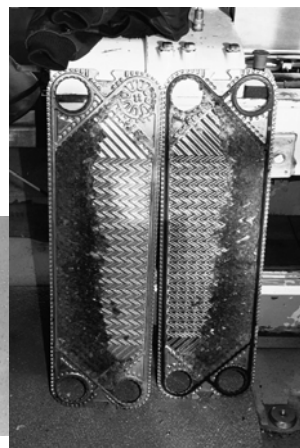
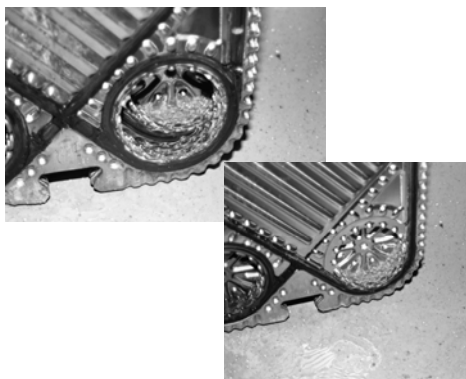


Hygienic processing systems - a practical approach



Poor cleaning in plate heat exchangers





Hygienic design – a practical approach

- All parts of the construction and the application
 - General rules for Construction
 - Choice of construction material and their composition
 - Knowledge of the specific limits concerning of use a machine
 - Good process hygiene built into a practical design
 - Good cleanability and effective cleaning procedure
 - Effects of fluid dynamic parameters and cleaning complex
 - Consideration of traditional design aspects: optimal product quality / optimal use of raw material, safe products as to chemical physical and microbiological risks, minimal use of energy and operator safety



Integrated Approach to hygienic design

- The facility must conform to all **specified requirements**
 - The **specified requirements** can originate from for example legislation, users, product quality, or safety
- Definition of **“Hygienic Integration”**:
 - The process of combining or arranging two or more entities to work together while eliminating or minimizing hygiene risks*
- The integrated approach also includes determining specifications for product flow, control strategy, automation, maintenance, change management, training of personnel etc.





Nomenclature – 1

- **Hygienic Entity:** An essential component of a hygienic system
 - **Part:** A one-piece item that comprises a single material, such as a pipe, screw, shaft, spring, plate, elastomeric or seal
 - **Module:** A combination of parts such as a coupling, floor or valve that accomplishes a new specific function
 - **Unit:** A combination of modules such as a centrifuge, or fryer
 - Any automation and instructions necessary to establish and maintain the specified level of hygienic performance
- **Process Line:** An arrangement of units, modules and/or parts that can produce a completed or intermediate food product, such as beer, cheese, flavors, spices, hamburgers, packed food etc.
- **Factory:** An arrangement of process lines, units, modules, and/or parts designed to manufacture a product: personnel, perimeters, buildings, process equipment, utility supplies and systems for management, zoning, maintenance, storage, cleaning etc.

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Nomenclature – 2

- **Hygiene Zone:** A permanent area with restrictions on access and egress of material, personnel and equipment, in which a defined level of hygiene and care is maintained
- **Transfer Zone:** A barrier/treatment zone that allows people and/or materials to pass from one zone to another without compromising the hygiene/care status
- **Static dead-zone:** An area of equipment where flow (drainage), is permanently inadequate for safe food production
- **Dynamic dead-zone:** An area of equipment where flow/drainage may temporarily become inadequate for safe food production, as a result of the operational positioning of valves
- **Domain:** A transient operational boundary with a cleanliness status inside, a section of the process equipment to be managed as sterile or clean or empty for a period of time

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Nomenclature – 3

- **Hygiene Barrier:** A hygienic entity, typically at the module or unit level, which separates and protects the hygienic integrity of a hygienic domain/zone
- **Hygiene Status:** The hygiene status of equipment, for example, *sterile, pasteurised, clean, clean and sterile, clean and pasteurised, clean and empty, clean and full, dirty, cleaning, sterilizing, pasteurising, opened, under maintenance*
- **Containment:** The total physical hygienic or aseptic boundary of an environmentally - managed domain/zone, e.g. the walls, floor, doors, air curtains and ceiling etc. of a building, room, cabinet, or isolator. Can also include transfer zones, differential air pressure systems and the seals, thermal barriers at physical penetrations for piping, light fittings, cables, ducts, vents and drains.

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Nomenclature – 4

- **Design Change:** Any alteration of any hygienic entity within a food production system (*procedure, part, module, unit, process line, specification, formulation, personnel, building, document, etc.*), including any substitution where the hygienic entity is not replaced by an **exact** copy, potentially causing hazards to food safety or quality. A design change is the result of a *reassignment*.
- **Change Management:** A documented procedure in which all design changes are documented and reviewed by a multifunctional team. This team must use an HACCP or similar risk assessment study. to manage safely any proposed or enforced alteration in parts of a food production hygienic system

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Food Quality and Safety



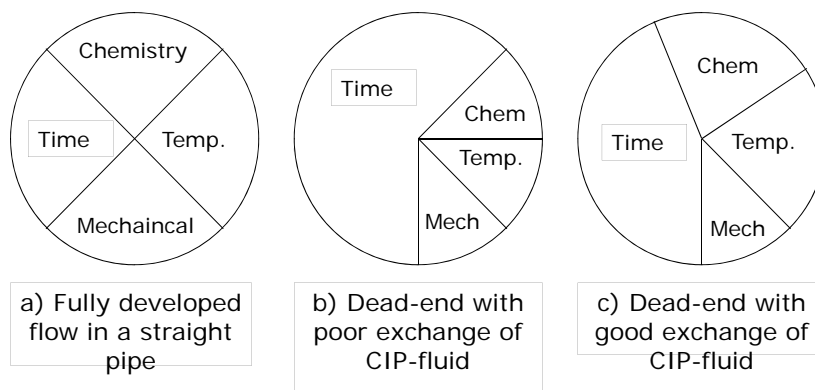


Critical points and connections

- Waste
 - E.g. containers containing product or used materials
 - Where is this placed?
 - Exit and entry (e.g. fresh air)
- Water
 - Piping (e.g. hot and cold streams, condensate)
 - Drain
- Air
 - Filtered (quality) or non filtered
 - Flow directions and connections in the plant



Sinners circle – closed equipment

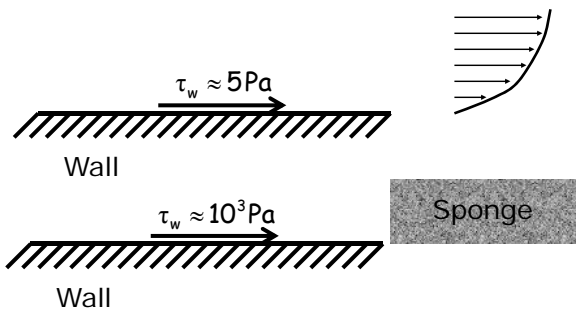




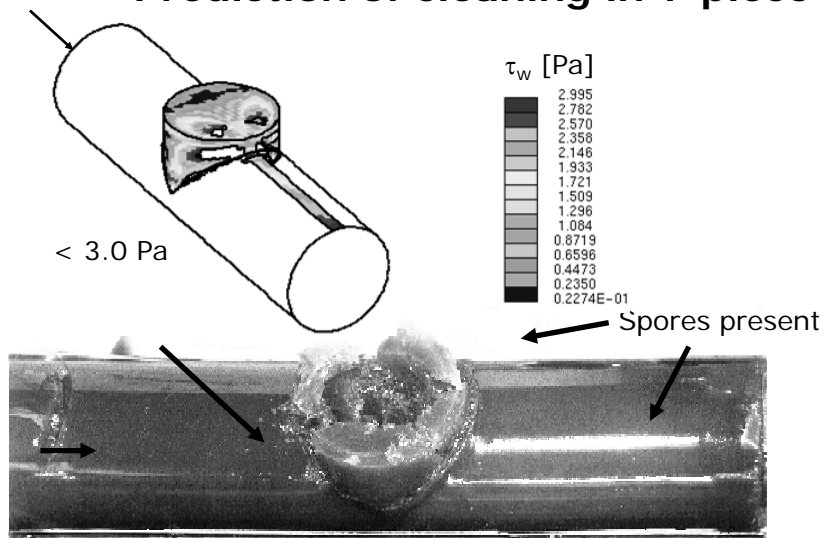
CIP – Mechanical "energy"

Wall shear stress

$$\tau_w = \mu \frac{du}{dy} \quad [\text{Pa}]$$

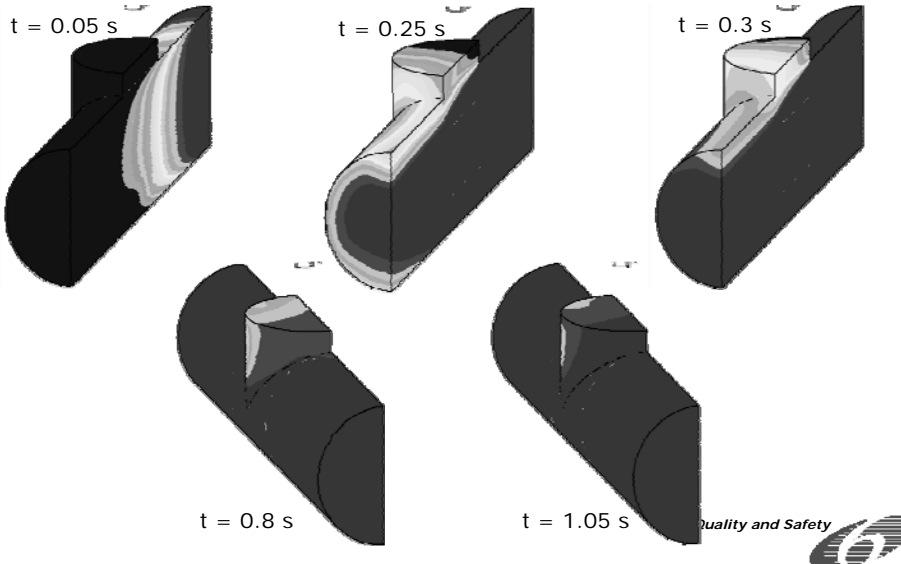


Prediction of cleaning in T-piece

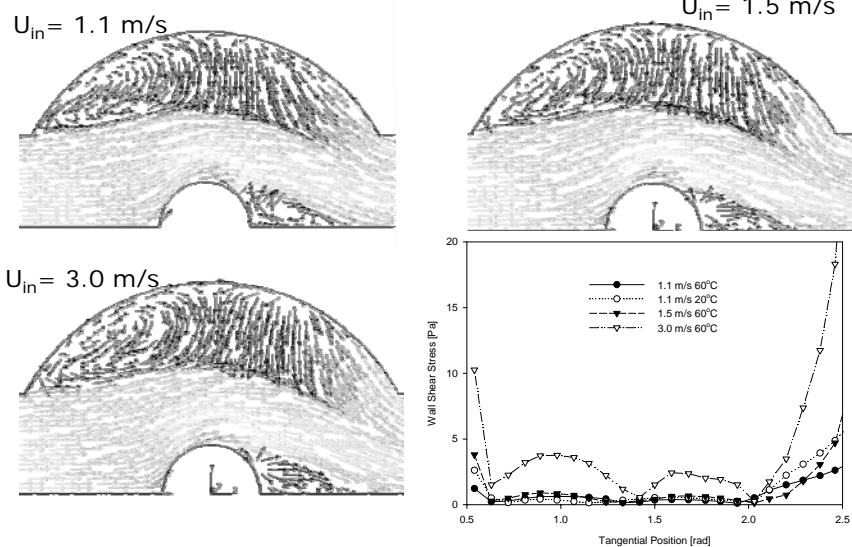




Fluid exchange in T-piece



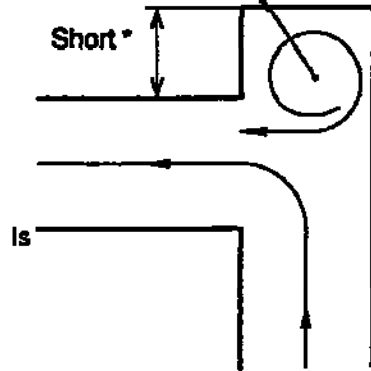
Greater velocity = better cleaning? NO!





Recommendations in guidelines

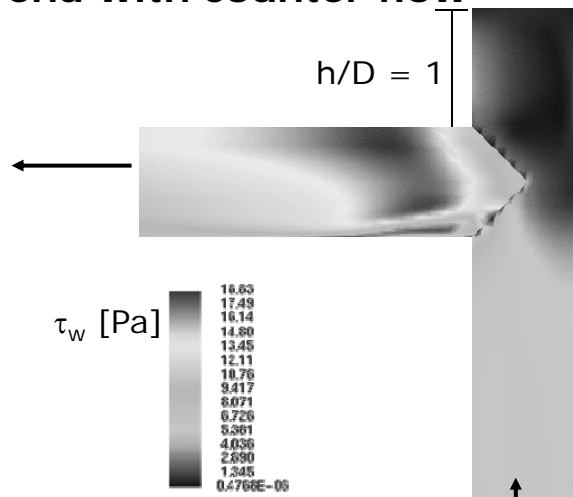
Sufficient exchange with main flow



ONLY ACCEPTABLE IF UNAVOIDABLE

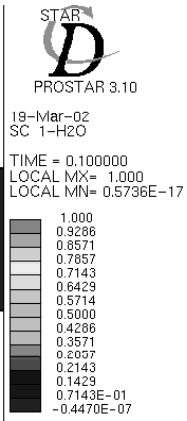
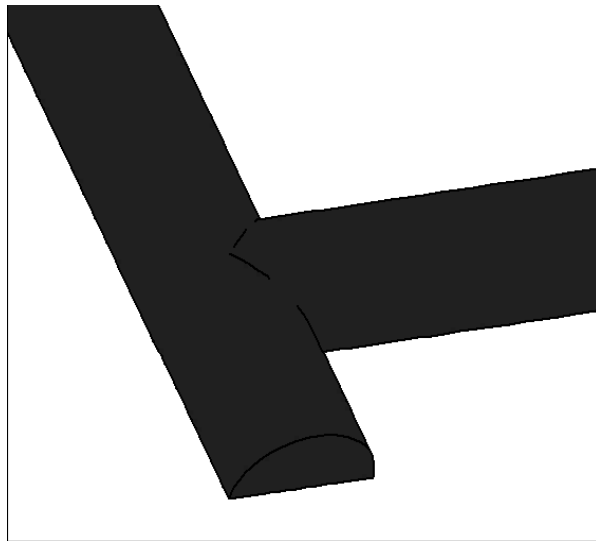


Dead-end with counter flow

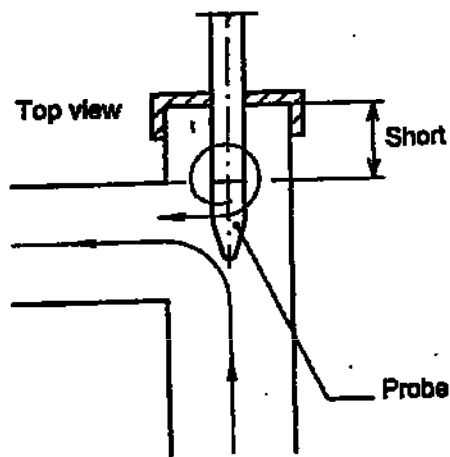




Dead-end with counter flow



Recommended in the guidelines



ACCEPTABLE





The test rig

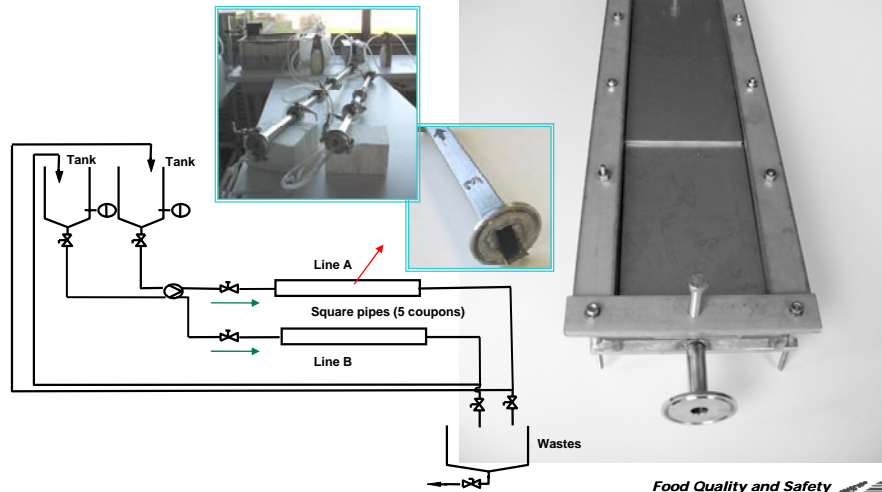
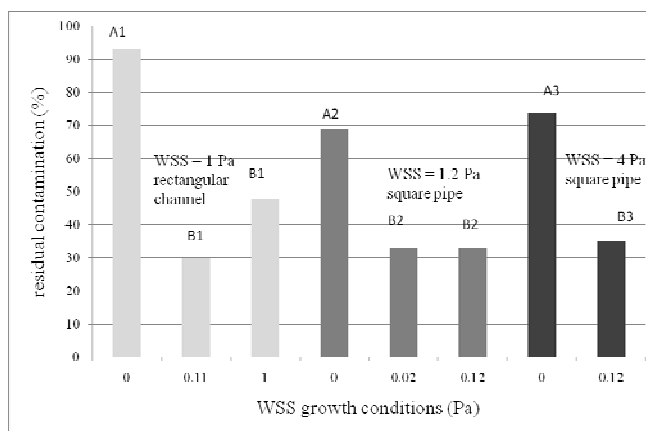


Figure 1 : set-up & square pipes

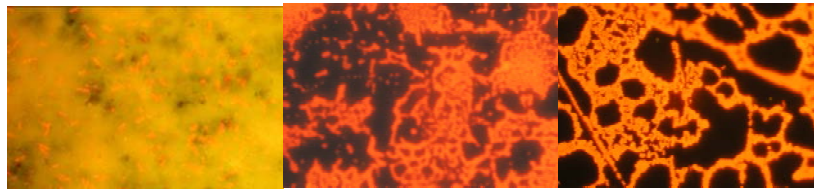


Remaining % of TVC for *Kocuria varians* biofilms rinsed under 3 WSS conditions after various growth conditions: static, laminar (0.02 Pa in the square pipes and 0.11 Pa in the rectangular channel) and turbulent (0.12 Pa in the square pipes)





Kocuria varians biofilm (x 100)
after rinsing for 3 growing conditions



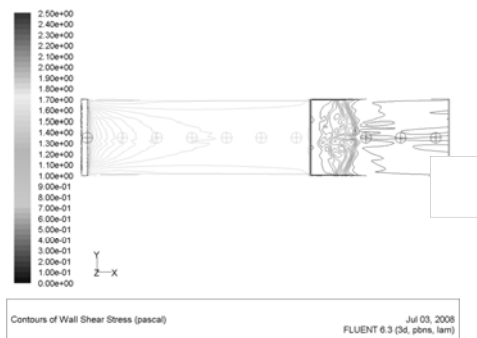
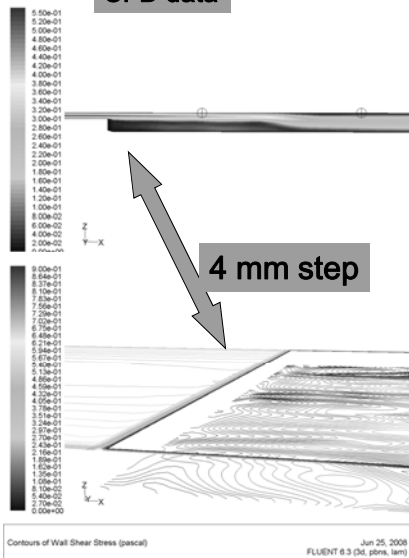
STATIC

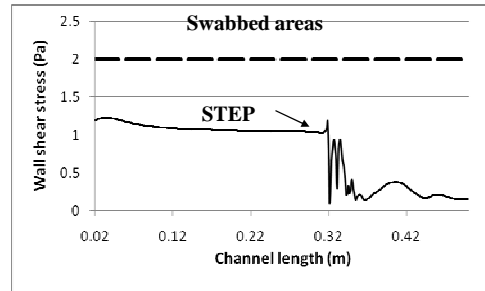
WSS= 0.02 Pa
LAMINAR

WSS= 1.2 Pa
TURBULENT

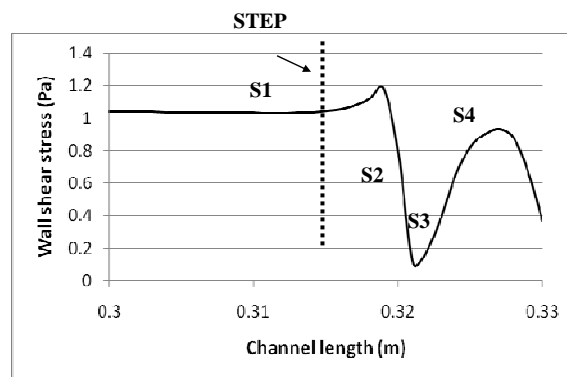


CFD data





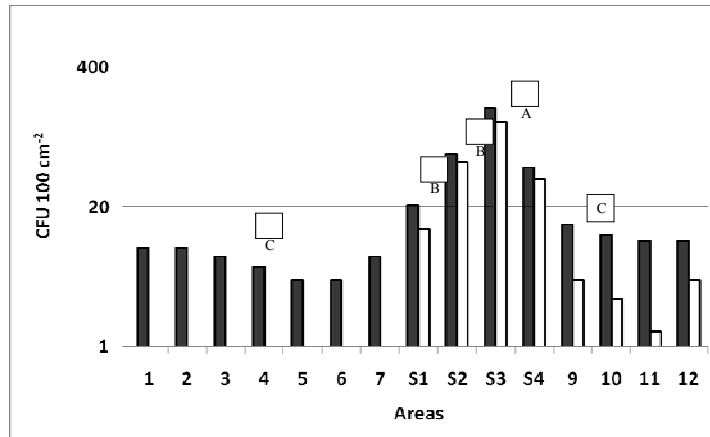
Wall shear stress at the middle of the channel for the 12 swabbed areas (straight horizontal lines)



Focus on the wall shear stress range observed at the step – area subdivided in S1, S2, S3 and S4



Remaining viable *Kocuria varians* cells after cleaning (NaOH, 0.5 %, 12 min) for two growth conditions (static: full bars; dynamic: empty bars).



Recommendations relation flow

- Fluid exchange
- Wall shear stress
- Breaking static patterns

The take home message

**By understanding fluid dynamics
it can work for you
not against you**





Conclusions – closed processes

- Results produced on dynamic growth and removal of biofilm under laminar and turbulent flow - industrial conditions
- Main effect for research and equipment design
- Relation to risk assessment
 - Be aware of static patterns in complex process parts – turbulent flow high WSS not a guaranty of cleanliness
- Public translation of results is production
- Research needs linking flow and cleanability in practice



Summing - up

- Think integration
- Be aware of intermediate conditions i the plant
- Make a master plan
- Identify your risk and focus on them specifically
- Increased understanding of the influence of fluid flow
 - Cleaning can be predicted using simulations
 - Identification of weak points
 - Promoting flow patterns
 - Be aware of poor fluid exchange
 - Mean flow velocity may be the control parameter in straight pipes
 - But not in complex equipment – local flow patterns dominates

