Process Validation to Meet FSMA Regulations Part 3: Validation Report

Moderator: Laure Pujol, Novolyze, France

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International Association for Food Protection WEBINAR

Webinar Housekeeping

- It is important to note that all opinions and statements are those of the individual making the presentation and not necessarily the opinion or view of IAFP.

- Questions should be submitted to the presenters during the presentation via the Questions section at the right of the screen. Questions will be answered at the end of the presentations.

- This webinar is being recorded and will be available for access by IAFP members at www.foodprotection.org within one week.

Today's Participants

Laure Pujol, Novolyze, France

Laure Pujol is a Food Safety and Quality Expert at Novolyze.
She has a PhD in Predictive Microbiology and Risk Assessment from ONIRIS & INRA in Nantes, France and a Food Engineering Diploma.
As a Preventive Control Qualified Individual (PCQI) and a process authority recognized by the Technical Expert Review Panel (TERP) and Almond Board of California (ABC), Laure is very experienced working with low water activity foods and has performed in-plant validation trials around the world.
She is an active member of the PDG Low Water Activity Food at IAFP and is part of the ASTA Validation Task Force. She organized symposium at the IAFP EU and participate to several scientific conferences helping food processor managing their food safety and quality issues.

Anett Winkler
Cargill, Germany

Anett Winkler joined Kraft Jacobs Suchard in December 1998 to head up the research microbiology laboratory in Munich. Later on Anett concentrated on chocolate, biscuits and other low moisture foods including supplier developments and approvals. She also consolidated the scientific basis for microbiological process controls in low moisture foods by performing validation studies for nut & cocoa processing. Following a regional role for Microbiology in the Eastern European, Middle East & African Region she was globally designing food safety programs, rolling out training modules related to food safety and further supporting supplier development. Anett was also the global expert for thermal processing within Mondelez International.
In October 2017 Anett moved to a new position as "EMEA Regional Food Microbiologist Lead" at Cargill, where she is supporting all Cargill businesses in that region (Europe / Middle East / Africa) for microbiological / food safety related topics.
Anett is also active in ILSI Europe (Microbiology Food Safety), and IAFP being the current committee Chair for the IAFP European Symposium. Since 2020 she is co-editor for the German handbook on Food hygiene.

Today’s Participants

Michiel Kokken

Michiel Kokken,
Olam Food Ingredients The Netherlands

Michiel Kokken holds a Master in Food Science at Wageningen University and joined ADM Cocoa in June 2006 occupying various roles in process engineering, laboratory management, quality management before joining the senior quality management team overseeing quality and food safety management for Europe and global project lead for quality and food safety related projects. Most recently Michiel took on the role of scientific and regulatory affairs for the cocoa product category within Olam Cocoa. Part of this role is also best practices with regards to compliance and food safety programs within the plants as well as in the supply chain. One of the programs which he manages in this regard is the global validation program for kill step across the cocoa processing plants.

Challenges in Process Validations- Validation Report

Dr. Anett Winkler

IAFP Webinar

December 01, 2021

www.cargill.com

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Validation – What does it mean?

Obtaining and evaluating scientific and technical evidence

that a control measure, combination of control measures, or the food safety plan as a whole,

when properly implemented,

is capable of effectively controlling the identified hazards.

Validation Report

Shall include (or reference)

- All team members and their qualification
- Target pathogens and target log reductions (include Hazard Analysis)
- Process description (line, process step equipment, process capability, sensor calibration)
- Product Description (product groups recipe variabilities)
- Experimental Design (sample / inoculum preparation, transport, introduction and retrieval from process, laboratory and methods)
- Study Results (log reductions achieved under which process conditions)
- Conclusions (final outcome, summary, recommendations / design of future monitoring / alarms / corrective actions)

The report shall be available at the site(s) as part of their Food Safety Management.

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Validation Report

Shall include (or reference)

- All team members and their qualification

„Process Authority“

Many firms utilize **in-house experts for process establishment**. FDA does not have any formal means of evaluating or accepting PA’s or their competency.

For both LACF and FSMA based regulations, qualified individuals must complete standardized training (BPCS for LACF; FSPCA for FSMA regulated products). FSPCA also permits one to be a qualified individual if they are “otherwise qualified through job experience…”.

IFTPS (Institute for Thermal Processing Specialists) Definition:
An **individual, or group, expert in the development, implementation and evaluation of thermal and/or aseptic processes**. The areas of competency listed below provide a functional description of areas of practice, but are by no means inclusive or exclusive:…

ABC recognized process authorities: process_authorities.pdf (almonds.com) – for almonds only

Food Processing Authorities Directory – Association of Food and Drug Officials (afdo.org)

Note: List not exhaustive, only listing externals, but not recognized thermal process authorities within companies – pay attention to field of expertise !!

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Validation Report

Shall include (or reference)

- ➢ Target pathogens and target log reductions (include Hazard Analysis)

Common Issues in Validations

☹ Inappropriate target pathogen for validated products / process

☹ log reduction not defined during experimental design

How do you identify your target pathogen(s)?

Target Pathogen(s) – BE SPECIFIC !!!

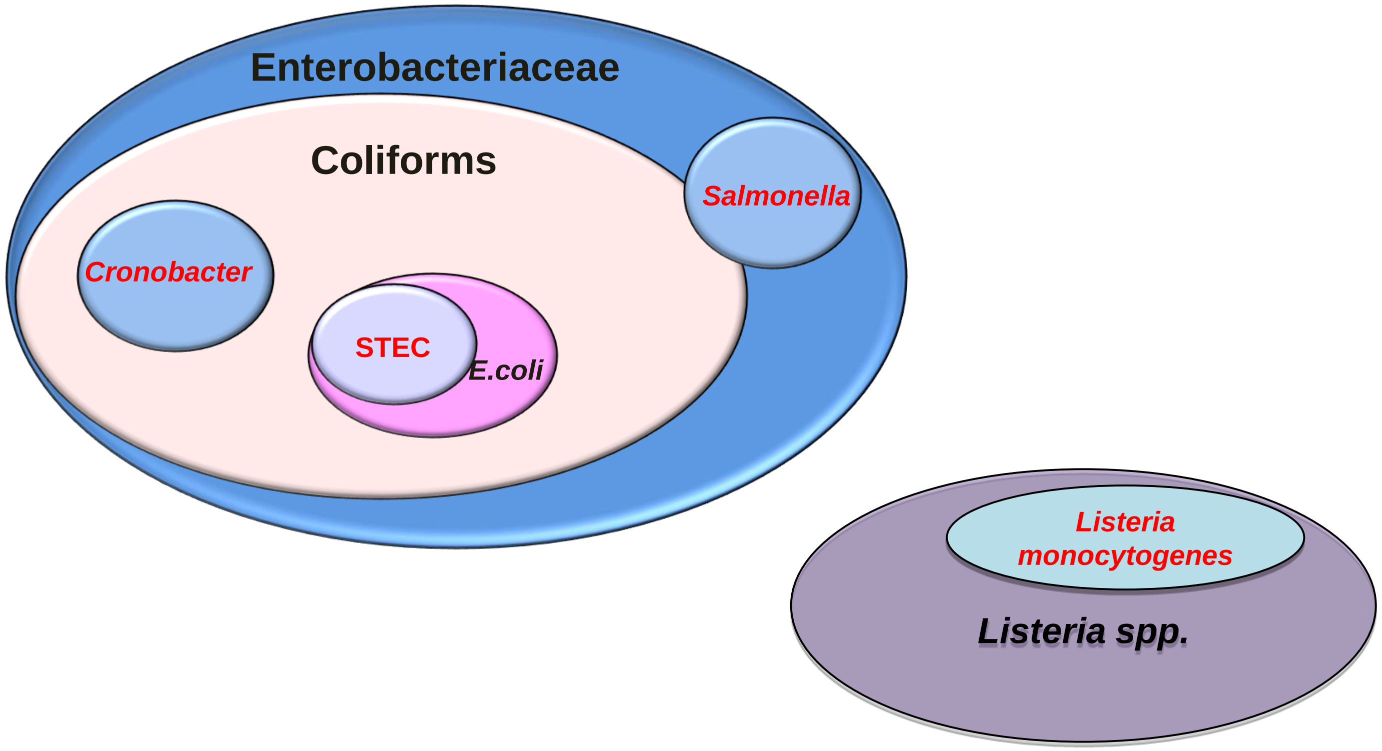
- HACCP Study – hazard analysis (also consider intended use)
- Epidemiological information
- Surveys, published literature (on prevalence, occurrence)

TABLE 5 Levels of *Salmonella* in positive samples of some types of naturally contaminated low water activity foods

Product	Where collected	Sample size (g)	*Salmonella* levels (MPN/g)	References
Nut				
Almond, raw kernel	Processor receiving, California	100 g × 1 and 3 each: 25 g, 2.5 g, 0.25 g	96 samples: 0.0044 to 0.15; four samples: 0.00080, 0.00080, 0.00095, 0.0034; 10 samples: 0.002 to 0.032	Bansal et al., 2010; Danyluk et al., 2007; Lambertini et al., 2012), Harris, unpubl. (2013 data)
Brazil nut	Retail, UK	10 g × 10	Two samples: 0.23, 0.09	Little et al., 2010

Source: Ceylan et al, 2021

How do you identify your target pathogen(s)?



How many log reductions are sufficient to control the biological hazard ??

Look at

- Prevalence rates and quantitative levels at initial stage
- Exposure assessments
  (including infective / harmful dosage, consumption pattern)

Commodity	Process	Target organism	Process parameter/criteria	Performance criterion	References
Meat and meat products					
Fermented dry sausage containing beef	Any validated process	*Escherichia coli* O157:H7	ND	5-log	USDA, 2001
Cooked beef, roast beef, and cooked corned beef products[f, g]	Lethality process which must include a cooking step	*Salmonella*	Shorter holding times for temperatures ≥146°F (63.3°C). For example, 85 or 91 s at 149°F (65°C) or equivalent. Longer holding times apply for temperatures ≤145°F (62.8°C). For example, 23 to 24 min at 137°F (58.4°C) or equivalent. Inactivation target is considered to be reached instantly at temperatures ≥158°F (70°C).	6.5- or 7.0-log reduction	Code of Federal Regulations, 2009b, Chapter III. Subchapter A. Part 318. Subpart A: Entry into Official Establishments; Reinspections and Preparation of Products. Section 318.17; FSIS, 2017
Meat and poultry jerky[h]	Heating process	*Salmonella*, *E. coli* O157:H7 for products containing beef	ND	5-log reduction	FSIS, 2014

Source: Ceylan et al, 2021

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„Safe Harbors“

- **Low-Acid canned food regulations / guidelines:** “12D *Clostridium botulinum* cook”, FDA 21 CFR 108 (USA)
- **Milk Pasteurization**: Codex Alimentarius (CAC/RCP 57-2004) CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS „The application of heat to milk and liquid milk products aimed at reducing the number of any pathogenic micro-organisms to a level at which they do not constitute a significant health hazard.” „As *C. burnettii* is the most heat-resistant non-sporulating pathogen likely to be present in milk, pasteurization is designed to achieve at least a 5 log reduction of C. *burnettii* in whole milk (4% milkfat).”
- **Almond Processing** (USA): 7 CFR 981.442 USDA (minimum 4-log reduction of *Salmonella* bacteria in almonds)
- **Nuts Processing** (USA): GMA “ Industry Handbook for the Safe Processing of Nuts” (recommendations for a 5 log reduction of *Salmonella* bacteria on nuts)
- **Juice Processing** (USA): Guidance for Industry: Juice HACCP Hazards and Controls Guidance (The 5-log pathogen reduction requirement in 21 CFR 120.24.)
- **Egg Processing**: International Egg Pasteurisation Manual
- **Meat Processing**: USA - FSIS 64 FR 732, UK – ACMSF

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Further Literature

Issues To Consider When Setting Intervention Targets with Limited Data for Low-Moisture Food Commodities:
A Peanut Case Study

(Schaffner et al.; 2013; JFP 76(2): 360-369)

compare various assumptions about prevalence and concentration and how they are combined. The discussions made clear that data and risk models developed for other low-moisture foods like almonds and pistachios may be applicable to peanuts. Workshop participants were comfortable with the use of a 5-log reduction for controlling risk in products like peanuts when the level of contamination of the raw ingredients is low (<1 CFU/g) and the process well controlled, even when limited data are available. The relevant stakeholders from the food safety community may eventually conclude that as additional data,

generally supportive of the effectiveness of a 5-log reduction, based on both a consideration of microbiological risk assessment concepts and the past use of such a requirement to protect public health.

Validation Report

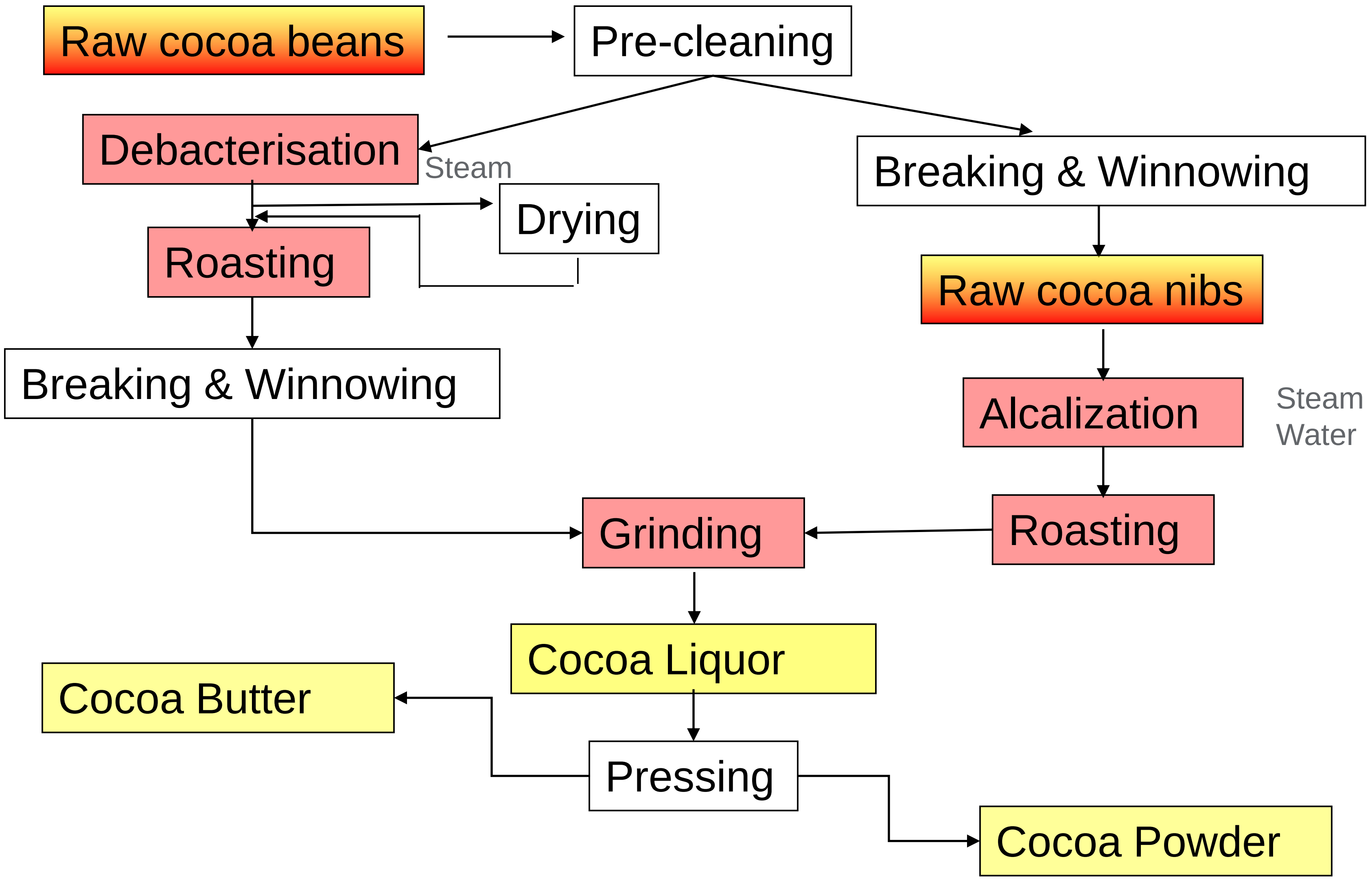
Shall include (or reference)

- Process description (line, process step equipment, process capability, sensor calibration)

Common Issues in Validations

☹ Process information not complete
☹ Process variabilities not considered
☹ Validation conditions / equipment / process not described in validation report
☹ “Worst-case” scenarios missed

Choosing a control measure…Cocoa Production



Process related facts

Is it…

Described: relevant critical parameters described and values / limits described

Controlled: Limits are met – confirmed by monitoring and verification activities
corrections / corrective actions defined and followed

Reproducible: Trend Analysis shows no drift

Examples of parameters to be considered:

- Moisture (Steam, Water additions)
- Time (Speed, Type of material flow – laminar – turbulent)
- Temperature (even distribution / cold spots)
- Pressure / Gas / Irradiation
- Weight and potential others (instrument specific)

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„exact same process and product“

Cooking ≠ Dry Roasting – different critical parameters

Heat ≠ Other technologies – different target microorganisms

Batch ≠ Continuous process – start-up, end of run, ingoing material

Feed meal ≠ cocoa husks

Validation Report

Shall include (or reference)

- ➢ Product Description (product groups recipe variabilities)

Common Issues in Validations

☹Validation product not described in validation report (variability of physical / chemical characteristics)

☹ "Worst-case" scenarios missed

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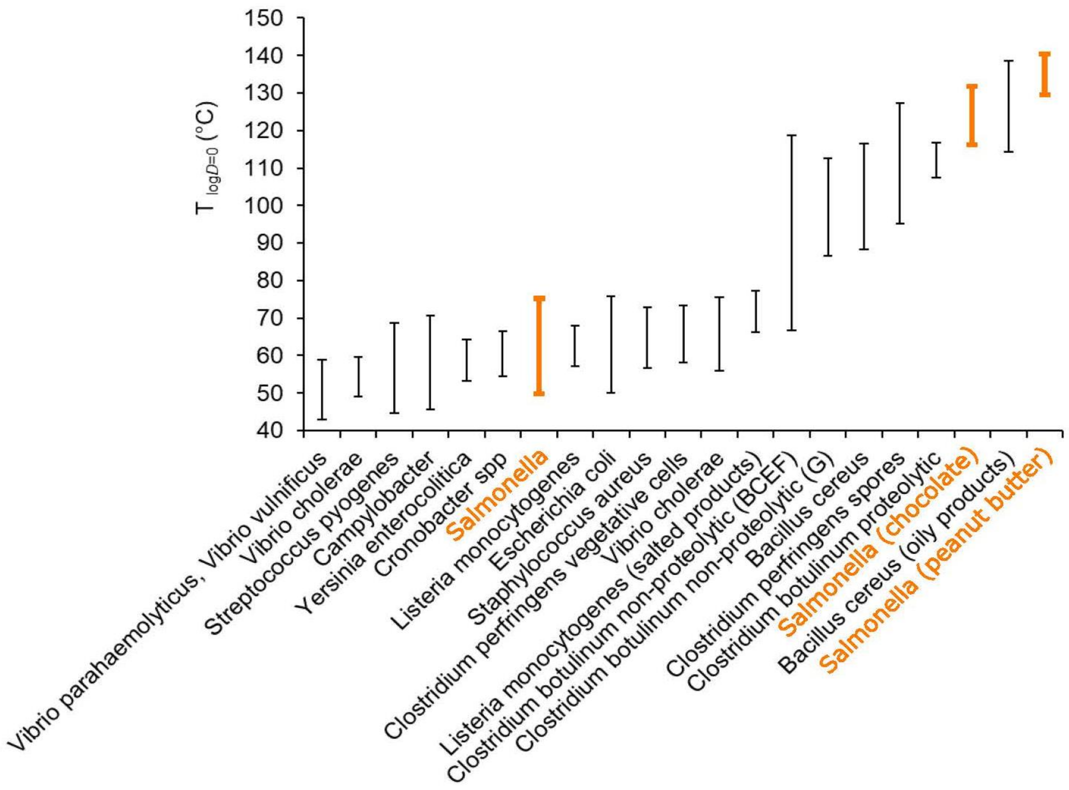
Heat resistance Comparison of various bacterial pathogens



Source: Ceylan et al, 2021

Heat resistance of *Salmonella* depends on water activity / moisture of the materials to be heat-treated.

<u>Examples</u>:

Salmonella Senftenberg in raw milk
D-value at 67.5° C: 0.046min = 2.76sec

Salmonella Senftenberg in chocolate
D-value at 70° C: min. 440 min

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How good to you know your product(s) ?

Physical Product Characteristics and their variability :

- Composition: Moisture / pH / Fat / Protein / Sugar / Salt / Preservatives
- Density / Size / Surface
- Initial Form (e.g. raw or pre-processed)
- Final Form (e.g. pieces, whole, pastes)
- Initial ingoing temperature

Intended usage:

- Ready-to-Eat
- Ready-to-Heat
- Ready-to-Cook…

Source: 24mantra.com

Markets:

- Normal Healthy Population
- Special Groups:
  - **Hospitals**
  - **Infant**
  - **YOPI…**

Source: heilpraxis.net

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Validation Report

Shall include (or reference)

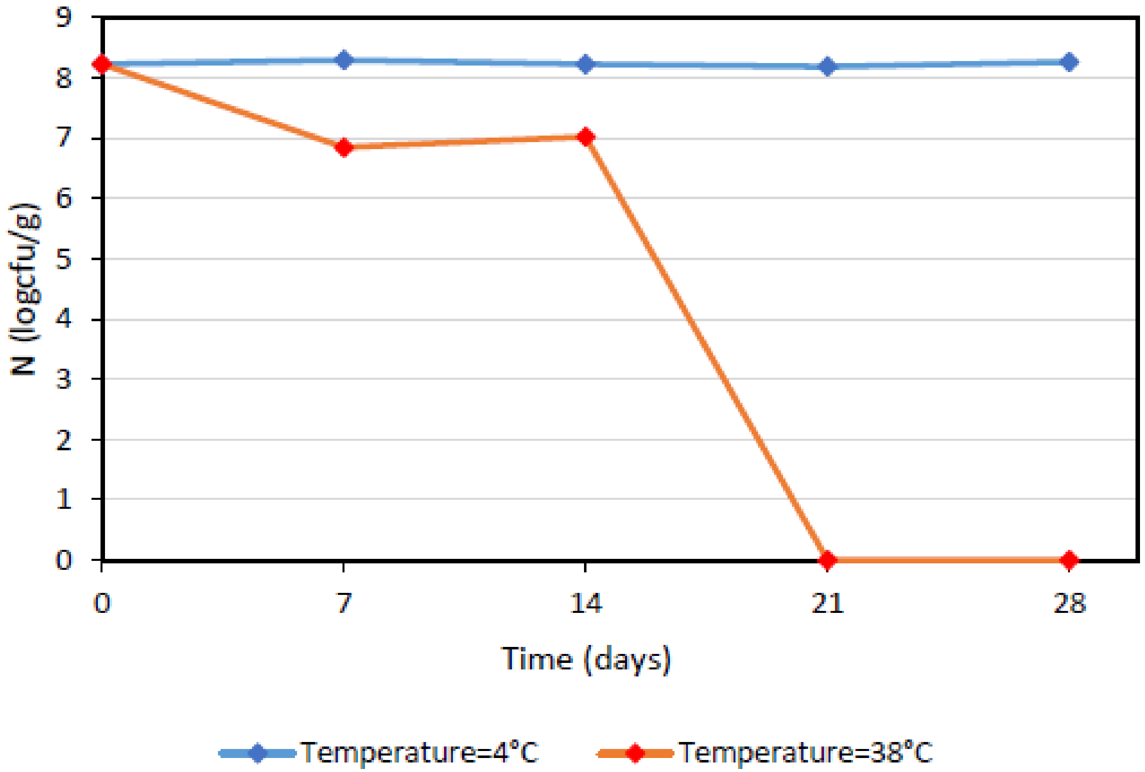
- Experimental Design (sample / inoculum preparation, transport, introduction and retrieval from process, laboratory and methods)

Common Issues in Validations

☹ Test Methodology not described in enough detail

Surrogate Stability on cocoa nibs

Temperature=4°C	
Time (days)	N (logcfu/g)
0	8,2
7	8,3
14	8,2
21	8,2
24	8,3



Temperature=38°C	
Time (days)	N (logcfu/g)
0	8,2
7	6,8
14	7,0
21	< detection
24	< detection

…because it needs to be shipped long ways

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Laboratories and Methods

Validated & trained

1 Enumeration of *Enterococcus faecium* on Treated Cocoa Nibs

1.1 Purpose and Scope

This method is used for the enumeration of *Enterococcus faecium* present on cocoa nibs, by counting colonies growing on a solid medium after aerobic incubation of plates at appropriate temperature and time.

The inoculated cocoa nibs have been treated to ensure a total viable mesophilic plate count (TVC) of $<10^2$ cfu/g of background flora. These are called “treated nibs”.

Validation Report

Shall include (or reference)

- Study Results (log reductions achieved under which process conditions)
- Conclusions (final outcome, summary, recommendations / design of future monitoring / alarms / corrective actions)

Common Issues in Validations

☹ Not enough samples / replicates tested

☹ No rationale provided for conclusions drawn

Calculation of log reduction

TABLE 13 Example of calculation with initial inoculum approximately 8 log CFU/g and targeting 5-log reductions

Replicate	N_0	N_F	Reductions	
			Deterministic	Minimal reduction case
1	8.04	3.24	5.00	4.66
1	8.08	2.71		
1	7.90	3.07		
2	8.23	3.44	4.93	4.61
2	8.39	3.52		
2	8.13	3.01		
3	7.92	2.52	5.19	4.91
3	8.07	2.92		
3	7.83	2.81		
		Mean	**5.04**	**4.73**
		SD	0.14	0.16

Source: Ceylan et al, 2021

Deterministic = calculating mean reductions

Minimal Reduction Case (MRC) = worst case appraoch (lowest log reduction achieved within all data)

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Samples and Replicates

Required number depends on system variability

- ➢ Higher variability requires more replicates and samples

Replicates – independent trials
Samples – within one run /batch

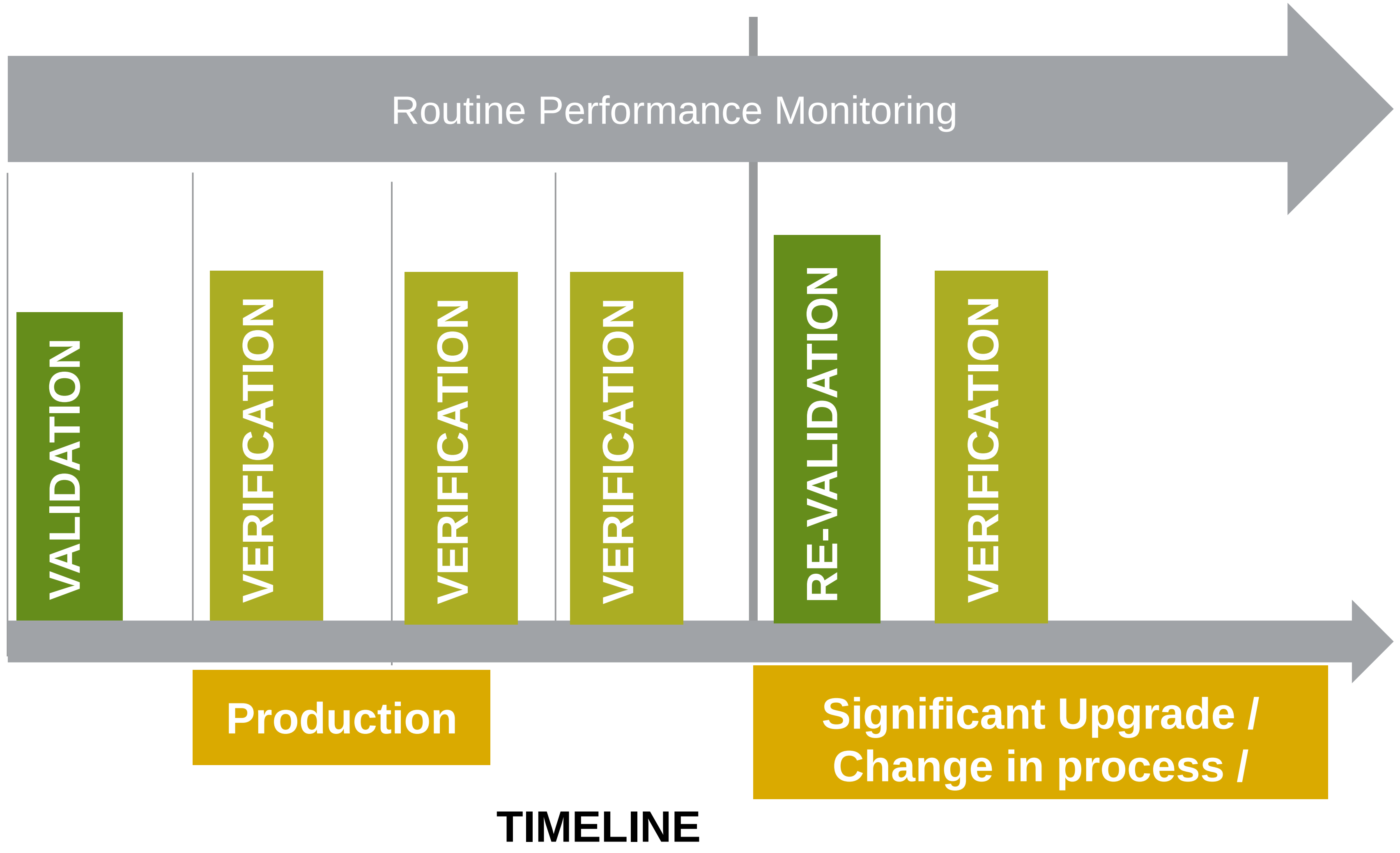
Variability is commonly higher between replicates.

Recommendation: minimum 3 replicates and 2-10 samples

Conclusions

- Validation successful or not
- Critical parameters and their limits
- Define corrective actions in case of deviation

Going further…



Reference / Guidance:

Received: 25 October 2020 | Revised: 3 February 2021 | Accepted: 3 March 2021

DOI: 10.1111/1541-4337.12746

COMPREHENSIVE REVIEWS IN FOOD SCIENCE AND FOOD SAFETY

Comprehensive REVIEWS in Food Science and Food Safety WILEY

Guidance on validation of lethal control measures for foodborne pathogens in foods

Erdogan Ceylan[1] | Alejandro Amezquita[2] | Nathan Anderson[3] | Roy Betts[4] | Laurence Blayo[5] | Francisco Garces-Vega[6] | Elissavet Gkogka[7] | Linda J. Harris[8] | Peter McClure[9] | Anett Winkler[10] | Heidy M. W. den Besten[11]

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Thank You very much for your Attention !!

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Cocoa

IAFP webinar 1st of December:
Process validations to meet FSMA requirements: Validation report

Validation sterilisation ofi cocoa lines

Michiel Kokken

Head of Regulatory and Scientific Affairs Cocoa

Agenda

Project phases validation study

- Phase 1, Determination heat kinetics salmonella and surrogate
- Phase 2, Validation of sterilisation lines
- Reporting: Certificate of validation/ validation report
- Reports evaluation
- Communication

Phase 1, determination heat kinetics salmonella and surrogate

1. Determination of D- and Z-values of pathogen in cocoa matrix/ determination surrogate

- Partners: NIZO (FOR BETTER FOOD & HEALTH), Novolyze

- Scope: Cocoa nib (high moisture/ low moisture), cocoa beans, cocoa liquor, cocoa cake/ powder, cocoa butter
- Determination of target pathogen based on hazard analyses
- *Cocktail of Salmonella Oranienburg, Salmonella Senftenberg, Salmonella typhimurium* selected
- Innoculation of nib/ beans → same 'resistency' as in raw nib/ beans
- Determining D and Z-values of Salmonella cocktail in matrix
- Determine surrogate → more heat resistent than the salmonella cocktail in the matrix

Phase 2, validation of sterilisation lines

Process validation for different sterilisation lines and different cocoa matrices

- Partner: Novolyze
- Scope: Cocoa nib/ cocoa beans/ cocoa liquor/ cocoa cake/ powder/ cocoa butter
  - Determine method of process validation in matrix
  - Determine worst case conditions of the cocoa sterlisation line with regards to recipe
  - Execute validation

Phase 1 results example cocoa beans

Design of experiment

The work for a product at 7% moisture was done in compliance with the following test parameters:

Test parameters
Cocoa beans

Salmonella:
S. Oranienburg TH-SAL 570 FDA collection
S. Typhimurium TH-SAL 453 FDA collection
S. Senftenberg DSM 10062 DSMZ collection

SurroNov®18 and SurroNov®19

85°C / 0-7.5-15-22.5-30 min
90°C / 0-5-10-15-20min
95°C / 0-4-8-12-16min

Phase 1 results example cocoa beans

The results at 7% moisture are presented below:

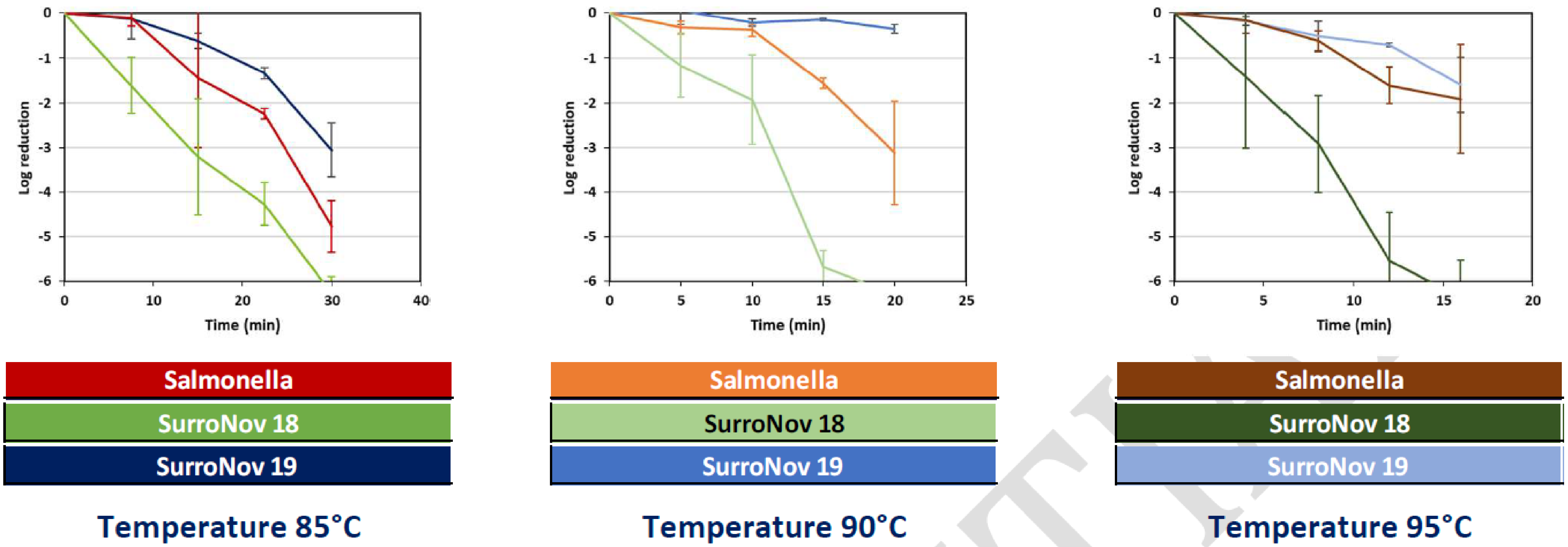
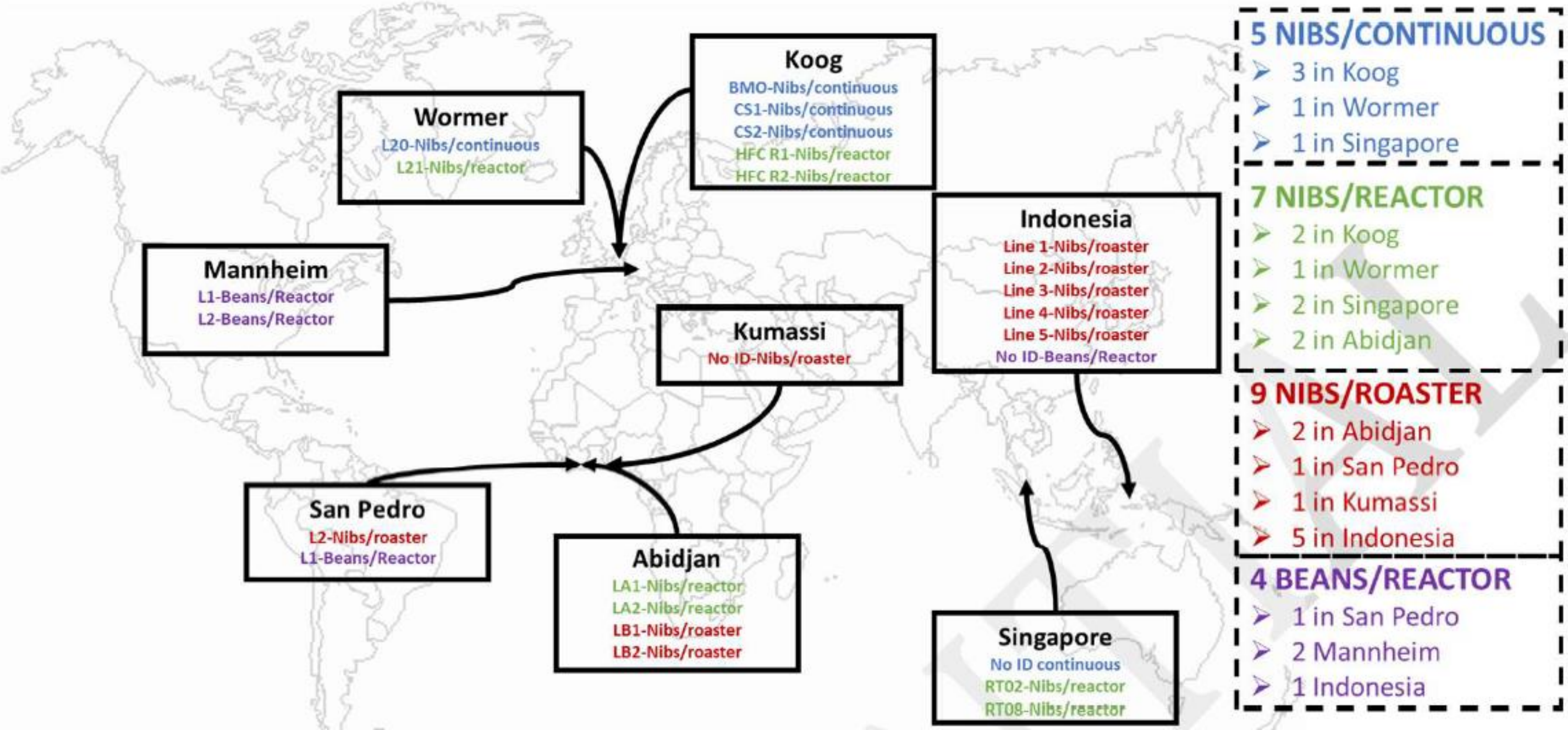


Figure 3: Inactivation curves at 3 temperatures for SurroNov® and Salmonella at 7% moisture

Phase 2: Approach validation sterilisation lines

1. Cocoa nibs low moisture
2. Cocoa nibs high moisture
3. Cocoa beans



Phase 2: Approach validation sterilisation lines

Technical comparison of the nib high moisture lines → no one size fits all approach for validaiton in the line possible

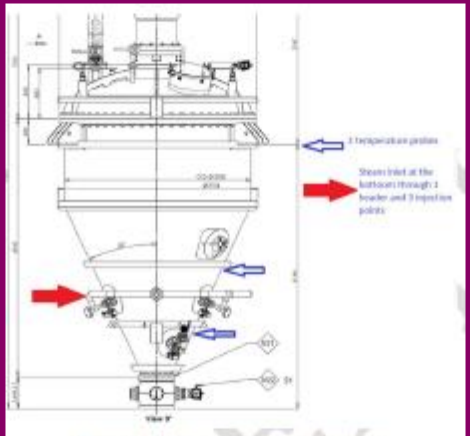


Figure 7: Koog reactor systems

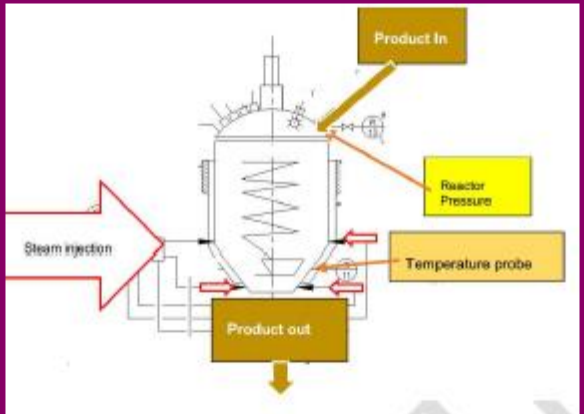


Figure 9: Singapore reactor RT02 and RT08 systems

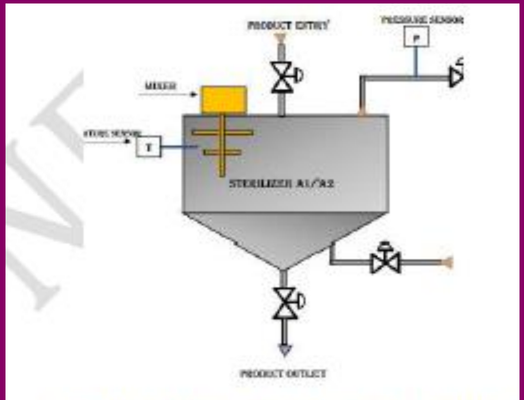
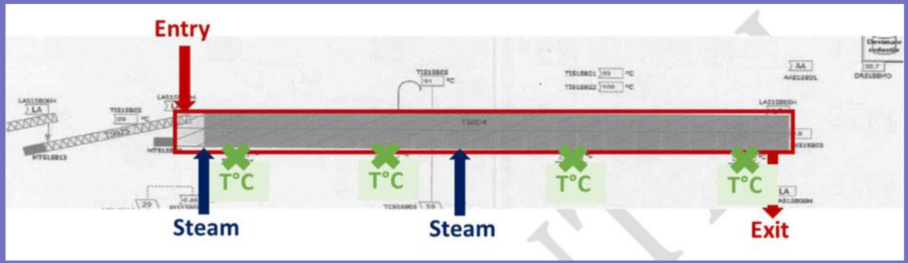
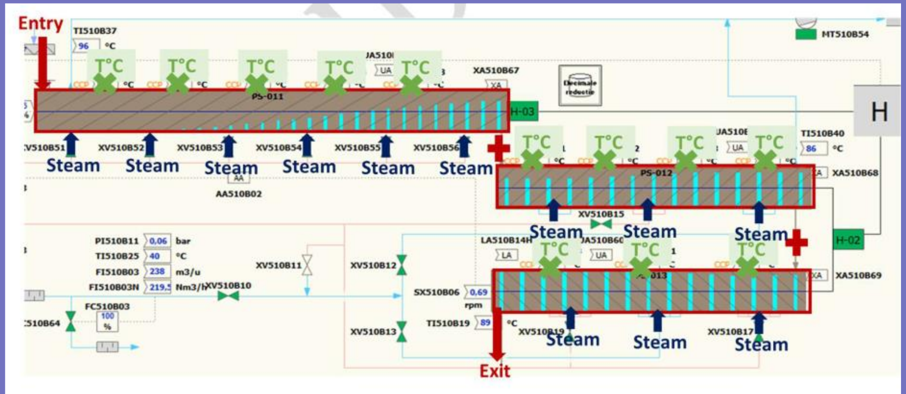


Figure 10: Abidjan reactor A1 and A2 systems

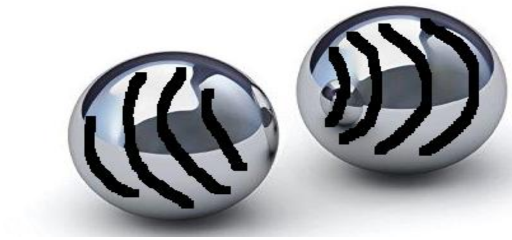


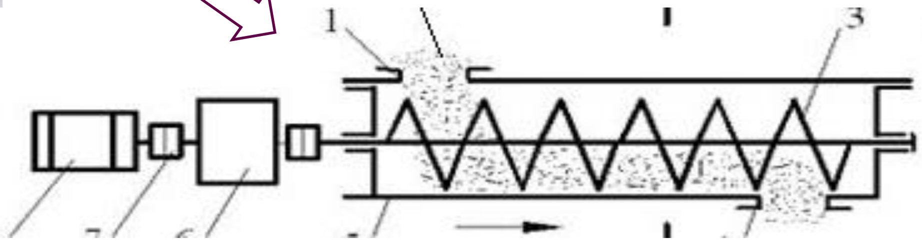


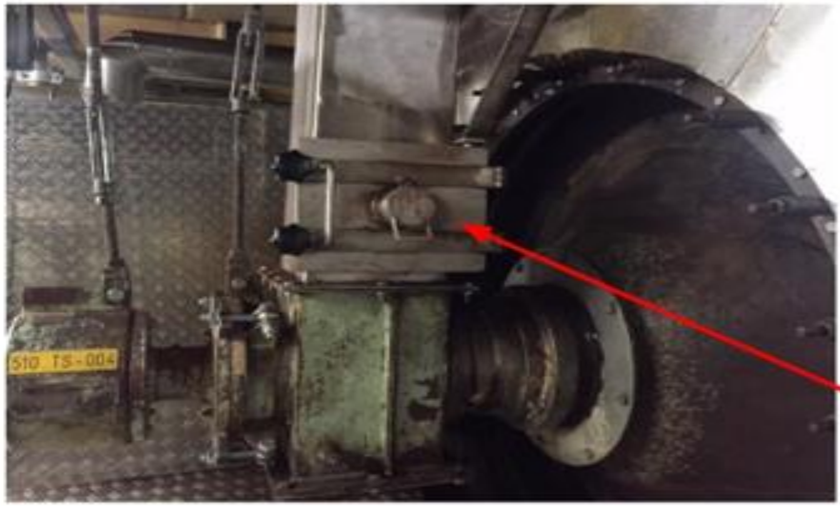
Phase 2: Approach validation sterilisation lines
Example continuous screw sterilisation

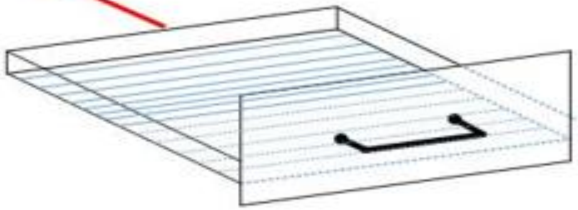
Surrogate

T-logger

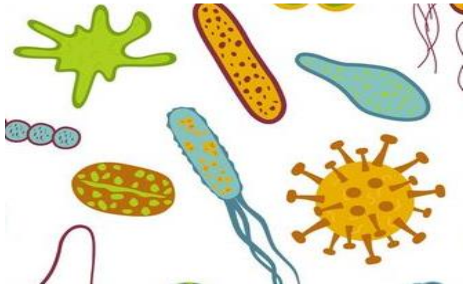








Bak met spijlen (afsluitend op de wand van de koker) die:
A. nib makkelijk doorheen valt
B. containers op blijven liggen



Phase 2: Approach validation sterilisation lines
Example continuous screw sterilisation

1st prototype transport vessel → too weak didnt "survive" the screw

2nd prototype transport vessel and grid for taking out the ball after heat treatment, entry point

Phase 2: Approach validation sterilisation lines
Example roaster validation

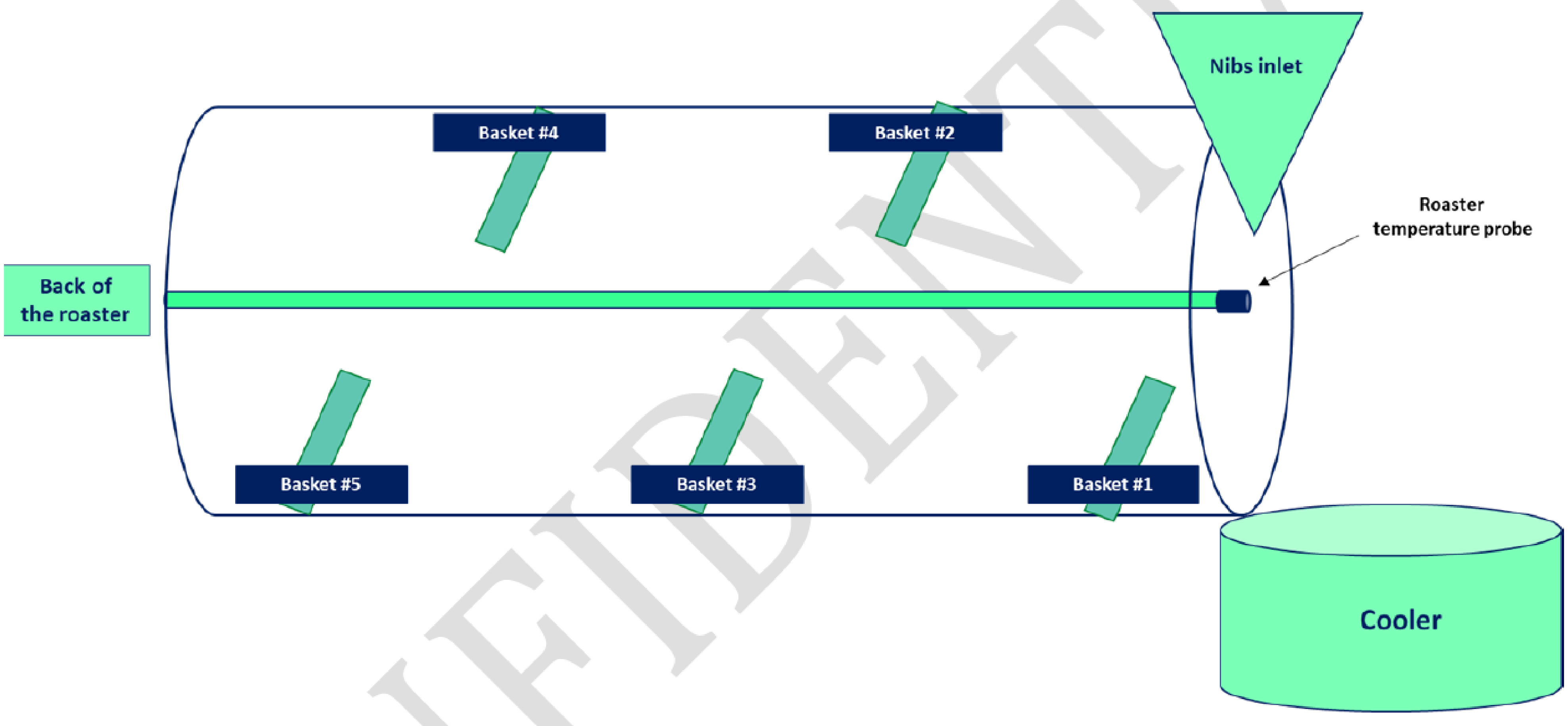


Figure 2: Placement of the samples and probes inside the roaster

Phase 2: Approach validation sterilisation lines
Example roaster validation

Validation target:

For instance minimum 6-log reduction of surrogate (in comparrison with the relevant target pathogen)

Determination of worst case conditions of the line:

-Temperature (minimum)

-time (minimum)

-Moisture addition (minimum)

-Capacity (maximum)

Comparison of heat profile generated by fixed temperature sensor with temperature sensor placed during validation study at different places in the roaster to showcase the variability of the roaster

Phase 2: Approach validation sterilisation lines
Example roaster validation

make it real

5.3 MICROBIOLOGICAL SAMPLE RESULTS AND LOG REDUCTION CALCULATION

Trial #1		
Non-processed samples (NPS)		
Sample ID	CFU/g	Log CFU/g
NPSA-1	800000000	8,9
NPSA-3	640000000	8,8
NPSA-4	633000000	8,8
NPSA-5	606000000	8,8
Average and standard deviation for trial #1		
8,8 ± 0,1		

Trial #2		
Non-processed samples (NPS)		
Sample ID	CFU/g	Log CFU/g
NPSB-1	540000000	8,7
NPSB-2	353000000	8,5
NPSB-3	440000000	8,6
NPSB-4	666000000	8,8
Average and standard deviation for trial #2		
8,7 ± 0,1		

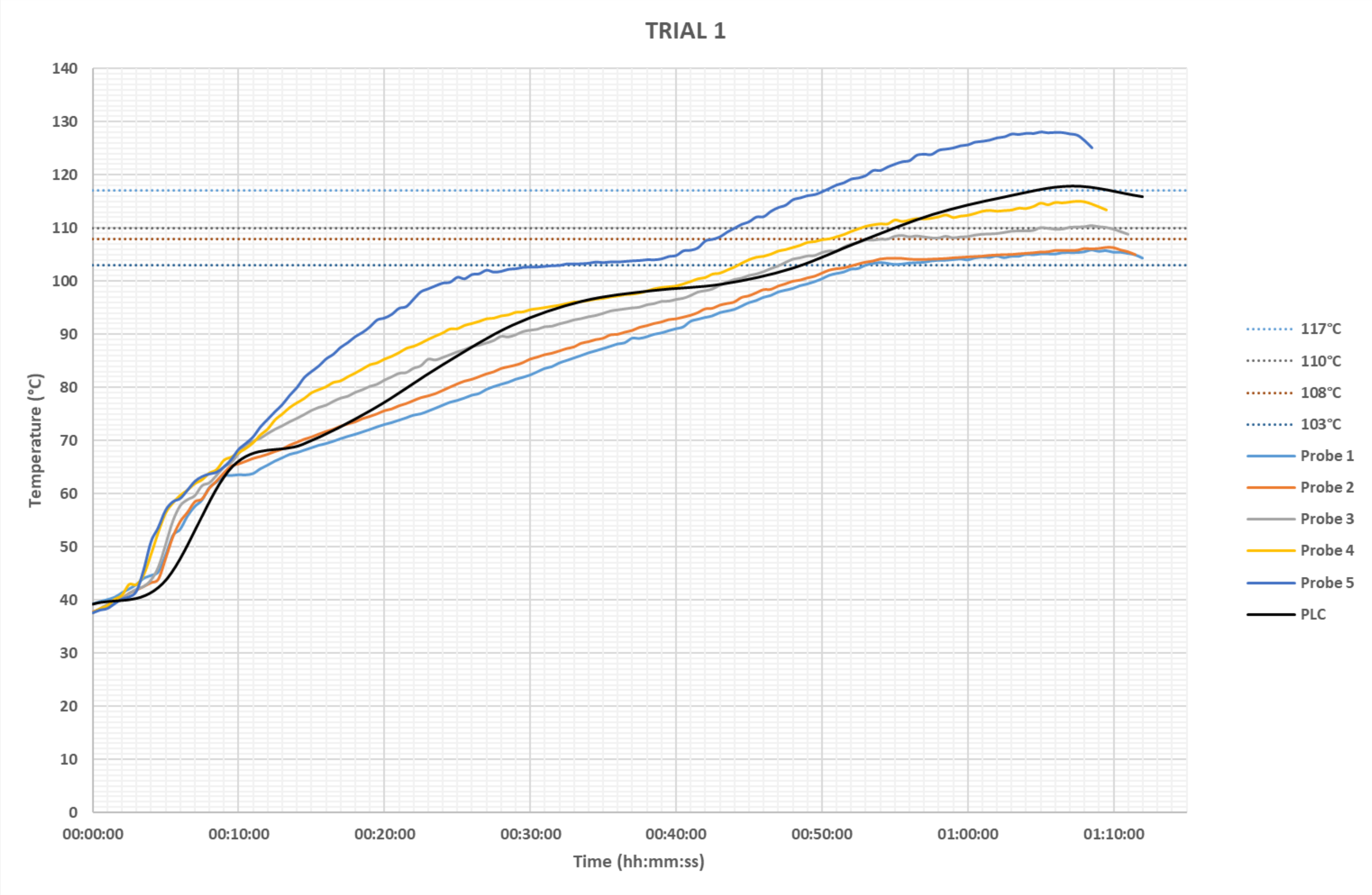
Trial #3		
Non-processed samples (NPS)		
Sample ID	CFU/g	Log CFU/g
NPSC-2	706000000	8,8
NPSC-3	430000000	8,6
NPSC-4	853000000	8,9
NPSC-5	860000000	8,9
Average and standard deviation for trial #3		
8,8 ± 0,2		

Trial #1			
Processed samples (PS)			
Sample ID	CFU/g	Log CFU/g	Log reduction
PSA-1	< 10	< 1,0	7,8
PSA-3	300	2,5	6,3
PSA-4	< 10	< 1,0	7,8
PSA-5	< 10	< 1,0	7,8
PSA-6	500	2,7	6,1
PSA-7	< 10	< 1,0	7,8
PSA-8	< 10	< 1,0	7,8
PSA-9	< 10	< 1,0	7,8
PSA-10	200	2,3	6,5
PSA-11	< 10	< 1,0	7,8
PSA-12	< 10	< 1,0	7,8
PSA-13	< 10	< 1,0	7,8
PSA-14	< 10	< 1,0	7,8
PSA-15	100	2,0	6,8
Average concentration			
1,39 ± 0,66			
Average log reduction achieved			
7,4 ± 0,66			
Minimum log reduction			
6,1			

Trial #2			
Processed samples (PS)			
Sample ID	CFU/g	Log CFU/g	Log reduction
PSB-1	< 10	< 1,0	7,7
PSB-2	< 10	< 1,0	7,7
PSB-3	< 10	< 1,0	7,7
PSB-4	< 10	< 1,0	7,7
PSB-6	< 10	< 1,0	7,7
PSB-7	< 10	< 1,0	7,7
PSB-8	< 10	< 1,0	7,7
PSB-9	< 10	< 1,0	7,7
PSB-10	< 10	< 1,0	7,7
PSB-11	< 10	< 1,0	7,7
PSB-12	200	2,3	6,4
PSB-13	< 10	1,0	7,7
PSB-14	300	2,5	6,2
PSB-15	100	2,0	6,7
Average concentration			
1,27 ± 0,54			
Average log reduction achieved			
7,4 ± 0,54			
Minimum log reduction			
6,2			

Trial #3			
Processed samples (PS)			
Sample ID	CFU/g	Log CFU/g	Log reduction
PSC-2	400	2,6	6,2
PSC-3	200	2,3	6,5
PSC-4	< 100	< 2,0	6,8
PSC-5	< 10	< 1,0	7,8
PSC-6	< 10	< 1,0	7,8
PSC-7	< 10	< 1,0	7,8
PSC-8	< 10	< 1,0	7,8
PSC-9	< 10	< 1,0	7,8
PSC-10	< 10	< 1,0	7,8
PSC-11	< 10	< 1,0	7,8
PSC-12	< 10	< 1,0	7,8
PSC-13	< 10	< 1,0	7,8
PSC-14	< 10	< 1,0	7,8
PSC-15	< 10	< 1,0	7,8
Average concentration			
1,28 ± 0,57			
Average log reduction achieved			
7,6 ± 0,57			
Minimum log reduction			
6,2			

Phase 2: Approach validation sterilisation lines
Example roaster validation



Reporting of Validation studies

Certificate of validation

- 3rd party validation certificate
- Validation target
- Surrogate used
- Equipment identification
- Plant location
- Matrix information
- Validation date
- Reference to the report

NOVOLYZE®

LEADING FOOD SAFETY REVOLUTION

CERTIFICATE OF VALIDATION

Olam Cocoa Processing Ghana Limited

The following parameters have been validated to achieve a 6-log reduction of *Salmonella* using SurroNov® 18 (*E. faecium*) as a surrogate organism.

***Salmonella* used at the lab scale:** Cocktail of *S.* Oranienburg, *S.* Typhimurium and *S.* Senftenberg

Equipment Identification: Bühler Bart Tornado 10500RS

Equipment Location: Olam Cocoa Processing Ghana Limited, P.O. Box KS 1966, Kumasi, Plot7-9, Kaase Industrial Area, Ghana

Tested Food Product: Cocoa nibs

Date of the Validation Trials: June 2, 2021

Tested Parameter: Worst case conditions of Time and Temperature for the system and moisture for the product.

Laure Pujol
Project manager

For more information about the methodological items and perimeter of Novolyze's missions, please refer to the complete validation report N°E-34_ REPORT_OLAM Kumasi_#30196272

Reporting of Validation studies

Validation report

- Product for validation (including validation target
- Proces for validation
- Validation methodology (surrogate selection/ materials and methods/ trial configuration/ process monitoring/ sample strategy/ analytical work)
- Results (thermal results/ matrix controls and microbial sample results)
- Conclusion
- Recommendations

Validation Report

NOVOLYZE LEADING FOOD SAFETY REVOLUTION

Project #30196272-R01

Olam Cocoa

VALIDATION REPORT

Evaluation of the Microbial Lethality of a reactor for Salmonella in cocoa beans

May 13, 2021

Olam Cocoa

Prepared for:	
Olam cocoa Deutschland GmbH Seilerstraße 15-23 Mannheim, 68159 Germany	

Prepared by:	
Priscilla Piller ***Project Manager***	**Date : May 13, 2021**

Reviewed by:	
Laure Pujol, PhD ***Project Manager***	**Date : May 13, 2021**

Validation Report

Project #30196272-R01

Table 2: Project team

Name	Position	Validation Lead
Novolyze		
Laure Pujol, PhD	**Scientific Project Manager**	✓
Virginie Pignard	Laboratory Technician	
Pierre-Olivier Beal	Contract Manager	
Olam cocoa Deutschland GmbH		
Michiel Kokken	**European Quality Manager**	✓
Irene ter Laak	R&D Manager	
Julian Rommel	Project- Process Engineer	
Pasquale De Tullio	Project- Process Engineer	
Validation team		
Maria Rodenas-Garcia	Quality Manager Mannheim	
Adrian Schymetzko	Technical Support / Fitter	
Andreas Heeschen	Production Manager	
Kai-Rene Meyer	Technical Support / Fitter	
Alexander Dolheimer	Laboratory assistant	

2 PRODUCT TO VALIDATE

The product to validate was cocoa beans. Product specifications are presented in Table below.

Table 3: Product specifications

Cocoa beans	Pre-process	After process
Moisture Content (%)	Not measured	>7%
Log TPC (log CFU/g)	2.0 to 5.5	<1.0±0.0

Since the level of the background microflora can be naturally high and was not determined before the trials, an overlay enumeration protocol was used (one layer of non-selective media and one layer of selective media).

Validation Report

3 PROCESS TO VALIDATE

3.1 GENERAL DESCRIPTION

Type of Process: Batch, steam reactor

Manufacturer - Model: Lehmann KS-2000S

Olam Process identification: L2

The system consisted of a batch reactor where the beans are loaded from the top of the system and discharged at the bottom of the system. The maximum capacity of the system is [redacted]. Once the beans are loaded, the pressure is applied. The current CCP parameters is [redacted] bar for [redacted].

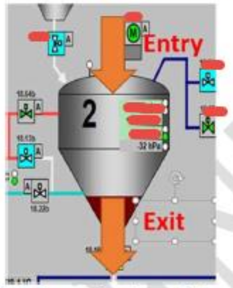


Figure 1: Schematic view of the process

Reactor inner **Reactor base (outer)** **After-dryer inner**

Figure 2: Pictures of the reactor

Validation Report

Table 4: Process parameters

	Routine production	Validation trials
Weight	[illegible]	[illegible]
Pressure (CCP)	[illegible]	[illegible]
Time (CCP)	[illegible]	[illegible]
Temperature	[illegible]	[illegible]

Surrogate selection:

SurroNov® 19 is a dry, ready-to-use version of Enterococcus faecium and is widely documented as suitable. Appropriateness for surrogate vs Salmonella in cocoa beans established reference REPORT_Olam cocoa beans _#27942189_v1” make it real

5.7 SAMPLING STRATEGY AND LETHALITY EVALUATION

Two types of inoculated samples were recovered from the trials in order to evaluate the lethality of the system:

- **Non-processed Samples (NPS):** These samples correspond to product inoculated with SurroNov® but non-processed through the system. These samples were used as non-treated controls to estimate the log reduction reached during the trial.
- **Processed Samples (PS):** These samples correspond to product inoculated with SurroNov® and processed through the system. These samples were used as treated controls to estimate the log reduction reached during the trials.

Lethality evaluation was performed by comparing the surrogate counts in the NPS and PS samples. The difference accounts for the microbial log reduction level achieved. A minimum and an average log reduction were calculated.

In addition, other types of analytical controls:

- **Matrix Control Samples (MC):** These samples correspond to product used for the inoculation.
- **Non-Inoculated and Non-Treated Control Samples (NINTC):** These samples correspond to non-inoculated product before distribution in the process.
- **Non-Inoculated and Treated Control Samples (NITC):** These samples correspond to non-inoculated product after processing.

Validation Report

Results section:

-Thermal mapping / pressure control

-Micro results

Log calculations

Table 7: Compliance achieved during the in-plant validation trials

Target log reduction 6,0	Target minimum inoculation level			7,0
	Trial 1	Trial 2	Trial 3	Total
Compliant NPS	10			10
Non-compliant NPS	0			0
Total NPS	10			10
% compliant NPS	100%			100%
Compliant PS	10	10	10	30
Non-compliant PS	0	0	0	0
Total PS	10	10	10	30
% compliant PS	100%	100%	100%	100%

All the Non-Processed Samples (NPS° were compliant to assess a potential 6-log microbial reduction. Inoculation of the cocoa beans with SurroNov® was homogeneous with an average concentration at 8.7±0.1-log CFU/g.

8 CONCLUSION

Results obtained during in-plant validation trials confirmed that the evaluated system can achieve, in the tested conditions, a minimum 6-log reduction for the surrogate microorganism and for *Salmonella* by correlation in a consistent and repeatable manner despite the variability of the temperature inside the reactor.

9 RECOMMENDATIONS

Novolyze recommends the following additional food safety measures:

- Monitoring: The processing parameters should be continuously monitored. Whenever possible, a real-time monitoring procedure should be in place in order to trigger faster corrective actions
- Verification: Further verification activities should be performed on a periodic basis in order to make sure that the process is still capable to achieve the target microbial reduction. Verification items can include (non-limitative): review of the critical parameters (process, product), thermal mapping, microbiological testing, audits etc. If needed, Novolyze can help you design further verification procedures for this system.
- Revalidation: A standard practice in the industry is to proceed with a new validation in the following cases:
  - If the processing configuration becomes less favorable for pathogen reduction (e.g. lower temperature, higher fat content of the product etc.)
  - Any modification of the design of the equipment which may affect the heat penetration to the product
  - At least every three years

Report evaluation

Validation report

- Process authority writes the validation report and certificate:
- -> it is however the company's responsibilty to verify and approve the certificate
- -> this shall be reviewed and approved both from the **technical / scientific team** within the company as well as from **validation team** (typically headed by the Quality /Food safety manager, could be same team as HACCP team) **at the sit**e to assure consistency with the quality and food safety documentation kept on site and consistency with other validation reports within the company.

Communication

Harmonized communciation internally and externally

Staff involved in communication of the validation program of the company understands the setup and the background of the validation program to ensure consistent communication to customers/ authorities

Non exclusive list of key functions /teams within a company are Quality and Food Safety managers/HACCP team members/ customer technical support teams/ global quality teams involved in communcation

- Quality/ Food safety managers need to understand the validation strategy of the company and also understand and can explain the content of the reports.

-Validation reports when setup as described are suitable to explain the details of the validation during audits.

Technical/ scientific team and the processing authority for complex enquiries

Thank you

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