13th October 2021

Cleaning Validation for Allergen Control in Food Manufacturing

Welcome to todays webinar

Thank you for attending

We will start soon

Vikan®
ADVANCING HYGIENIC CLEANING

Webinar housekeeping

- The webinar will be recorded.
- The recording and the slides will be sent to you after today.
- The presentation will last about 45 mins
- You are all muted, please ask your questions via the chat box.
- We will answer as many questions as possible during the 15 min Q&A session. Any unanswered questions will be answered by email as soon as possible.
- If you have any technical difficulties please let our Organiser (Mads) know via chat and he will be happy to help.

About Vikan and Remco

Vikan®

- Leading provider of advanced hygiene and cleaning products and solutions for key sectors, with a global presence in over 90 countries.

Remco
a Vikan company

- Supplies color-coded sanitation and material handling tools for the food industry in North America.

For further information, visit us at:

https://www.vikan.com/uk/#

http://www.remcoproducts.com/about

About our presenter

- From Jan 2021, Principal Corporate Scientist:-Food Safety and Public Health, for the Kersia Group, France
- Honorary Professor of Food Safety, Cardiff Metropolitan University, Wales
- From April 2014, Technical Director for Holchem Laboratories in Bury, UK
- Previously Head of Food Hygiene at Campden BRI in the Cotswolds, UK, for >25 years
- Working in food safety with the food industry in >500 factories in 6 continents
- Supporter of the EHEDG, IAFP and GFSI
- Friend and colleague for 20 years

Cleaning Validation for Allergen Control in Food Manufacturing

Dr. John Holah, Principal Corporate Scientist - Food Safety & Public Health, Kersia Group

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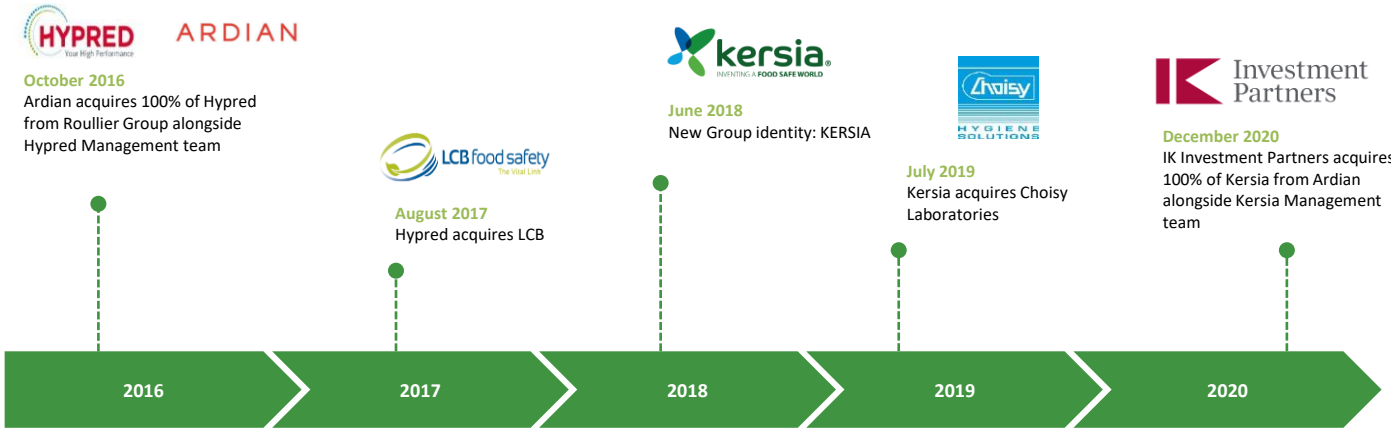
Kersia - history

c€375m	>120	30	>10,000	>1,700	>700	>3,000
2020e PF Sales	Countries where we sell	Industrial Sites worldwide *o/w 23 owned o/w 7 sub-contracted*	Active customers	FTEs worldwide	# rep sales worldwide	Active registrations



Global pure player specialised in biosecurity and food safety

Allergens

- Second most important hazard in food manufacturing after microbial pathogens
- Most frequent subject of public recalls
  - Wrong labelling – undeclared allergen
  - Incorrect recipe – wrong ingredient
  - Ingredient adulteration – unknown ingredient
  - Cross-contamination – no cleaning
  - Cross-contamination - ineffective cleaning
- Influence of Vegan – UK's fastest growing food sector

ALLERGY ALERT

Graze recalls Sea Salt & Vinegar Veg Crunchers because it is labelled vegan and contains milk

6 March 2019

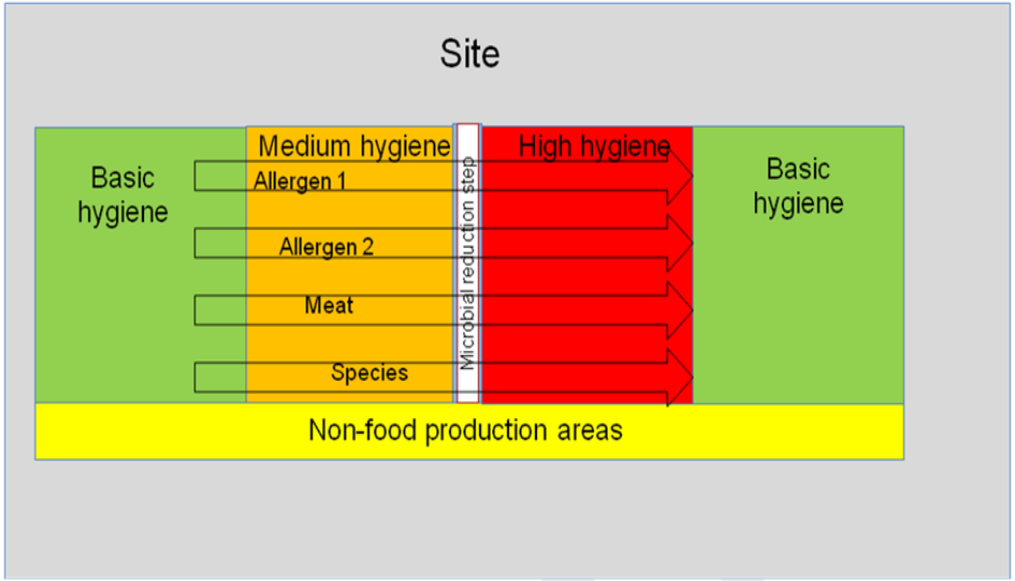
View PDF Print this page Share

Graze is recalling Sea Salt & Vinegar Veg Crunchers because it has been incorrectly labelled as suitable for vegans, however the product contains milk. This means the product is a possible health risk for anyone with an allergy or intolerance to milk or milk constituents.

Allergen control hierarchy

1. Separate factories
2. Segregated areas
3. Segregation by time and cleaning

   Cleaning is thus the major control to ensure that allergens are removed from the processing line and environment prior to the production of allergen-free products



Ref: EHEDG Guidance Document 44
Hygienic design of food factories

Cleaning knowns and unknowns

Innovate UK
Knowledge Transfer Network

Manchester Metropolitan University

- Cleaning geared to specific soil removal – the cleaner the surface the less the hazards present
- Caustic chlorinated products are best for protein removal (e.g. blood) - should we treat allergens differently to other proteins?
- No specific agents to remove allergens – would we adopt a second cleaning phase?
- Can we optimise allergen removal - what can we practically achieve as a cleaning target (the equivalent for a 6 log reduction of pathogens)?
- Is it possible to make residues non-allergenic?

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Definitions

Validation

- Generic - evidence of capability – the designed cleaning and disinfection programme is fit for purpose.

  (Codex Alimentarius) Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling a hazard to a specified outcome

  Once the cleaning process has been validated, it is routinely applied and monitored and verified:

Monitoring

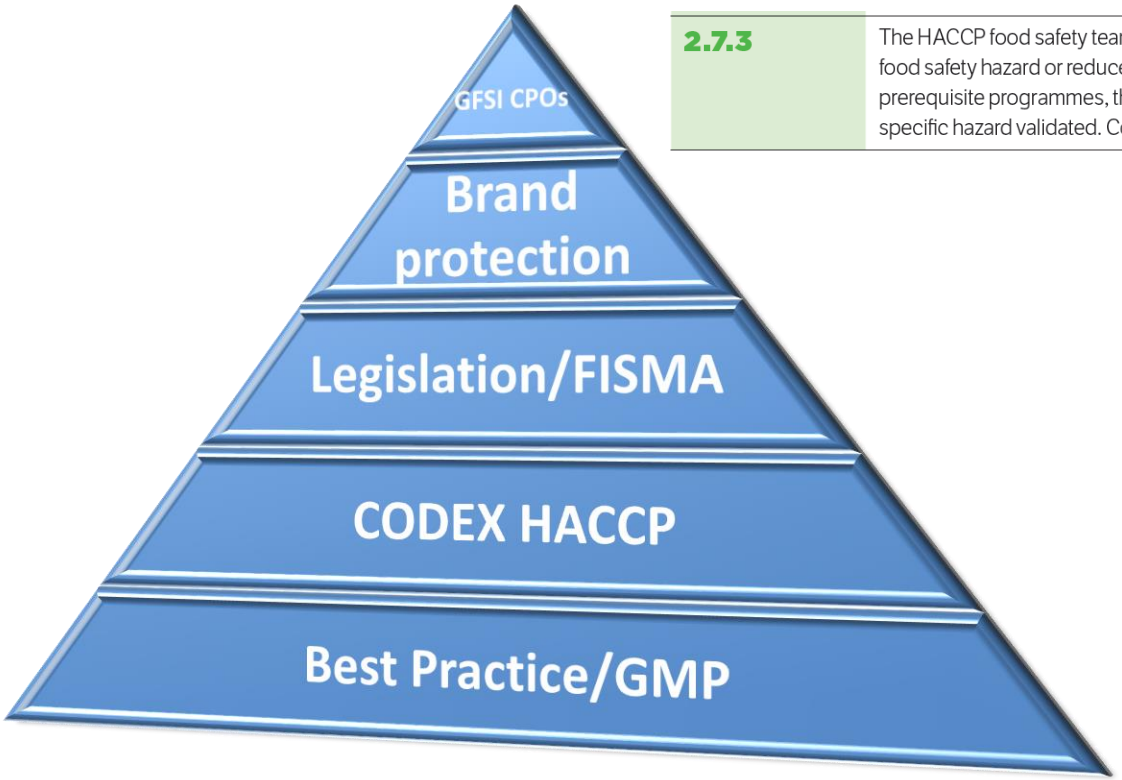
- Planned process assessment relative to real-time control (observations and measurements) assesses hazard control measures

Verification

- Determination of compliance – the cleaning and disinfection programme is/has been routinely working by producing objective evidence

Why validate, monitor, verify, record

Why validate, monitor, verify, record



2.7.3	The HACCP food safety team shall consider the control measures necessary to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Where the control is achieved through existing prerequisite programmes, this shall be stated and the adequacy of the programme to control the specific hazard validated. Consideration may be given to using more than one control measure.

BRC GLOBAL STANDARD FOR FOOD SAFETY

BRC Global Standard Issue 8

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Why validate, monitor, verify, record

Validation is the responsibility of the food producer (through guidance from the equipment manufacturer, chemical supplier, cleaning contractor)

Reason for cleaning	Cleaning objective	Validation recommended	Monitoring and verification recommended
Provide a safe working environment (housekeeping)	Visual cleanliness	Basic	Infrequent
Undertake a clean-as-you-go for GHP/GMP	Visual cleanliness	Basic	Infrequent
Extend the life of, and prevent damage to equipment and services	Visual cleanliness	Basic	Infrequent
Maintain plant operating parameters (heat transfer/ flow)	Visual cleanliness	Basic	Frequent
Remove materials that could lead to foreign body contamination	Visual cleanliness	Basic	Frequent
Remove food soils that would be detrimental to organoleptic quality	Visual cleanliness	Basic	Frequent
Remove DNA to prevent species cross-contamination	Visual cleanliness DNA	Enhanced Optional	Every clean
Remove spoilage microorganisms	Visual cleanliness freedom of spoilage microorganisms	Enhanced Optional	Every clean
Remove cleaning chemical residues (MRL)	Visual cleanliness freedom of chemical residues	Enhanced	Every clean
Remove allergens	Visual cleanliness freedom of allergens	Enhanced	Every clean
Remove pathogens	Visual cleanliness freedom of pathogens	Enhanced	Every clean

Basic and enhanced

Prerequisite

Operational Prerequisite

Preventative controls

Simple sign-off

Cleaning validation report

Validation Procedure Steps

For a given area, cleaning and disinfection programme and hazard, to ensure that the hazard is always controlled under the worst case conditions of hygienic design, process, product hazard concentration, soiling and cleaning performance

Reduce time and costs

https://www.ehedg.org/guidelines/
(Guideline No. 45)

Validation prerequisites

- 1: Validation prerequisites
  - 1.0 Develop a validation team
  - 1.1 Validation scope/hazard evaluation
  - 1.2 Cleaning acceptance criteria
  - 1.3 Equipment qualification
  - 1.4 Cleaning qualification
  - 1.5 Sampling techniques
  - 1.6 Analytical methods
  - 1.7 Soiling

- Senior management support
- Similar to a HACCP team
- Production, engineering, technical, hygiene, hazard specialist (microbiologist, chemist), consultant
- Scribe

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- Processing area
- Cleaning type
  - Interim, end-of-production, periodic, (not decontamination), fogging
- Allergen Cross-contamination-vectors
  - Surface cleaning – line, equipment, utensils, containers
  - Tray washers, Tote washers, operatives hands/gloves, PPE, laundry
- Cleaning cross-contamination-vectors
  - Cleaning aerosols
  - Cleaning equipment and cleaning solutions

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Validation prerequisites

- Visual cleanliness
- Freedom of allergen below analysis quantification/detection limit in subsequent product (most sensitive technique – traditionally ELISA)
- Freedom of allergen below analysis quantification/detection limit on food contact surfaces (sensitive but practical – factory based, Lateral Flow Devices (LFD))
- Routine hygiene monitors e.g. ATP, protein (if used routinely in lieu of LFD)

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Hygienic design

- ISO 14159 Safety of machinery. Hygiene requirements for the design of machinery
- EN 1672-2 Food processing machinery. Basic concepts. Hygiene requirements
- 3-A, EHEDG
- NSF, GMA, NAMI……

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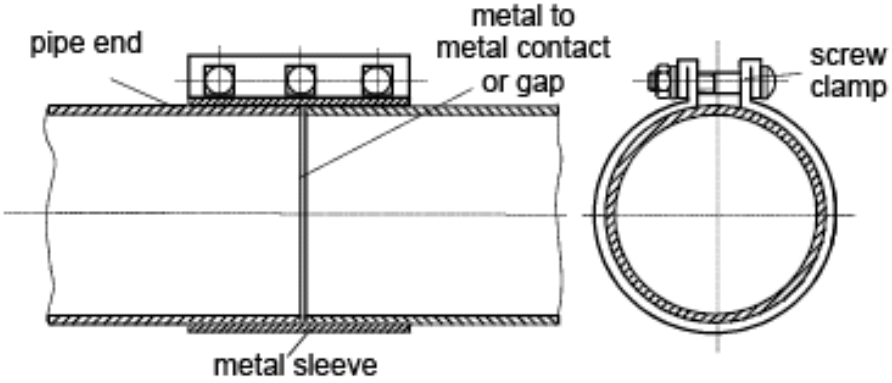
Equipment qualification



- Assessment of the hygienic design of the equipment to be cleaned – essentially, is it cleanable (crevices, dead area, drainability)
- Define the hardest part(s) of the process line to clean
- Equipment ancillaries – lubricants, seals, gaskets
- Determine how to access unhygienic features e.g. by dismantling
- Determine how to access and sample safely (isolation, guarding, platforms, PPE)

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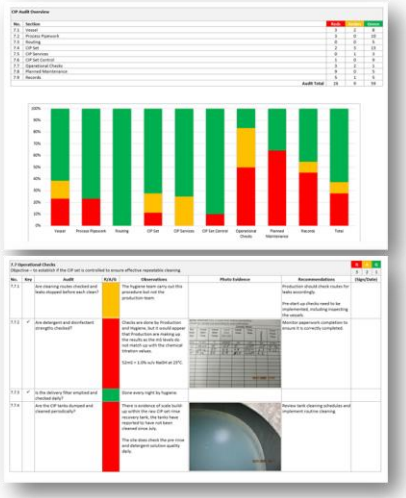
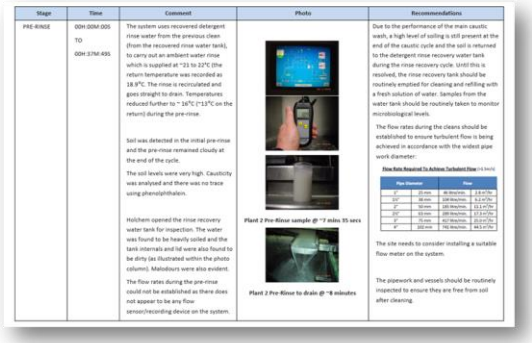
- Develop method
- Draft SOP/CIC
- Audit/advice





Cleaning qualification

- Is the proposed cleaning action appropriate for the process environment and the types of soils present so as to achieve the desired cleaning objective – does it work!
  - What is the minimal cleaning window and number of operatives
  - What is the acceptable detergent and concentration (e.g. 3-5%)
  - What is the application method
  - What is the application equipment
  - What is the acceptable range of rinse/detergent temperatures
  - What is the acceptable range of pressures, flow rates, cleaning times etc.

- Calibrate all cleaning measurement parameters
- Validate at the lowest acceptable cleaning parameters

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- Visual assessment
  - If not clean – stop!
- Beyond visible cleanliness
  - Direct sampling
    - Swabs, wipes/sponges
  - Indirect sampling
    - Flushes, final rinses
- Rapid swab tests
  - ATP, Protein, Lactose or Glucose
  - LFT

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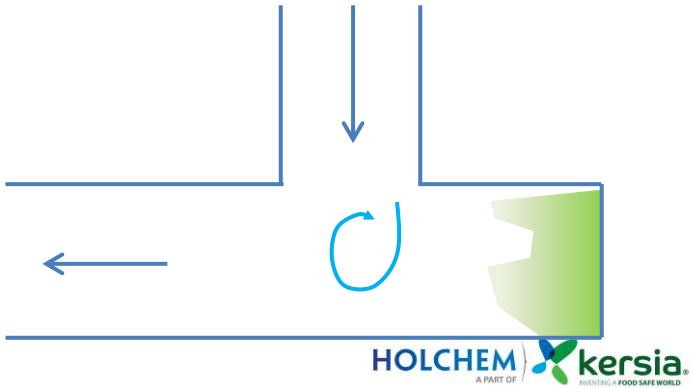
Sampling techniques - product

Methods of sampling (by trained/competent staff)

- Product (in general)
  - Open – first product down the line
  - Closed – first, middle and final product down the line
- Relate validation scope surface/equipment to product, e.g. bread in a sandwich



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- Specific, sensitive, representative, reproducible
- Qualitative/quantitative (for allergens)
  - ELISA, DNA, Mass spectroscopy for validation
  - Lateral flow devices for verification
- Positive controls – e.g. allergen in allergen containing product and on process surfaces during the manufacture of such product
- Effect of cleaning/disinfectant residues (on allergen and hygiene tests)

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Allergen inoculated cleaning chemicals

Test / Cleaning fluid (level)	Kit a	Kit b	Kit c	Kit d
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.	NI			
Peracetic acid 1/100 dilution	NI		NI	

Below expected Above expected False negative NI No impact

Campden BRI
food and drink innovation

Validation of cleaning to remove allergens
Campden Guideline no.59

Test after detergent rinse

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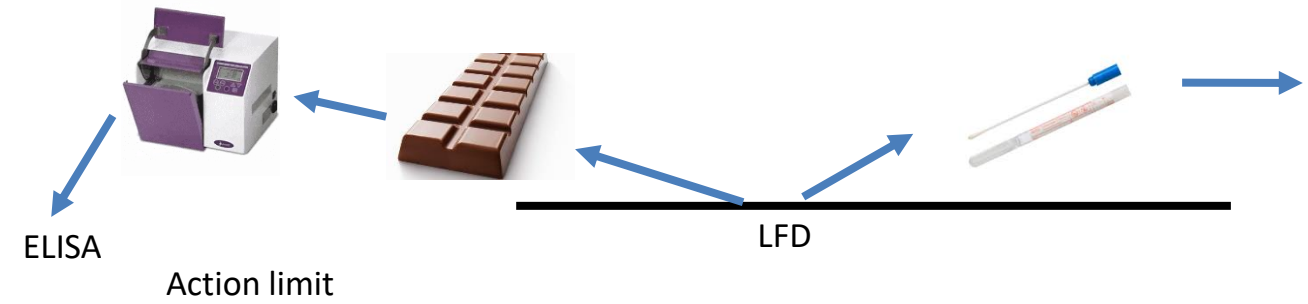
Objectives and limits of detection

Objective	Desired in Product	Detected in Product	Desired on a Surface	Detected on a surface
<Vital Action Limit mg/kg (4ppm for peanut in a 50g chocolate bar)	<ppm (mg/kg, µg/g)	1-40 (0.1) ppm (ELISA peanut)	µg/ml (g) (swabbed size)	1 µg/25cm^2 (LFD peanut)

To cross-contaminate from the surface to the food there is a transfer coefficient (not all allergen present on the surface will transfer to the food) and a dilution factor (the whole food portion is macerated as part of the allergen detection test and a small subset of the macerated sample is actually analysed). For the swab there is also a transfer coefficient, but the swab suspension fluid is directly sampled.



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- Influence of product
  - Strongest adhering soil
  - Highest level of allergen
  - Most significant allergen
  - Most likely subsequent allergen free product to pick up an allergen
- Influence of process
  - Longest process time
  - Highest temperature
  - Product scheduling
  - Time before cleaning
- Determine soiling worst-case scenario

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Validation Procedure Steps

Prospective validation – (Steps 1-5)

Evidence of capability under expected, worst case scenarios.

Experimental approach for new processes

Concurrent validation – (Steps 1-5)

Evidence of capability under current, worst case scenarios.

Experimental approach for existing processes

Retrospective validation – (Steps 1, 4, 5)

Evidence of capability from existing, historical data

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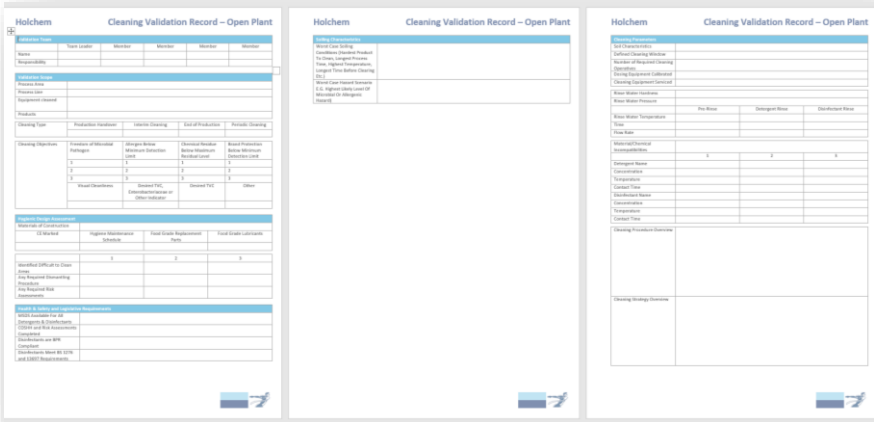
Validation protocol



- Scope, Objective, Responsibilities
- Identification of the equipment, process line
- Hygienic design assessment
- Worst case scenarios
- (Draft) CIC/SOP
- Number of cleaning cycles to be performed (3 min?)
- Sampling points, procedures and analytical methods
- Sign-off sheet for parameters and procedure compliance

Template example

Validation Procedure Steps

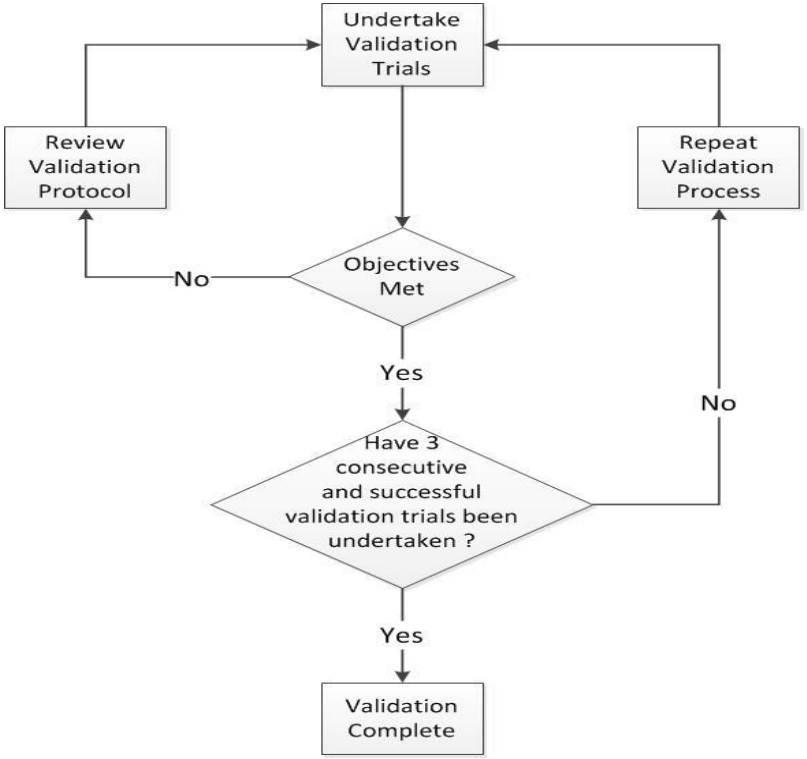
1: Validation prerequisites

2: Cleaning validation protocol

3: Cleaning validation process

4: Cleaning validation report

5: Validation review



- Clean quality
- Evidence

Validation Procedure Steps

1: Validation prerequisites

2: Cleaning validation protocol

3: Cleaning validation process

4: Cleaning validation report

5: Validation review

- Date of validation and persons involved
- Cleaning and disinfection programme (SOP/CIC)
  - Sign-off sheets/photos/records (reviewed by technical)
  - Cleaning measurements (times, temps, conc., flow etc.)
- Deviations and corrective actions
- Target setting (critical points for monitoring and verification)
- Develop as cleaning KPI's – e.g. average ATP result plus a comfort factor, dependent on data variability (e.g. 3 times standard deviation)

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Cleaning validation report – CIP Example

CIP Validation

ABC

Tank 4

Cleaning validation is undertaken to demonstrate that a cleaning and disinfection programme has been designed to meet the objective of the clean and that that when undertaken correctly, meets these objectives. It is thus proof, based on physical testing, that the designed cleaning and disinfection programme works.

The objectives of a cleaning and disinfection programme can be threefold-

- To control a hazard such as a pathogen or an allergen
- To control a brand protection issue such as the presence of meat in a product labelled suitable for vegetarians
- To prevent quality and organoleptic issues in subsequent products e.g. the presence of previous products, colours or taints, or to promote process control or safety e.g. prevent fouling of heat exchanges.

Cleaning validation is not directly a legal requirement but is seen as food manufacturing best practice.

Validation must be undertaken on a minimum of three occasions
Consideration should be given to the timings of the three validation runs, including:

- New equipment
- Seasonal influences
- Production influences
- Scheduling influences

Validation Team					
	Team Leader	Member	Member	Member	Member
Name	Rose Wild	Lily Green	Daisy Brown	Poppy Smith	
Responsibility	Technical Mgr	QA	Engineering	Production Mgr	

Validation Approval	
Name	James McDougal
Job Title	Site Manager
Date	20th February 2014
Signature	J McDougal

Background Information			
Validation Scope		**Cleaning Type (tick as appropriate)**	
Process Area	High Care		Production Handover
Process Line	Main Production Hall		Interim Cleaning
Equipment	Tank 4	✓	End of Production
Products	Soups / Sauces		Periodic Cleaning
Soiling Characteristics (tick as appropriate)		**Hygienic Design Assessment (tick as appropriate)**	
✓	Hardest Soiling / Product to Clean	✓	CE Marked
	Longest Process Time	✓	Suitable Materials of Construction
	Highest Temperature Processing	✓	Food Grade Replacement Parts
	Longest Time Before CIP Commences	✓	Food Grade Lubricants
Hazard (tick as appropriate)		✓	Hygiene Maintenance Schedule
✓	Microbial	✓	Shadow Zones Present
	Allergenic	✓	Spray device suitable (if applicable)
	Chemical	**CIP Set (tick as appropriate)**	
	Brand Protection (DNA)	✓	Instrumentation Calibrated
CIP Set		✓	Pumps / Valves Serviced
CIP Set	Gamma Set		Turbulent Flow Achievable (if applicable)
Programme Name	Tank 4 – Caustic / Acid		
Max Pipe Diameter	N/A	**Legislative Requirements (tick as appropriate)**	
Water Hardness	250ppm	✓	BPR Compliant
Health & Safety Requirements (tick as appropriate)		✓	Disinfectant - BS EN1276
✓	MSDS Available	✓	Disinfectant - BS EN13697
✓	COSHH		
✓	Risk Assessments		

Cleaning Parameters					
Stage	**Parameter**	**Set Point**	**09/01/14**	**18/01/14**	**11/02/14**
Pre Rinse	Time	330s	280s	280s	280s
	Temperature	Ambient	24°C	21°C	22°C
	Flow Rate	8,000 l/hr	7,800 l/hr	7,800 l/hr	7,800 l/hr
Detergent - Caustak	Time	1250s	1650s	1240s	1280s
	Temperature	68°C	70°C	71°C	68°C
	Flow Rate	8,000l/hr	7,800 l/hr	7,800 l/hr	7,800 l/hr
	Chemical Strength	38 - 42mS	42mS	40mS	44mS
Inter Rinse	Time	300s	300s	310s	305s
	Temperature	Ambient	22°C	21°C	20°C
	Flow Rate	8,000l/hr	7,800 l/hr	7,800 l/hr	7,800 l/hr
Acid Cycle - Nivac	Time	1250s	1250s	1200s	1280s
	Temperature	Ambient	22°C	21°C	20°C
	Flow Rate	8,000l/hr	7,801 l/hr	7,800 l/hr	7,800 l/hr
	Chemical Strength	3 - 4% v/v	3.2%	3.0%	3.3%
Final Rinse	Time	300s	300s	305s	310s
	Temperature	Ambient	22°C	23°C	20°C
	Flow Rate	8,000l/hr	7,800 l/hr	7,800 l/hr	7,800 l/hr
Disinfectant - Perbac	Time	300s	310s	300s	288s
	Temperature	Ambient	22°C	21°C	19°C
	Flow Rate	8,000l/hr	7,800 l/hr	7,800 l/hr	7,800 l/hr
	Chemical Strength	250 ppm	200ppm	220ppm	250ppm
		Start Time	14:02	14:15	14:08
		End Time	15:10	15:22	15:12
		Total Time	68m	67m	64m

Surface Swab Testing						
Tank Internals	**Test**		**Limits**	**09/01/14**	**18/01/14**	**11/02/14**
	TVC	✓	X cfu/cm²	< X cfu/cm²	< X cfu/cm²	< X cfu/cm²
	Entrobacteriaceae	✓	X cfu/cm²	< X cfu/cm²	< X cfu/cm²	< X cfu/cm²
	Allergen					
	ATP	✓	< X rlu	X rlu	X rlu	X rlu
	DNA					
	<Other>					
Paddle Undersides	**Test**		**Limits**			
	TVC	✓	X cfu/cm²	< X cfu/cm²	< X cfu/cm²	< X cfu/cm²
	Entrobacteriaceae	✓	X cfu/cm²	< X cfu/cm²	< X cfu/cm²	< X cfu/cm²
	Allergen					
	ATP	✓	< X rlu	X rlu	X rlu	X rlu
	DNA					
	<Other>					
Outfeed Valve	**Test**		**Limits**			
	TVC	✓	X cfu/cm²	< X cfu/cm²	< X cfu/cm²	< X cfu/cm²
	Entrobacteriaceae	✓	X cfu/cm²	< X cfu/cm²	< X cfu/cm²	< X cfu/cm²
	Allergen					
	ATP	✓	< X rlu	X rlu	X rlu	X rlu
	DNA					
	<Other>					
Outfeed Pipe	**Test**		**Limits**			
	TVC	✓	X cfu/cm²	< X cfu/cm²	< X cfu/cm²	< X cfu/cm²
	Entrobacteriaceae	✓	X cfu/cm²	< X cfu/cm²	< X cfu/cm²	< X cfu/cm²
	Allergen					
	ATP	✓	< X rlu	X rlu	X rlu	X rlu
	DNA					
	<Other>					

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Allergen interpretation

No allergen in product

Essential for a pass

No allergen on a surface by lab. ELISA
No allergen on a surface by LFD

Pass

Allergen in product

Re-design cleaning programme

If not possible, risk assess product.
May choose to use ‘may contain’ label

Allergen on a surface by lab. ELISA
No allergen on a surface by LFD

Risk assess

Allergen on a surface by LFD
Re-design cleaning programme

May choose to use ‘may contain’ label

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Maintaining validated state

- Monitor
  - Visual cleanliness sign-off sheets
  - ATP, protein
  - Lateral flow strips
- Verification
  - 1st, 2nd, 3rd party audits
  - Operative training records
- Records

Hazard (e.g. allergen)/hygiene method correlation

1. ATP positive, allergen negative - OK
2. ATP negative, allergen negative – possible OK
3. ATP negative, allergen detected – cannot use ATP to validate allergen clean

Validation Procedure Steps

1: Validation prerequisites

2: Cleaning validation protocol

3: Cleaning validation process

4: Establishing the cleaning validation report

5: Validation review

- Periodic review to reflect slow changes in process and equipment – e.g. equipment surface wear. At least biannually
- To fit in with HACCP/prerequisite management schedules
- Following any change in:-
  - Ingredients
  - Product
  - Process
  - Equipment
  - CIP programme deviations
  - Routine/Increased KPI failure (negative quality or safety trends)
  - Cleaning and disinfection SOP
  - Process line shut-down and overhaul
  - New knowledge or legislation (e.g. allergen thresholds)

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L4 Validation VT 2021

Shop / Training Courses 2021 / L4 Validation VT / L4 Validation VT 2021

£ 150.00 £

Date Venue	Quantity	Code
27 Apr/Virtual	1	

This course has elapsed please continue to **register** your interest in this course and we will make contact to discuss your training requirements and future course availability.

Description

COURSE RUN ON MICROSOFT® TEAMS

Due to the current Coronavirus pandemic and the restrictions on unnecessary travel and social distancing, we are pleased to be able to offer this Level 4 – Validation training via Microsoft Teams.

WHO SHOULD ATTEND

The course gives detailed and practical training for Technical Teams and Hygiene Managers and Supervisors who are directly involved with the validation and verification of open plant and cleaning in place regimes within food and drinks manufacturing environments.

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Further hygiene/food safety support

https://www.vikan.com/uk/knowledge-centre/

https://www.remcoproducts.com/knowledge-centre/

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