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Testing and verification of the hygienic requirements of food processing equipment*

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Summary

In the EC, the Council Directive on the approximation of the laws of Member States relating to machinery (89/392/EEC) was published on the 14th June 1989 and was subsequently updated by 98/37/EC. The Directive includes a short section dealing with hygiene and design requirements which states that machinery intended for the preparation and processing of foods must be designed and constructed so as to avoid health risks and consists of seven hygiene rules that must be observed. These rules are concerned with the suitability and cleanability of materials in contact with food, surface finish and design features such as joints, absence of ridges and crevices, avoidance of the use of fasteners, the design of internal angles and corners, drainage of residues from equipment surfaces, dead spaces and voids, and lastly bearings and shaft seals. The Directive requires that all machinery sold within the EC after January 1995 shall meet these basic standards and be marked accordingly to show compliance (the 'CE' mark). In other words, it is a legal requirement in the EU for food processing equipment to be hygienically designed. To provide further advice to equipment manufacturers in implementing 98/37/EC, the standard EN 1672-2 "Food processing machinery-Safety and hygiene requirements-Basic concepts-Part 2, Hygiene requirements" can be followed.

Since the implementation of this directive and standard, a number of issues have arisen in the food industry that has re-focused attention on hygienic design. These include,

- Is manufacturers' self-certification of cleanability sufficient or is third party approval of design and cleanability preferred?
- Do the design standards of particularly) dry processing equipment have to be increased to allow wet cleaning to remove allergens and other product contamination issues?

* Lecture presented at the conference „Hygienic Design” on September 11-12, 2008 in Zurich

- Are lubricants capable of controlling microbial growth through their use life-cycle?
- Are replacement parts (e.g. belts and gaskets) always suitable for food contact purposes? Should suppliers provide certificates of compliance?

The presentation will consider, with examples, how these issues can be addressed.

Verification of Food Processing Equipment Hygiene

Dr. John Holah, Head, Food Hygiene Department



Hygiene requirements

- Legislation conformance
 - Machinery safety directive 89/392/EEC
 - EN 1672-2 Hygiene guidance for food equipment
 - EN ISO 14159 Hygiene guidance for all equipment
 - EN ISO 21469:2006 Lubricants
 - EC No. 852/2004 General hygiene requirements
 - Third Party approval
- Hazard control
 - Microorganisms
 - Allergens
 - Materials of construction

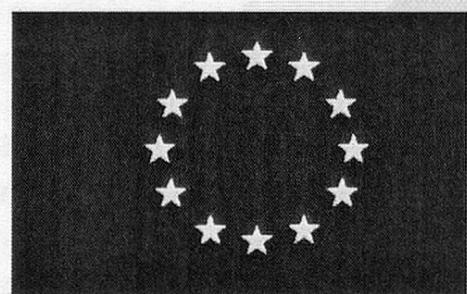


Legislation



European Legislation

- EU COUNCIL DIRECTIVE
 - 98/37/EC
- (14 June 1989 89/392/EEC)
 - on machinery including agri-foodstuffs machinery



Annex 2.1

- 'Where machinery is intended to prepare and process foodstuffs (e.g. cooking, refrigeration, thawing, washing, handling, packaging, storage, transport or distribution), it must be so constructed as to avoid any risk of infection, sickness or contagion and the following hygiene rules must be observed'



Hygiene rules

- Relevant 'materials in contact' rules. Machinery designed such that these materials can be clean before use
- All surfaces including their joinings must be smooth, and must have neither ridges nor crevices which could harbour organic materials
- Projections, edges and recesses must be minimised, joints should be by welding or continuous bonding, screws, screwheads and rivets used only where technically unavoidable



Hygiene rules continued

- All surfaces in contact with food must be easily cleaned and disinfected, where possible after removing easily dismantled parts. Inside surfaces curves must be radiused to facilitate cleaning
- Liquids derived from foodstuffs and cleaning should be able to be discharged without impediment
- Design and construction should prevent the entry of liquids or animals and prevent accumulation of soil in areas that cannot be cleaned
- Design and construction such that no ancillary substances (e.g. lubricants) can come into contact with foodstuffs. Compliance should be able to be checked



Verification

- Verification of hygienic design conformance is manufacturer self-certification based primarily on visual assessment and is demonstrated by use of the CE mark



CEN/TC 153

- EN 1672-2: 1997 Food processing machinery - Basic concepts. Part 2: Hygiene requirements
- Working Groups concerned with:-
 - slicing equipment – EN 1974:1998 Food Processing machinery – Slicing machines –Safety and hygiene requirements
 - Bakery machines
 - meat processing machines
 - catering equipment
 - centrifuges for edible oils
 - vending machines
 - pasta processing plants
 - bulk milk coolers on farm
 - cereal processing
 - dairy
 - seafood processing



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EN 1672-2: Hygiene requirements

- Materials of construction
- Surface finish
- Joints
- Fasteners
- Drainage
- Internal angle and corners
- Dead spaces
- Bearings and shaft entry points
- Instrumentation
- Panels, covers and doors
- Covers



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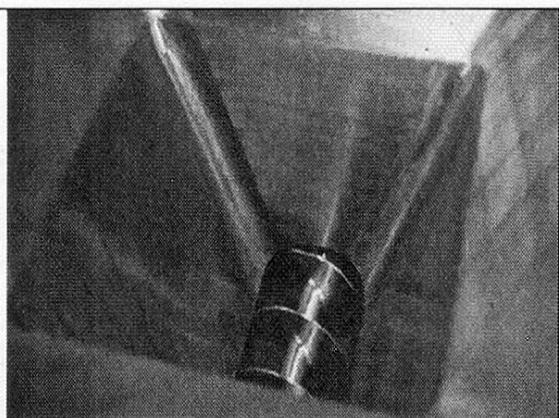
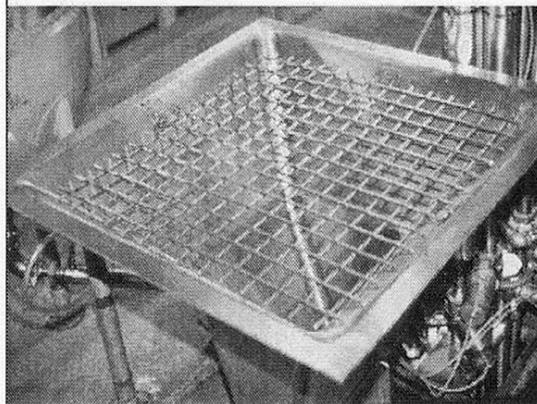
ISO/TC 199 WG2

- ISO EN 14159 Safety of machinery - Hygiene requirements for the design of machinery
- Harmonizes the hygiene requirements of 98/37/EC and the American bodies 3-A and NSF
- Introduces the concept of identification of hazards arising from equipment to the processed products consumer and the risk assessment to suggest suitability for purpose



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EHO's
"It's wonderful"



HSE's
"It's a disaster"



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Risk (hazard) assessment

- Identify the process for which the machine is intended
- Identify the hazards associated with the products produced
- Design methods/measures which can eliminate or reduce their risk
- Identify any other hazard introduced by the methods used to reduce the hazard under analysis
- Verify the effectiveness of the hazard elimination or risk reduction
- Describe any residual risks or precautions



Hazard assessment in-use

- The intended use of the equipment
- The product type to be processed
- The degree of further processing
- The product consumer
- The degree of cleaning and/or inspection
- The frequency of use of the machine



Hygiene level

Hygiene level	Description
1	Machinery which, following a hygiene risk assessment, needs only to partially conform to this standard to meet the identified risk(s) and to produce safe product
2	Machinery which conforms with the requirements of this standard but requires disassembly for cleaning
3	Machinery which conforms with the requirements of this standard and can be cleaned without disassembly
4	Machinery which conforms with the requirements of this standard and has been designed for a specific treatment to free the equipment from relevant microorganisms
5	Machinery which conforms with the requirements of this standard and will prevent microbial ingress and has been designed for a specific treatment to free the equipment from relevant microorganisms

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Food Grade Lubricants

- Since 1998 no H1 and H2 approvals from the USDA based on the FDA positive list (21 CFR § 178.3570 'lubricants with incidental food contact')
- 1999 ELGI / NLGI / EHEDG Working Group established and DIN Standard V10517 published 2001. Application to ISO for International Standard
- NSF Registration Programme set up for new products and verification of compliance for existing products
- ISO TC/199 WG2 adopted 'Food grade lubricants - Terms, definitions and requirements'



Food Grade Lubricants

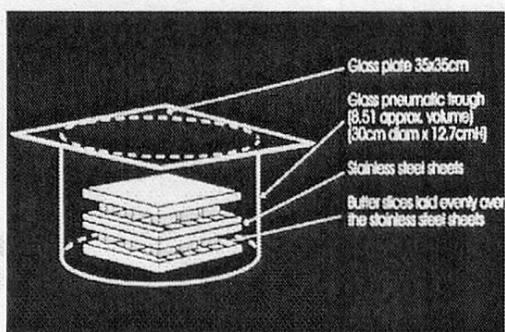
- NSF on-line listings, CD ROM and hard copy White Book™ made available in 2002
- EHEDG Guideline Document No. 23 Production and use of food-grade lubricants published 2002
- EN ISO 21469:2006 Safety of Machinery. Lubricants with incidental product contact. Hygiene requirements. This introduced concepts of hazard identification, risk assessments, hygienic design (composition, organoleptic change, GMP).



ISO 21469 Hygiene requirements

Compositional ingredient toxicity - Yes

- Organoleptic (taste, odour) – No
- (Micro) biological contamination - No
- I have investigated 3 food safety incidents in chilled food plants caused by Listeria and E. coli in lubricants
- Are lubricants preserved – through use?



General hygiene EC No. 852/2004

All articles, fittings and equipment with which food comes into contact are to:

- be effectively cleaned and, where necessary disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination
- be so constructed, of such materials, in good order, repair and condition, as to minimise any risk of food contamination
- be so constructed, of such materials, in good order, repair and condition, as to enable them to be kept clean and, where necessary, disinfected
- be installed to allow adequate cleaning of the equipment and surrounding area



Third Party Assessments

- Use a qualified independent inspector/ recognised expert.
- Inspection of 2D/3D drawings, equipment, Technical Construction File.
- Consider machine use
- Compliance with 98/37/EC and EU machine specific standards where available.
- In the absence of specific standards refer to ISO or CEN plenary hygienic design standards

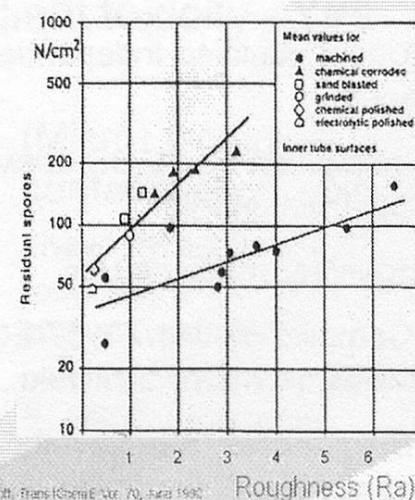
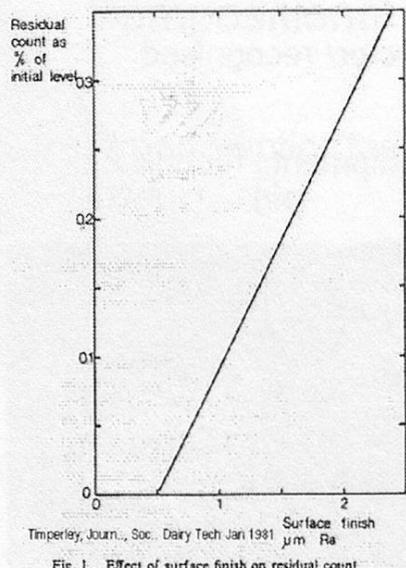


Hazard control

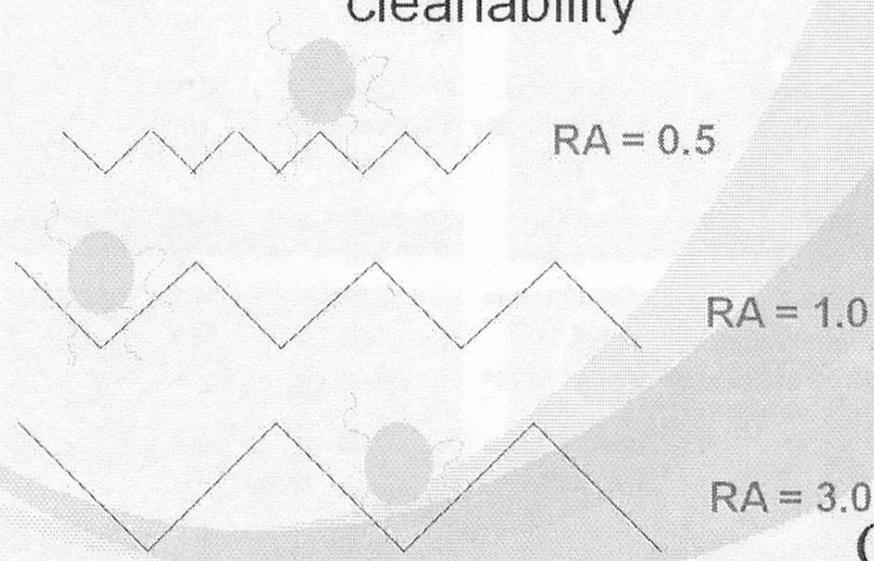
- Microorganisms and surface finish



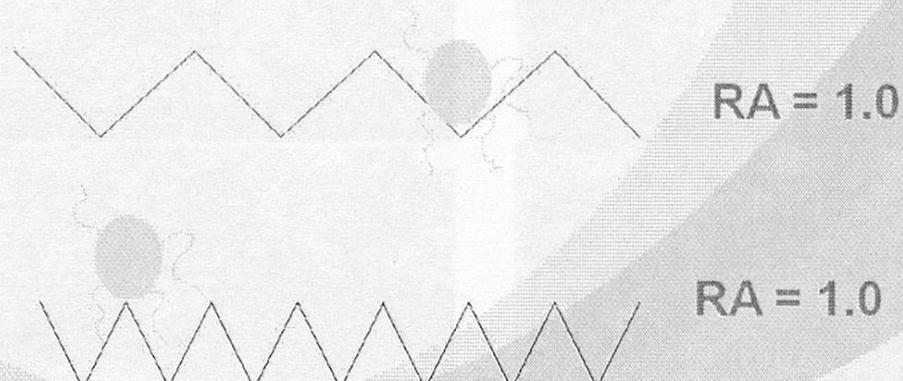
Surface finish vs. Cleanability



Positive relationship between surface finish (RA) and cleanability



Negative relationship between RA and cleanability



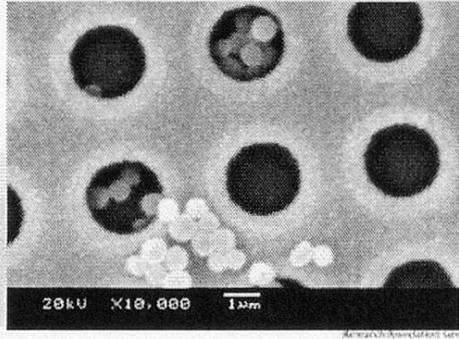
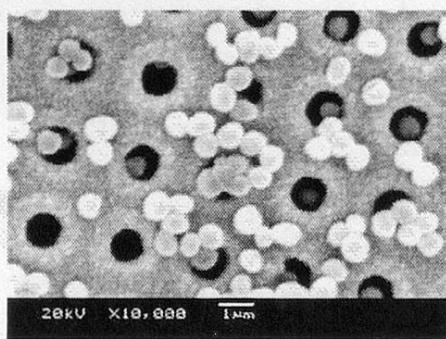
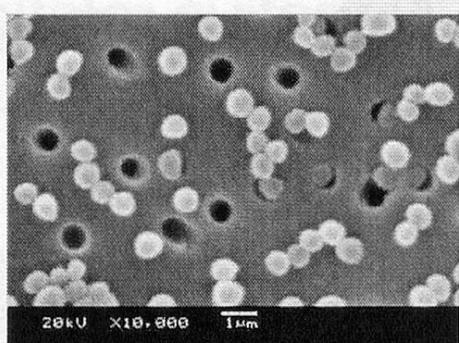
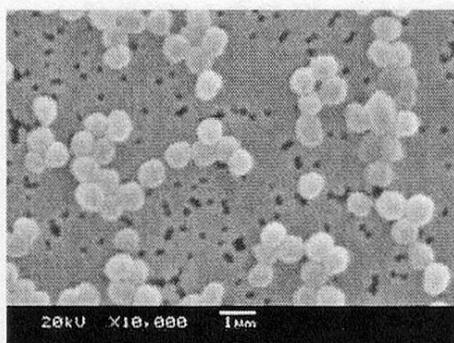
Roughness measurements (Ra)

Material	Surface	Laser	AFM
	Profilometer	Profilometer	nm
PP	0.24	0.81	73
PTFE	0.49	1.37	72
PMMA	Out of range	0.02	2.2
Stainless steel	0.11	0.63	75
Polished stainless steel	Out of range	0.06	7.9
Glass	Out of range	0.05	1.6
Porcelain	1.16	6.69	216

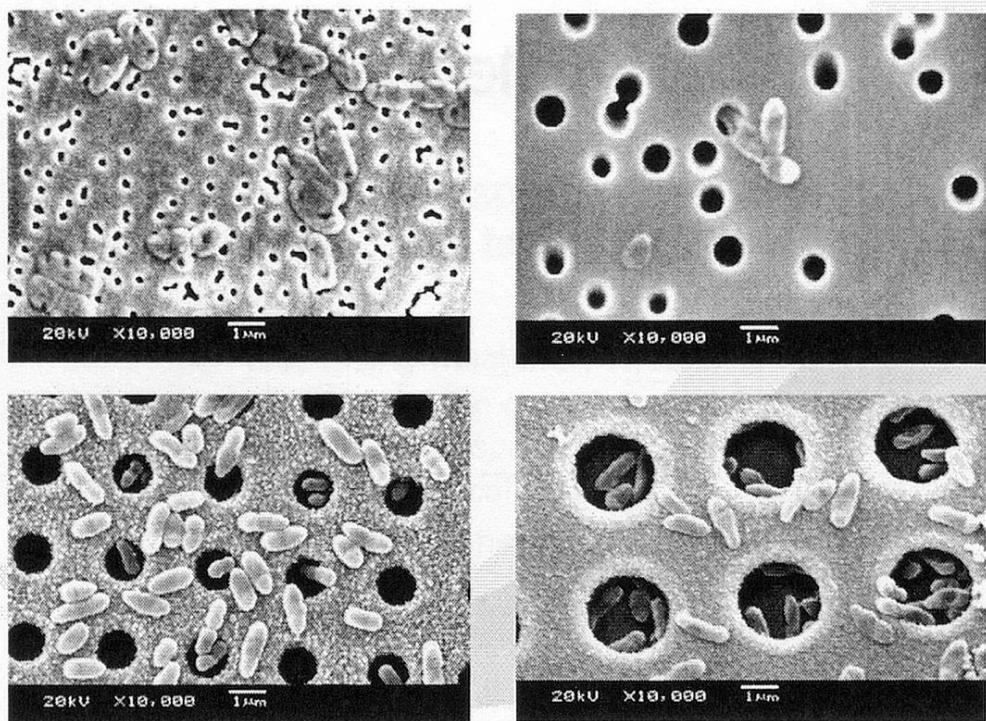


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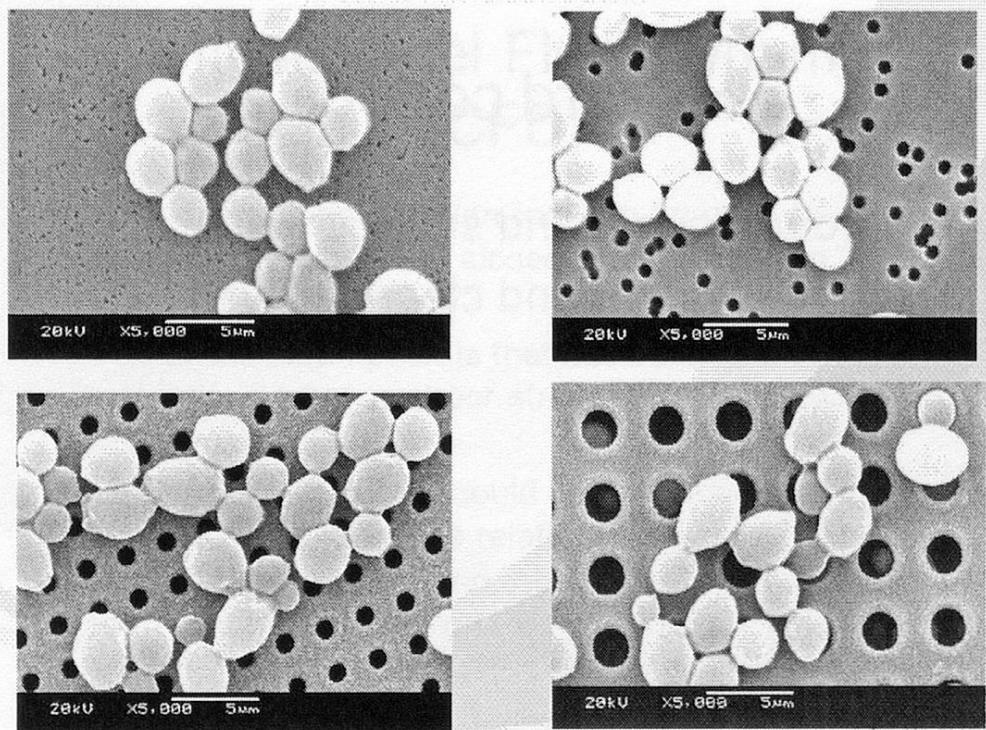
Staphylococcus aureus



Pseudomonas aeruginosa



Candida albicans



When is a hole a surface?



Hazard control

- Microorganisms and surface finish
- Microorganisms and cleanability



Cleanability requirements

- EN 1672-2 Visual inspection and/or practical test, microbiological test or functional test
- ISO EN 14159
 - Open processing machinery is considered cleanable if its design complies with Clause 5 (*essentially visual inspection*). Some machinery may require a practical test
 - Closed process machinery is considered cleanable if cleaning can be verified by means of a practical test. Some machinery may only require compliance with Clause 5



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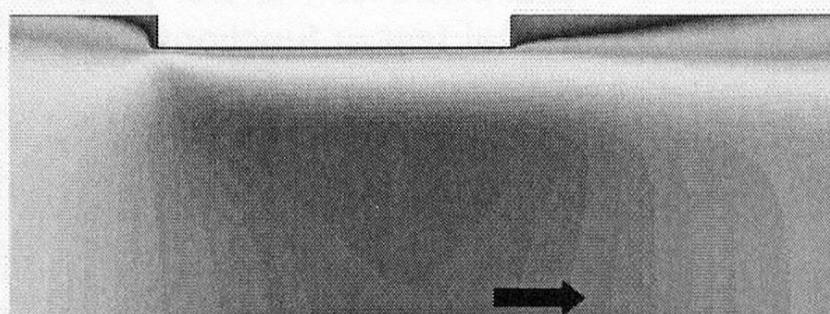
Computational Fluid Dynamics (CFD)

- CFD analysis as a design tool can be used for optimising the design of closed food processing equipment
- The basic assumption is that microbial and soil removal is related to shear stress, which in turn is related to velocity
- Unclear whether CFD could be described as a 'practical test' unless the relationship between cleanability and shear and the suitability of the CFD programme is established

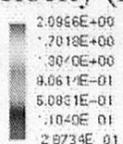


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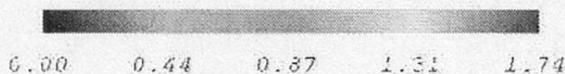
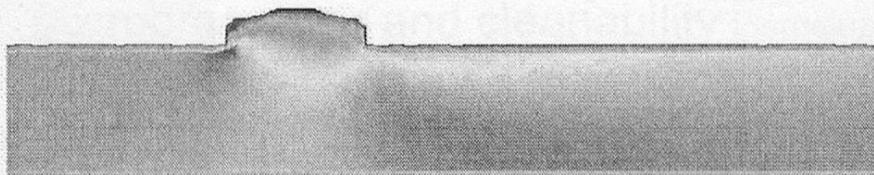
1mm Protrusion - u-Velocity Contours



Velocity (m/s)



Speed contours (m/s)



Third Party Certification Schemes

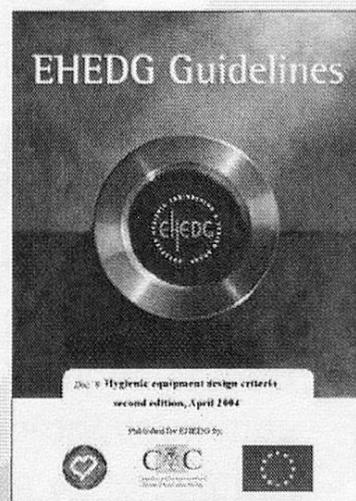
- EHEDG have established a scheme for liquid handling equipment such that equipment can be certified (and a logo placed on the equipment)
- NSF certification scheme is in place
- 3-A have moved away from self certification to third-party audit (TPA) in June 2003



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Certification criteria

- Hygienic design to meet the requirements of EHEDG Guideline No. 8 *Hygienic Equipment Design Criteria*
- If appropriate, cleanability assessment is required to meet the requirements of EHEDG Guideline No. 2 *A method for the in-place cleanability of food processing equipment*
- In all cases, the requirements of the machinery directive 98/37/EC, via EN 1672-2 should be met



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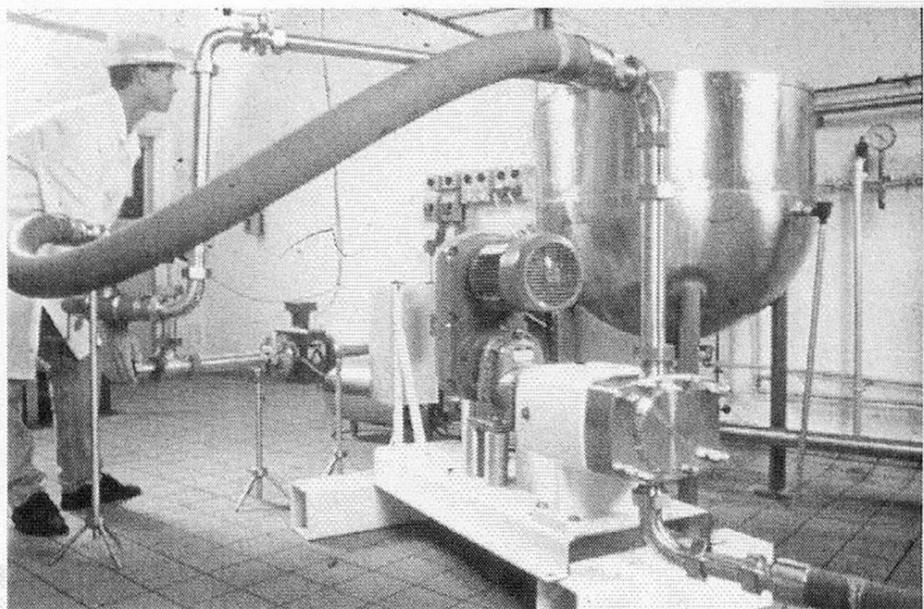
A. HYGIENIC DESIGN AND CONSTRUCTION	Evaluation		Observations
	Yes	No	
absence of direct metal to metal joints (other than welding)			
absence of misalignment in equipment and pipe connections			
seals and gaskets make flush with the surface (both product and non-product side)			
absence of O-rings in contact with food product			
absence of screw threads in contact with food product			
radius of corners ≥ 3 mm			
absence of cracks and crevices			
average roughness (R_a) $\leq 0,8 \mu\text{m}$ (product contact surfaces)			



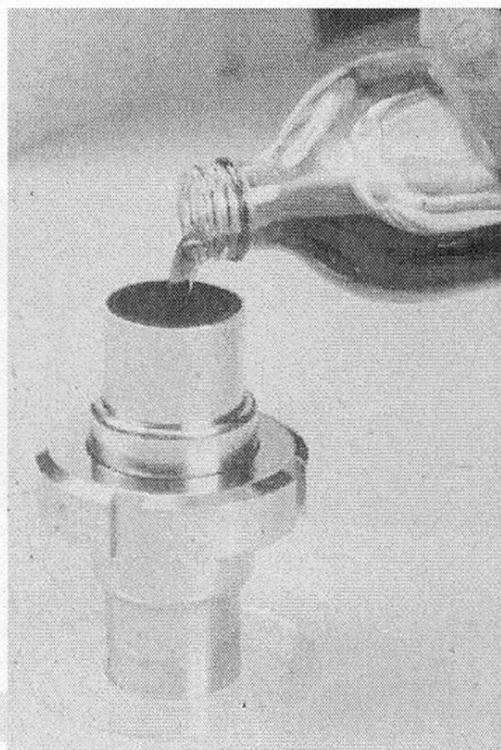
Procedure

- Client contact with EHEDG or Test House - CCFRA, TNO, TU Munchen, DTI, Ainia
- Hygienic design assessment/test
- Report issued
- Sent to another test house (on rotation) for comment/agreement
- Confirmed by EHEDG
- Logo contract issued
- Client added to EHEDG Certification List

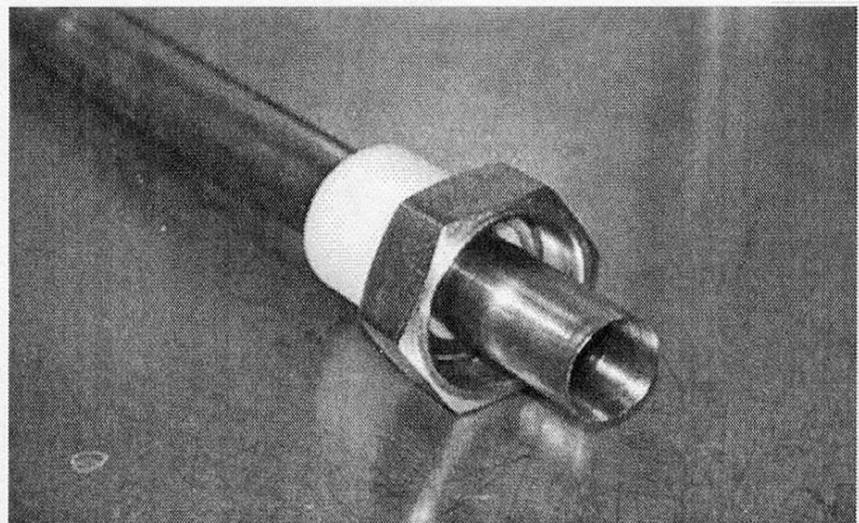




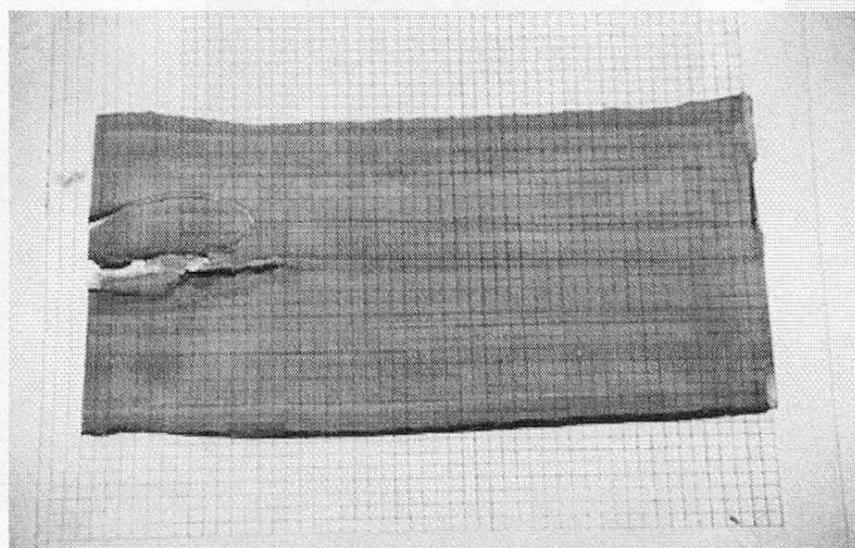
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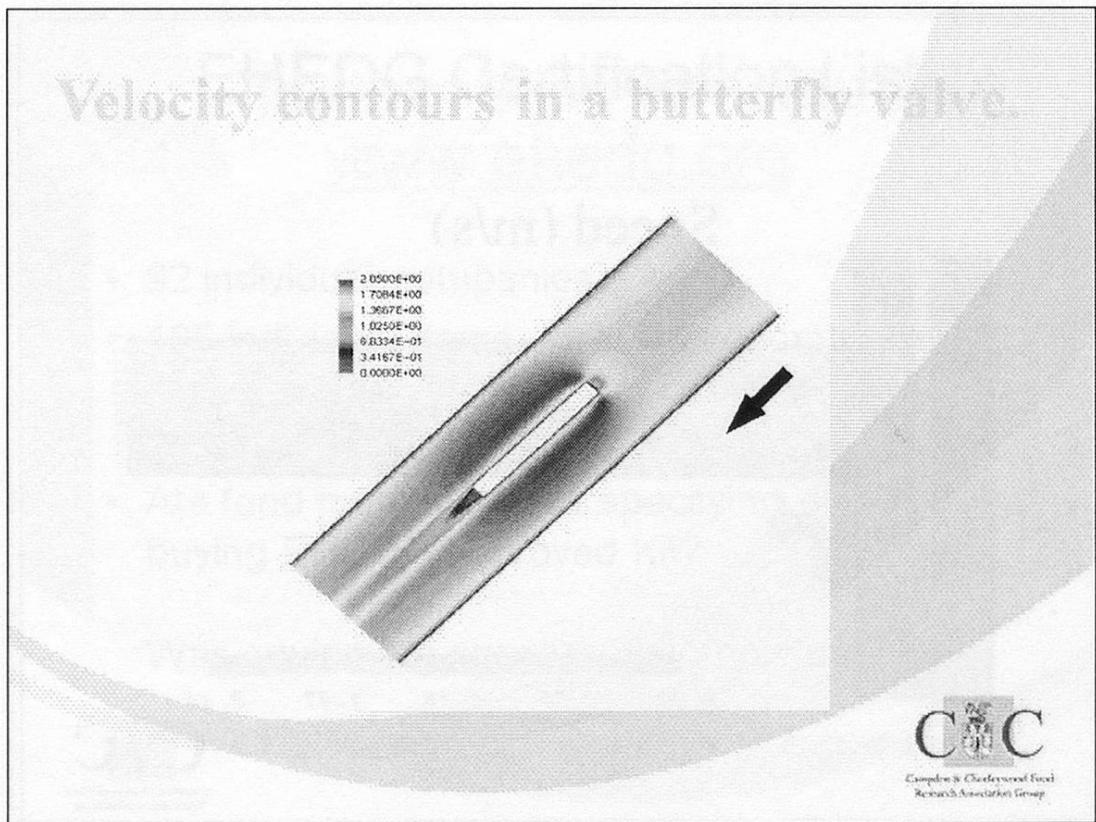
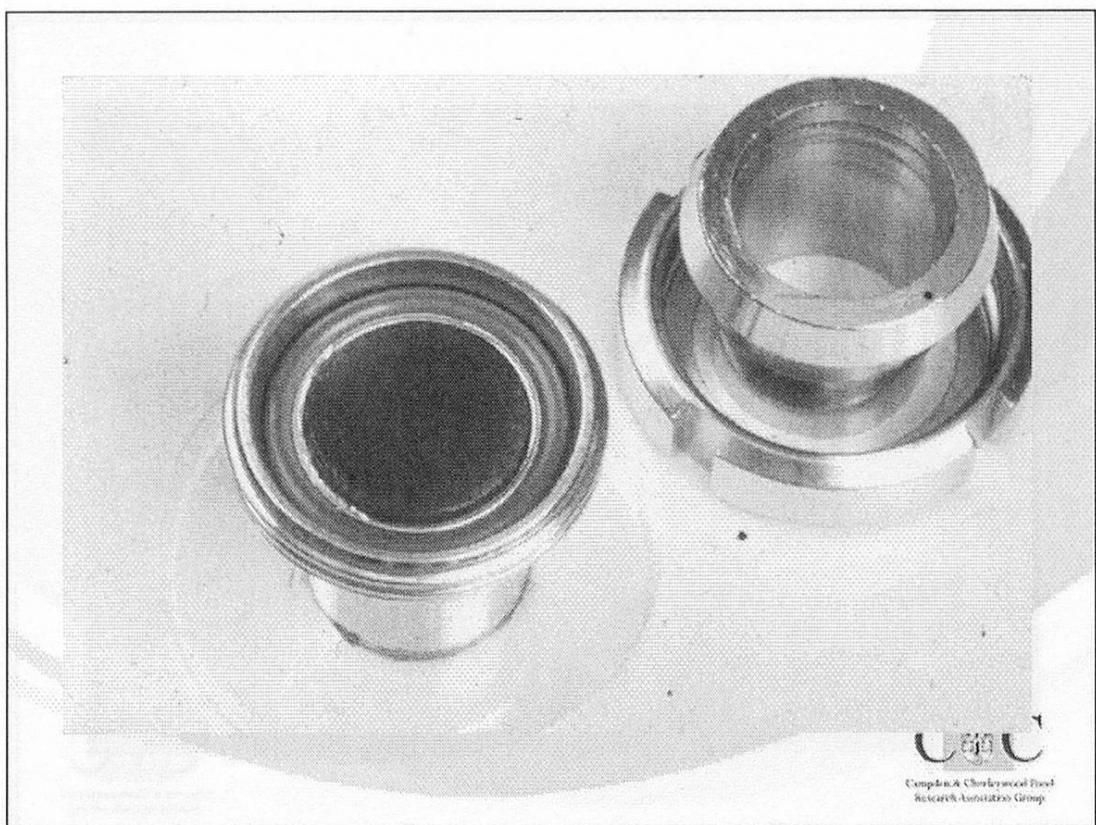
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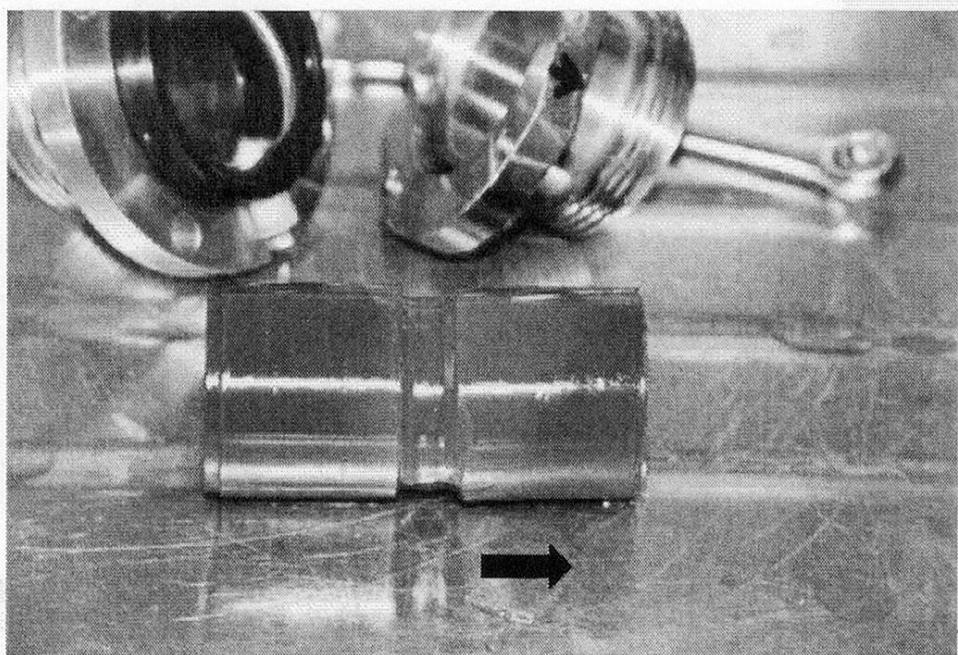


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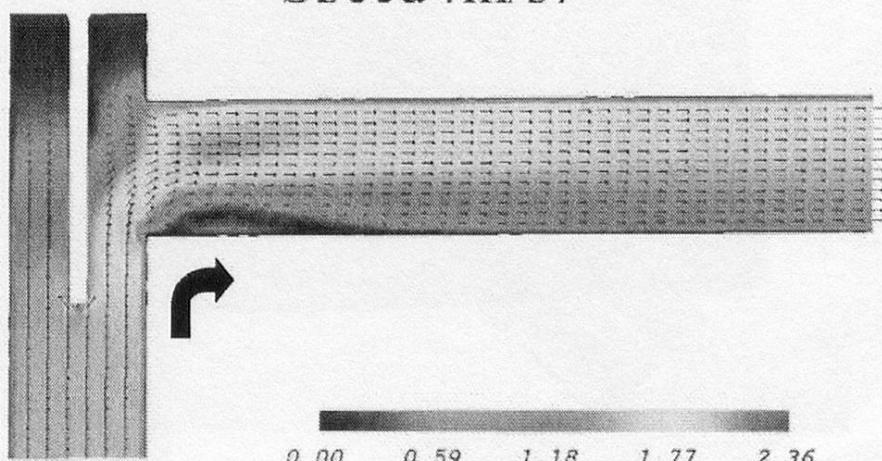




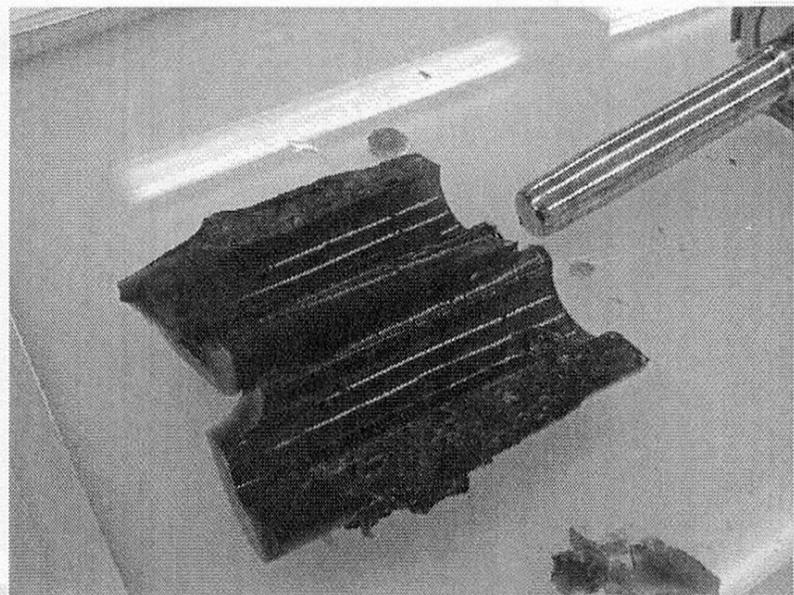
© 1991
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Instrumentation Mounting

Speed (m/s)



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EHEDG Certification List

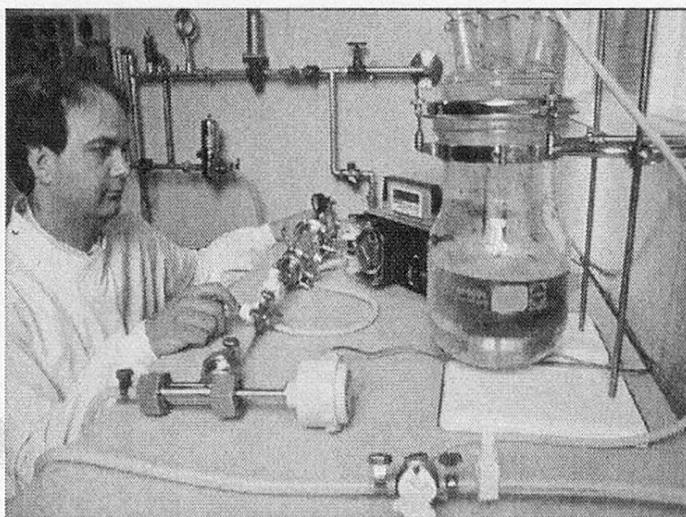
www.ehedg.org

- 92 individual companies
- 198 individual items - includes geometrically scaled series
- Are food manufacturers specifying and/or buying EHEDG approved Kit?

Was equipment supplier push now user pull!



Aseptic equipment – additional requirements -Steam Sterilisability and Bacteria Tightness Testing



Hazard control

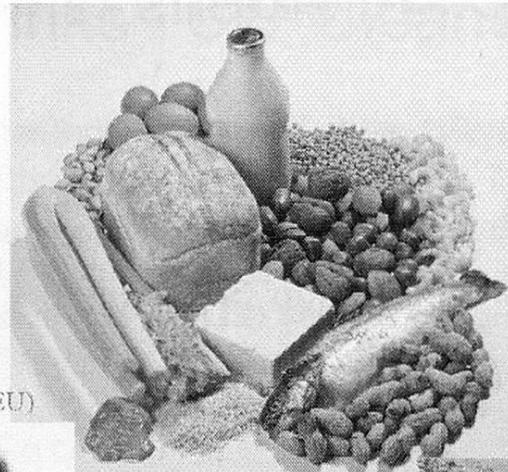
- Microorganisms and surface finish
- Microorganisms and cleanability
- Allergens and dead spaces



Allergens - EU legislation

- Cereals containing
- Gluten
- Eggs
- Milk
- Celery (EU)
- Mustard (EU)
- Sesame seeds (EU)

- Molluscs (EU)



and products thereof

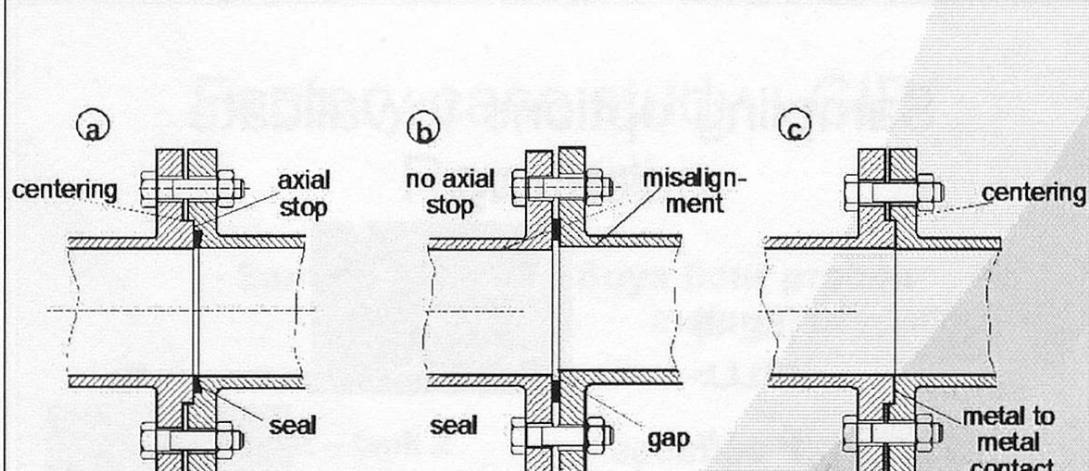
- Crustaceans
- Fish
- Peanuts
- Soybeans
- Nuts
- Sulphur dioxide
>10mg/kg (EU)



- Lupin (EU)



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Examples of static flange seals for dry products:

a) hygienically designed seal usable for wet cleaning.

b) seal creating a gap and misalignment.

c) metal-to-metal flange joint (only for dry cleaning)



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Allergens

- The allergenic 'dose' for each allergen has not been defined
- In practical terms, a surface has to be assumed to be allergen free if no residue can be detected by the appropriate immunoassay (ELISA) test specific for the allergenic or marker proteins.
- Can we relate the results from the specific allergen test kit to rapid hygiene tests such as ATP or Protein for design verification practical tests and to allow routine verification?



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Sampling options to validate cleaning

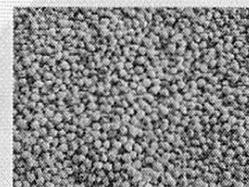
- Rinse/wash waters
- Swabs from surfaces
- 1st product down the line



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Factory case study Drinks - CIP Cleaned

- A production run of soya milk was followed by a run of goat milk, with a CIP clean between. The same raw silos, pasteuriser and filler were used
- Risk: cross-contamination of goat milk with soya
- The factory is segregated into 3 areas
 -  - Raw tanks
 - - Pasteurisers
 - - Filling area



Factory case study - CIP Raw tanks

Sample	Soya flour protein (mg/l)
Raw goat milk – tank 1	<LLOQ
Raw goat – tank 2	<LLOQ
Raw soya milk	4,700

LLOQ = lower limit of quantification,
2.5 mg/l soya flour protein



Factory case study - CIP Pasteuriser

Sample	Soya flour protein (mg/l)	Coomassie protein (mg/l BSA eq.)
Final rinse water	<LLOQ	1.9
Swab	<LLOQ	2.7
First goats milk	<LLOQ	not tested

Rinse water/swabs taken post soya CIP

Allergen LLOQ = 2.5mg/l soya flour protein for products;

0.25mg/l soya flour protein for swab solutions and rinse waters

Coomassie LLOQ = 1mg bovine serum albumin equivalent/l



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Factory case study - CIP Filling hall

Sample	Soya flour protein (mg/l)	Coomassie protein (mg/l BSA eq.)	Protein (RCU)	ATP (RLU)
Filler nozzle swab	<LLOQ	1.5	195	16

Allergen LLOQ = 0.25mg/l soya flour protein for swab solutions

Coomassie LLOQ = 1mg bovine serum albumin equivalent/l

Hygiene protein negative = 221 relative colour units

Hygiene ATP negative = 14 relative fluorescence units



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Factory case study - CIP Final products

Sample	Soya flour protein (mg/l)
Pasteurised soya milk	>ULOQ
First goat milk off the line	<LLOQ

LLOQ = 2.5 mg/l soya flour protein

ULOQ = 25 mg/l soya flour protein

Soya most difficult product to clean;
therefore assume cleaning OK for all other allergens
ATP/protein tests not always as sensitive



Effect of cleaning fluids on allergen detection

- to determine whether cleaning fluids affect the ability of ELISA tests and a general protein assay to detect allergens/protein
- laboratory based study involving cleaning fluids at different concentrations and their influence on ELISA test kits for detection of milk and a general protein assay



Cleaning fluids tested directly

Test Cleaning fluid (level)	BioKits Casein Assay	Verator [®] Total Milk Allergen	RIDASCREEN [®] β-Lactoglobulin R-Biopharm	Coomassie Plus Bradford™
Neutral detergent Working conc.		NI	NI	
Neutral detergent 1/100 dilution	NI	NI	NI	NI
QAC blend Working conc.		NI		
QAC blend 1/100 dilution	NI	NI	NI	NI
Chlorine tablets Working conc.				NI
Chlorine tablets 1/100 dilution	NI	NI	NI	NI
Sodium hydroxide Working conc.		NI		
Sodium hydroxide 1/100 dilution	NI	NI	NI	NI
Low foam acid Working concentration		NI		NI
Low foam acid 1/100 dilution	NI	NI	NI	NI
Peracetic acid Working concentration		NI		
Peracetic acid 1/100 dilution	NI	NI	NI	NI

= false positive results; NI = no interference

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Cleaning fluids & allergen

Test Cleaning fluid (level)	BioKits Casein Assay	Verator [®] Total Milk	RIDASCREEN [®] β-Lactoglobulin R-Biopharm	Coomassie Plus Bradford™
Neutral detergent Working conc.	NI		NI	NI
Neutral detergent 1/100 dilution	NI			
QAC blend Working conc.				
QAC blend 1/100 dilution	NI		NI	
Chlorine tablets Working conc.	NI			
Chlorine tablets 1/100 dilution	NI			
Sodium hydroxide Working conc.				
Sodium hydroxide 1/100 dilution				NI
Low foaming acid Working conc.				
Low foaming acid 1/100 dilution	NI			NI
Peracetic acid Working conc.				
Peracetic acid 1/100 dilution	NI		NI	

Below expected

Above expected

False negative

Hazard control

- Microorganisms and surface finish
- Microorganisms and cleanability
- Allergens and dead spaces
- Safety (and traceability) of replacement parts



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Retailer requirements

- “Product contact surfaces, including those not in direct contact with food, must be constructed of materials that will not contribute a food safety risk” – SQF (Annex 1: Guidance-premises and equipment construction and design)
- “All materials used for maintenance and repair shall be fit for the intended use” – IFS, Version 5, 2007
- “Certificates of conformity or other evidence shall be available for equipment in direct contact with food to confirm its suitability for use, e.g. Conveyor belts” – BRC, Issue 5, 2008



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Food contact materials

- Regulation (EC) No. 1935/2004 relating to materials and articles intended to come into contact with food
- Covers:- Active and intelligent materials, adhesives, ceramics, cork, rubbers, ion exchange resins, glass, metals and alloys, paper and board, plastics, printing inks, textiles, regenerated cellulose, silicones, varnishes and coatings, waxes and wood.



Progress to date

- 84/500/EEC relating to ceramic articles intended to come into contact with food
- 2002/16/EC relating to the use of certain epoxy derivatives in materials and articles intended to come into contact with food (BADGE, BFDGE, NOGE)
- 93/10/EEC Materials and articles made from regenerated cellulose film and intended to come into contact with food



Progress to date - continued

- 2002/72/EC Plastic materials and articles intended to come into contact with food
- 82/711/EEC Check the migration of the components of plastic materials and articles intended to come into contact with food
- 85/572/EEC List of simulants used to check the migration of the components of plastic materials and articles intended to come into contact with food. Amended as 93/8/EEC and 97/48/EC
- 78/142/EEC relating to materials and articles containing vinyl chloride monomer and intended to come into contact with food
- 80/766/EEC Community analysis method used to officially check the vinyl chloride monomer content of materials and articles intended to come into contact with foods
- 81/432/EEC Community analysis method used to officially check the quantity of vinyl chloride monomer transferred by materials and articles to foods



National regulations

- The list of about 300 monomers in Directive 2002/72/EC does not contain all substances which are currently accepted in one or more Member State. These may be added pending a decision on inclusion e.g. Si No.3817 (1995) on the use of mineral hydrocarbons in the UK



Food materials To do

- Active and intelligent materials, adhesives, ceramics, cork, rubbers, ion exchange resins, glass, metals and alloys, paper and board, plastics, printing inks, textiles, regenerated cellulose, silicones, varnishes and coatings, waxes and wood.
- No GRAS



Other relevant EC legislation

- Directive No. 88/388/EC on flavourings for use in foodstuffs
- Directive No. 94/35/EC on sweeteners for use in foodstuffs
- Directive No. 94/36/EC on colours for use in foodstuffs
- Directive No. 95/2/EC on food additives other than colours and sweeteners



Council of Europe

- Guidelines on Metals and Alloys Used as Food Contact Materials, 2001
- Resolution ResAP(2005)2 Packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs



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FAO/WHO

- Joint FAO/WHO Expert Committee on Food Additives
- Online database – Combined Compendium of Food Additive Specifications
- <http://www.fao.org/ag/agn/jecfa/additives/search.html?lang=en>



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CFR Title 21- Food and Drugs Chapter 1 - Food and Drug Administration

- Part 170 Food additives
- Part 172 Food additives permitted for direct addition to food for human consumption
- Part 173 Secondary direct food additives permitted in food for human consumption
- Part 175 Indirect food additives: Adhesives and components of coatings
- Part 176 Indirect food additives: paper and paperboard components
- Part 177 Indirect food additives: Polymers



CFR Title 21- Food and Drugs Chapter 1 - Food and Drug Administration

- Part 178 Indirect food additives: Adjuvants, production aids and sanitizers
- Part 180 Food additives permitted in food or in contact on an interim basis pending additional study
- Part 182 Substances generally regarded as safe
- Part 184 Direct food substances affirmed as generally regarded as safe
- Part 186 Indirect food substances affirmed as generally regarded as safe
- Part 189 Substances prohibited from use in human food



Traceability

- The traceability of materials must be ensured ... to facilitate control, the recall of defective products, consumer information and the attribution of responsibility
- Identification of the business from which and to which the materials are supplied and how the user, uses them!
- Materials must be identifiable (e.g. by labelling) which allows their traceability



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