of circuits, etc.).
- The manufacturing process (heating, storage, UHT, evaporation, etc.).
- The properties of the soil which needs to be cleaned (age, composition, viscosity, allergens, etc.).
- The purpose or goal of the cleaning programme based on a risk assessment.

The CIP validation consists of the following activities:

- DQ: Design Qualification
- IQ: Installation Qualification
- OQ: Operational Qualification
- PQ: Performance Qualification

Hygienic Design criteria relevant to CIP – Design Qualification

- **Process and machine description**
- CIP liquid / Cleaning agent
- Process control.
- CIP Supply Pump
- CIP Return Pump
- CIP nozzles

Hygienic Design criteria relevant to CIP – Installation Qualification

Several items of the CIP-loops are qualified on presence, compliance to specification and layout of the installation

- Capability CIP nozzles flow and pressure
- CIP nozzles correctly placed
- Drainability CIP piping:
- Dead ends in piping
- Capacity of CIP tanks
- Water source
- Added chemicals + %

Hygienic Design criteria relevant to CIP – Operational Qualification

The Operational Qualification, performed during the pilot CIP runs, verifies that the equipment perform as intended throughout the anticipated operating ranges.

Prerequisites - Installation Qualification complete

Tests/simulations

- Verification of CIP at start-up
- Verification of CIP after # batches/ Mt
- Verification of CIP performance
- Verification of works instructions

Verification presence minimal required devices

Verification procedures

- Procedure to verify if CIP was performed in the right way
- E.g. reviewing and signing off PLC-output like graphs, alarms etc.
- Procedure to verify if the CIP was sufficiently effective (*equipment clean as specified)*
- E.g. visual inspection, swaps etc.

Hygienic Design criteria relevant to CIP – Performance Qualification

Purpose of the performance qualification is to verify that the process will consistently produce acceptable products under normal operating conditions.

Data analysis
All CIP parameters passed the verification tests as intended
• Flow, pressure, temperature, time etc.

Draining Verification
The system was completely drained after CIP

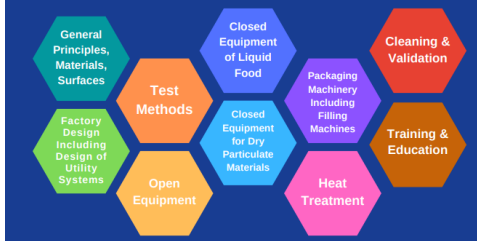
Information regarding the process itself
Verification of the CIP did not reveal potential hazards or (quality) issues in the process lines.

Organisational Fact Sheet | 2021

OUR VISION

To be recognized as the leading source of hygienic engineering expertise and its application, focused on solutions for enhancing food safety and quality across the food industry

OUR PRODUCT PORTFOLIO



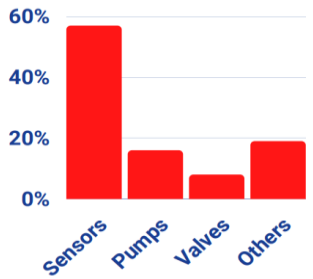
10 Focus Areas
29 Working Groups
50+ Guidelines
50+ Authorised Trainers

OUR CERTIFICATION PROGRAMME

400
Certified equipment components

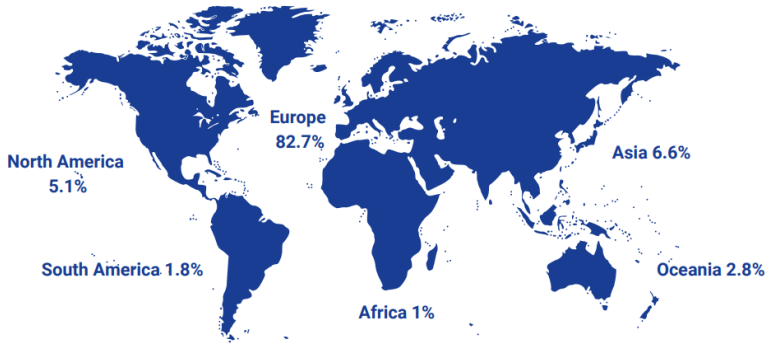
12
Authorised Evaluation Officers

8
Authorised Testing Laboratories

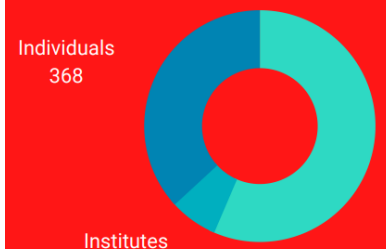


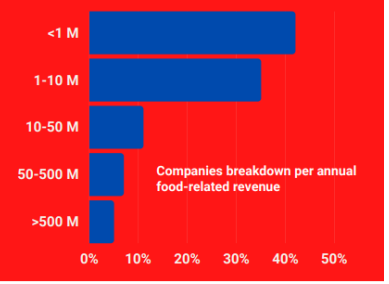
Certified components breakdown

OUR GEOGRAPHICAL PRESENCE



OUR MEMBERS





Companies breakdown per annual food-related revenue

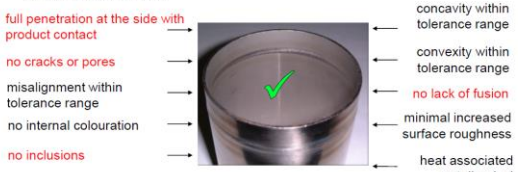
Hygienic Engineering and Design

- Mod.03 - Hazards_In_Hygienic_Processing_03-22
- Mod.04 - Cleaning_and_Disinfection_03_2021
- Mod.05 - Hygienic_Design_Criteria_07_2018
- Mod.06 - Materials_of_Construction_10_2020
- Mod.07 - Welding_2018_10
- Mod.08 - Weldinginspection_09_2021
- Mod.09 - Static_Seals_and_Couplings_07_2021
- Mod.10 - Installation_and_Maintenance_Version_One
- Mod.11 - Pumps_and_Homogenizers_06_2018
- Mod.12 - Valves_07_2021
- Mod.13 - Chemical_Treatment_of_SS_Doc.18
- Mod.14 - Dry_Materials_General_04_2017
- Mod.15 - Packaging_ENG
- Mod.16 - Building_layout_07_2018
- Mod.17 - Verification_and_Test_Procedures_05_2021
- Mod.18 - Conveyor_Systems_09_2019

European Hygienic Engineering & Design Group

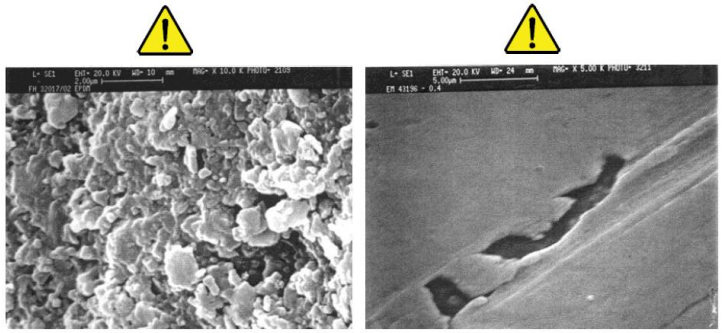
Definition of an "ideal" hygienic weld

Although manual welding can achieve equally good individual results, the required repeatability and consistency of the welds cannot be guaranteed with manual methods.



Source: Kopitzke, Arc Machines GmbH, Much/ Barnicket

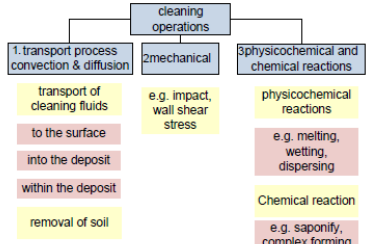
Seal Surface Finish and Defects



The presence of pores in the material and location of split lines/mould flashings is important due to loss of cleanability.

Source: Timberley Consulting

What happens during cleaning?



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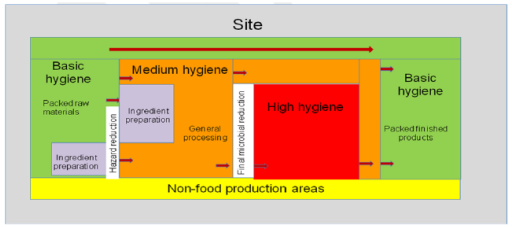
Factory zoning



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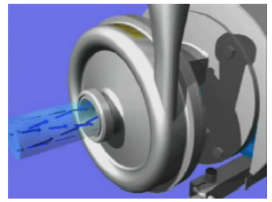
Pumps

Dynamic pumps

- Centrifugal pump
  - Flow direction: radial / axial / diagonal
  - Priming: non-self-priming / (self-priming)



source: Alfa Laval

Radial Flow Pump

Pros	Cons
• High flow rate • Good for low viscous fluids • Simple, robust design • Hygienic design possible • Good for CIP application	• Not for very viscous fluids • Cavitation

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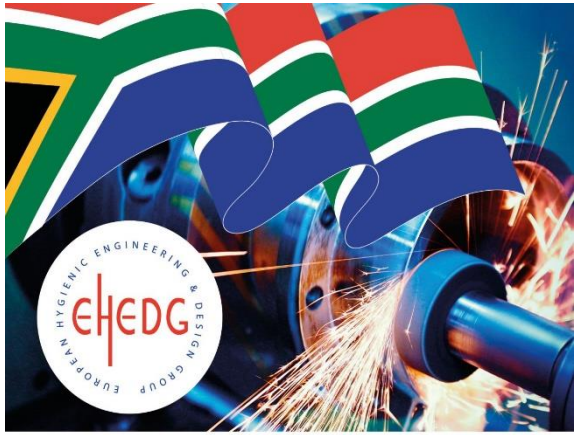
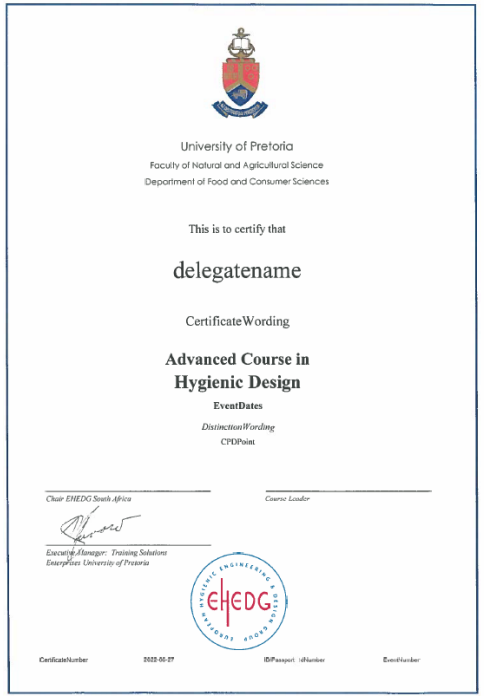
Regional Section – South Africa




University of Pretoria
Faculty of Natural and Agricultural Science
Department of Food and Consumer Sciences

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CertificateWording

Advanced Course in Hygienic Design

EventDates

DistinctionWording

CPDPoint

Chair EHEDG South Africa

Course Leader

Executive Manager: Training Solutions Enterprises University of Pretoria

CertificateNumber 2022-00-27 IDPassport idNumber EventNumber

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Thank You!

Any Questions?