


International Association for Food Protection®

Process Validation to Meet FSMA Regulations – Tips & Tricks from Case Studies

Moderator: Vidya Ananth, Novolyze, United States

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International Association for Food Protection® WEBINAR

Today's Participants

Vidya Ananth, Novolyze, United States
Novolyze, United States

Vidya Ananth is a VP of Food Safety & Quality, Application Support and Customer Success at Novolyze. She received her MS in Food Microbiology from Iowa State University and has been in the food industry for over 25 years and has made significant contributions in the areas of food safety, quality and regulatory affairs with a main goal to bend the curve of food borne illness globally. Vidya has held various Food Safety and Quality positions through her journey in the food industry and a few companies to name would be General Mills, The National Food Lab, Safeway, Clorox, Before Brands, Kohana Coffee and now Novolyze. Vidya has helped small and large companies build effective food safety and quality systems using risk-based prevention strategies and has helped build the food safety culture within these organizations. She has collaborated with trade organizations (IAFP, FIMRT, CSPA, PCPC, GMA, ADS) and FDA and USDA, universities and has hosted conferences and chaired many sessions, published patents, papers and a compendium chapter.
An interesting note is that Vidya can converse in 6 languages and engages in humanitarian work during her spare time.

Juliany Rivera Calo
Ardent Mills, United States

Juliany joined Ardent Mills in April 2016 as Sr Food Safety Microbiologist. In her role, Juliany is responsible for microbiology programs, environmental monitoring, process validations, food safety and research projects. Prior to Ardent Mills, she worked for Hain Celestial, Tyson Foods and FDA CFSAN.
Juliany holds a BS in Industrial Microbiology from the University of Puerto Rico and a master's degree in Food Safety and Microbiology from the University of Arkansas, Fayetteville.
During her career Juliany has published several peer reviewed articles and two book chapters.

Today's Participants

Dessa Hix
International Specialty Supply , United States

Dessa Hix is Controller at International Specialty Supply for more than 4 years, an world-wide supplier of seeds and equipment to the sprouting industry.

She has worked in the industry for ten years and has served as SQF Practitioner and PCQI. She led the team that validated a purification method for reducing pathogens on the surface of seed for sprouting.

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.

Ardent Mills®

Process Validation to Meet FSMA Regulations

IAFP Webinar, May 25, 2021

Juliany Rivera Calo

ARDENT MILLS LOCATIONS

ALABAMA
Decatur Mill

CALIFORNIA
Colton Mill
San Bernardino Mill
Stockton Mill
Yuba City – Andean Naturals

COLORADO
Commerce City Mill
Denver Mill
Denver Headquarters

FLORIDA
Tampa Mill

ILLINOIS
Alton Mill
Chester Mill

KANSAS
Newton Mill
Wichita Mill

LOUISIANA
Port Allen Mill

MASSACHUSETTS
Ayer Mill

MINNESOTA
Hastings Mill
Lake City Mill
Mankato Mill
Minneapolis Office

NEBRASKA
Omaha North Mill
Omaha South Mill
Omaha Office

NEW YORK
Albany Mill

NORTH DAKOTA
Fairmount Mill

OHIO
Columbus Mill

OREGON
Arlington Blending
IBR Bakery
Klamath Falls Elevator

PENNSYLVANIA
Martins Creek Mill
Mt. Pocono Mill
York Mill

TENNESSEE
Chattanooga Mill

TEXAS
Galena Park Mill
Saginaw Mill
Sherman Mill

UTAH
Ogden Mill

VIRGINIA
Culpeper Mill

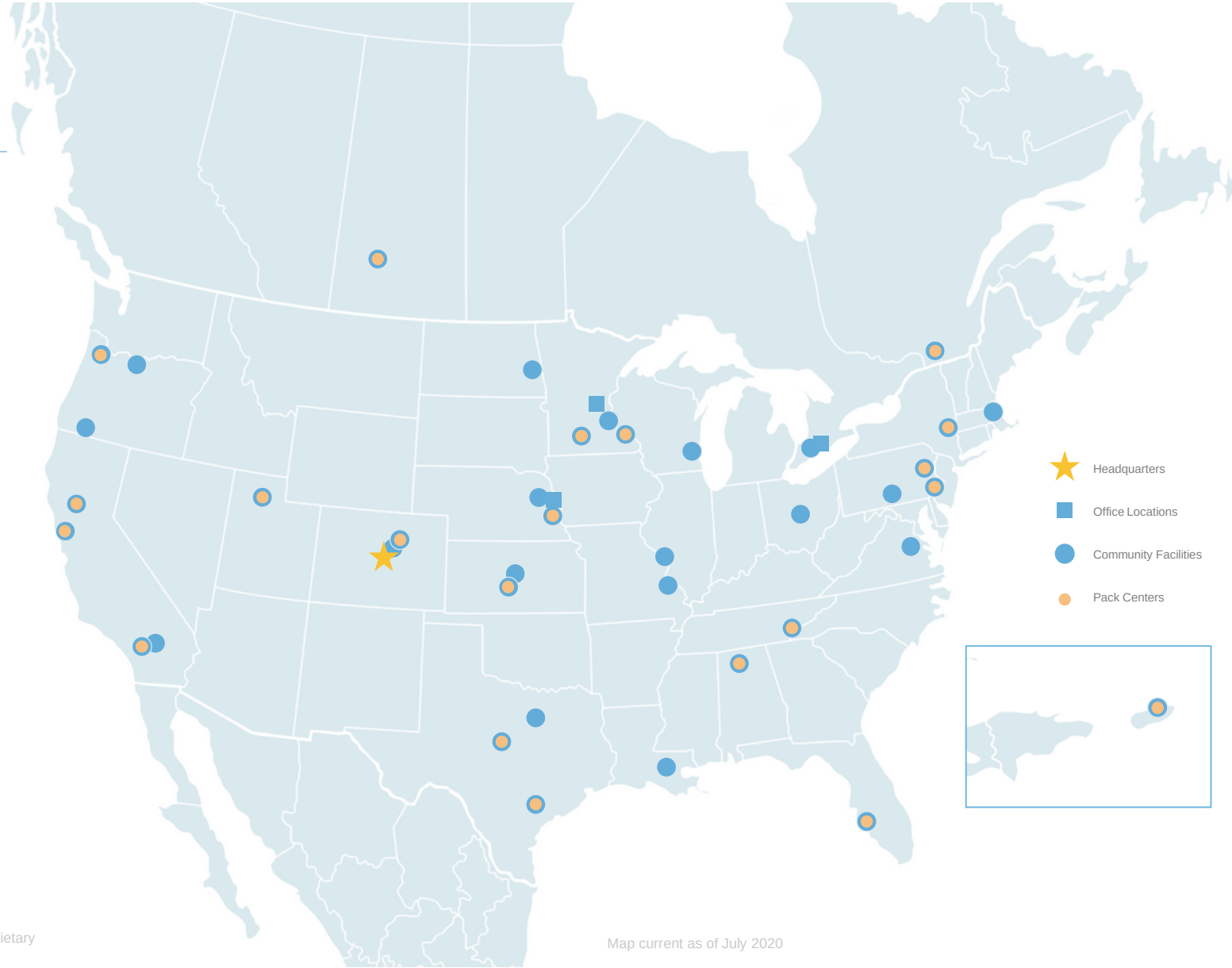
WISCONSIN
Kenosha Mill

ONTARIO, CANADA
Mississauga Office
Streetsville Mill

PUERTO RICO
Guaynabo Mill

QUEBEC, CANADA
Montreal Mill

SASKATCHEWAN, CANADA
Saskatoon Mill and Mix Facility



Map current as of July 2020

Ardent Mills®

Nourishing what's next.®

OUR VISION

Ardent Mills is the TRUSTED partner in nurturing our customers, consumers, and communities through innovative and nutritious grain-based solutions.

OUR MISSION

Enhancing the Quality of Life and Standard of Health

OUR VALUES

We will make a positive impact with our team members, customers, communities, and partners by:

+ Working to earn **TRUST** every day, always operating with reliability and integrity.
+ **SERVING** others with understanding, respect, and care.
+ Operating with **SIMPLICITY**, clarity, and transparency, removing barriers and letting people do what they do best.
+ Ensuring the **SAFETY** of our products and people; doing what's best to create the safest environment now and for the future.





Background

- *Validation* means 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. (*21 CFR 507.3)*
- FSMA outlines several approaches to validating a Preventive Control.
    - Regulatory agencies
    - Mathematical model
    - Peer-reviewed journals
    - Microbial challenge studies
- In-plant validation using surrogate microorganism that mimic the kinetic behavior of a pathogen under the same processing conditions is the gold standard approach.

Background

FDA Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food

Chapter 6 provides examples of heat treatment processing for soups, salsa and cookies.

- Chapter 5: Application of Preventive Controls and Preventive Control Management Components (PDF: 146KB)
- Chapter 6: Use of Heat Treatments as a Process Control (PDF: 384KB)
- Chapter 7: Use of Time/Temperature Control as a Process Control (coming soon)
- Chapter 8: Use of Formulation as a Process Control (coming soon)
- Chapter 9: Use of Dehydration/Drying as a Process Control (coming soon)
- Chapter 10: Sanitation Controls (coming soon)
- Chapter 11: Food Allergen Controls (coming soon)
- Chapter 12: Preventive Controls for Chemical Hazards (coming soon)
- Chapter 13: Preventive Controls for Physical Hazards (coming soon)
- Chapter 14: Recall Plans (PDF: 118KB)
- Chapter 15: Supply-Chain Program for Human Food Products (PDF: 920KB)
- Chapter 16: Validation of a Process Control (Coming Soon)

Source: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food

Preparing for an In-plant Validation

- Identifying the hazard
- Single product or multiple products to be validated?
    - Product categorization
        - Reduce cost, more efficient
        - One or two products per category that represents the worst-case scenario
- Determine worst case scenario
    - Lowest moisture content / water activity
    - Highest pathogenic resistance (highest fat, highest protein)
    - Lowest cooking temperature or zone temperature
    - Coldest spot possible
    - Shortest time exposed

Table 4-6. Factors That Influence the Heat Resistance of Microorganisms in Foods.

Factor	Effect on Microbial Heat Resistance
Water	As the humidity or moisture goes down, in general the heat resistance increases
Fat	As the fat content increases, there is a general increase in heat resistance of some microorganisms
Salts	The effect of salt varies and depends on the kind of salt and concentration. Some salts that decease water activity appear to increase heat resistance of microorganisms while other salts that may increase water activity (e.g., Ca^{2+} and Mg^{2+}) appear to decrease heat resistance.
Carbohydrates	The presence of sugars can increase the heat resistance of microorganisms due in part to the decrease in water activity. However, the impact can be variable, particularly among sugars and sugar alcohols.
pH	Most microorganisms are more heat resistant near their optimum pH for growth. Generally, as the pH increases or decreases relative to this optimum pH, the microorganisms become more sensitive to heat.
Proteins	Proteins have a protective effect and, thus, increase the heat resistance of microorganisms.

Source: FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Chapter 4: Preventive Controls

Preparing for an In-plant Validation

- Surrogate selection
  - Scientific literature
  - Surrogate appropriateness / thermal death time
    - D and Z Values
    - Understanding the relationship between target pathogen and surrogate in terms of log reduction
- Identifying process parameters and target log reduction
  - Time and temperature to achieve target log reduction
  - Can the desired log reduction be achieved? Understanding there are products that may not achieve the target log reduction
- Applying the data to conduct in-plant validation of products
- In-plant validation design

Key Points for Conducting In-Plant Validation

- Third-party to conduct the validation (or at minimum review the method, results and analysis)
- Ensure sampling size and number of samples are statistically significant
- **Adequate control samples**
- **Surrogate inoculation to be performed correctly.**
    - Inoculated samples to be placed properly in product or system
    - Mass inoculation
- Independent trials (replicates)

Key Points for Conducting In-Plant Validation

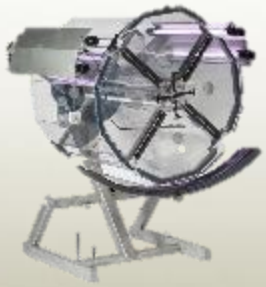
- Results analysis: the final log reduction to be the **minimum achieved log reductio**n, not the average
  - Example: the average log reduction was 6-log, but the minimum log reduction was 3-log
- Scientific literature or references
- Verification
  - *Verification* means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan. (*21 CFR 507.3)*

Sprouts

The Original Super Food

Sun Garden® Seed

The Ultimate Premium Seed



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SENTREX™ SYSTEMS MANUFACTURING

OUR VALUES

- ✓ Safety
- ✓ Integrity
- ✓ Value Creation
- ✓ Teamwork

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THE COMPANY

- **SunGarden Fresh Living -** Supplies the Health, Wellness, and Nutrition industry with sprouts and sprout powders
- **Sentrex Manufacturing –** Highest quality sprouting equipment & services
- **SunGarden Seed –** Global supplier of the Ultimate Premium Sprouting Seed

Who we are:

- Global leader in sprouts & equipment
- 100,000 sq. ft. facility
- Over 40 years of experience
- Best in class food safety systems

We Produce:

- Ultimate Premium Sprouting Seed
- Sprouts
- Sprout powders
- Healthy alternatives
- Unique ingredients

3rd Party Certifications

- SQF Level 2
- HACCP/HARPC
- Kosher
- NSF GMP
- Organic
- MUI Halal

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BACKGROUND INFORMATION

- Sprouts are a nutrition powerhouse and a great source of fresh food in areas with limited growing space. Sprouts can also be dried and used as an ingredient.
- Sprouts represent a special food safety concern because the conditions under which they are produced are also ideal for the growth of pathogens.
- Industry standard has been to sanitize seed immediately before sprouting with Calcium Hypochlorite solution in concentrations up to 20,000 ppm.
  - Can only achieve up to 3.5 log reduction in pathogens
  - Variability in effectiveness
  - Highly corrosive, noxious fumes

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BACKGROUND INFORMATION

- In January 2017 FDA released Proposed Guidance for the sprouting industry that offered sprout growers an alternative to treating seeds themselves before growing.
- Growers could rely on prior treatment of seeds if the treatment was conducted using a scientifically-valid method to reduce microorganisms of public health significance (CFR 21 §112.142(e)).
- Agri-Neo technology had been used successfully on a number of foods to reduce pathogens while leaving the foods raw and organic.
- Needed to validate Neo-Pure on seeds for sprouting.
- We partnered with Novolyze for our validation studies.

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3RD PARTY VALIDATION

NOVOLYZE
LEADING FOOD SAFETY REVOLUTION

- Offers solutions to help the food industry manufacture safer food
- Ensure strong compliance with international Food Safety & Quality standards
- Research work mainly focuses on evaluating the inactivation of foodborne pathogens
- Dried, ready-to-use surrogate bacteria

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VALIDATION STRATEGY

- 3 samples of non-inoculated, non-treated seed to serve as Control Samples.
- Inoculated 250 lbs. of seed and recovered 10 Non-Processed Samples
- Apply sanitizing solution
- 10 Intermediate Processed Samples
- 30 samples in thermal cages
- After drying, the thermal cages were recovered from the dryer to serve as Processed Samples.

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SUNGARDEN SEED SYSTEM

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TESTING PARAMETERS

	Usual Production	Validation Trials
Batch Size	1200 lbs. (544 kg)	250 lbs. (113 kg)
Applicator – Residence Time	3-5 minutes	3-5 minutes
Applicator – Application Ratio	40L/metric ton of seed	40L/metric ton of seed
Neo-Pure Solution Used	21.8L	4.5L
Holding Time	1 hour	1 hour
Dryer – Temperature	140°F (60°C)	140°F (60°C)
Dryer – Drying Time to return seed to pre-treatment moisture level	Depends on seed type	Depends on seed type

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VALIDATION RESULTS

Broccoli

Log Reduction
6.17 ± .20

Clover

Log Reduction
5.67 ± .00

Alfalfa

Log Reduction
5.51 ± .40

Radish

Log Reduction
5.37 ± .40

Sunflower

Log Reduction
3.52 ± .57

Treated Seed Validation Results

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CATEGORIZATION STUDY

- Objective was to categorize 25 seed types according to factors that influence the growth of pathogens and the efficacy of chemical treatments to eliminate pathogens
- Use data to select one or two seeds per category that represent the worst-case scenario—the seed that would be hardest to sanitize in that category

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GROUPING OF SEED

How do we group seed?

- Water Activity Level
- Moisture Level
- Total Fat Content
- Total Protein Content
- Carbohydrate Content

Summary of the impact of these factors on the efficacy of chemical treatment

- Low moisture and low water activity
  - ➔**Higher bacterial resistance**
- High carbohydrate and high protein environment
  - ➔**Higher bacterial resistance**
- High fat environment
  - ➔**Higher bacterial resistance**

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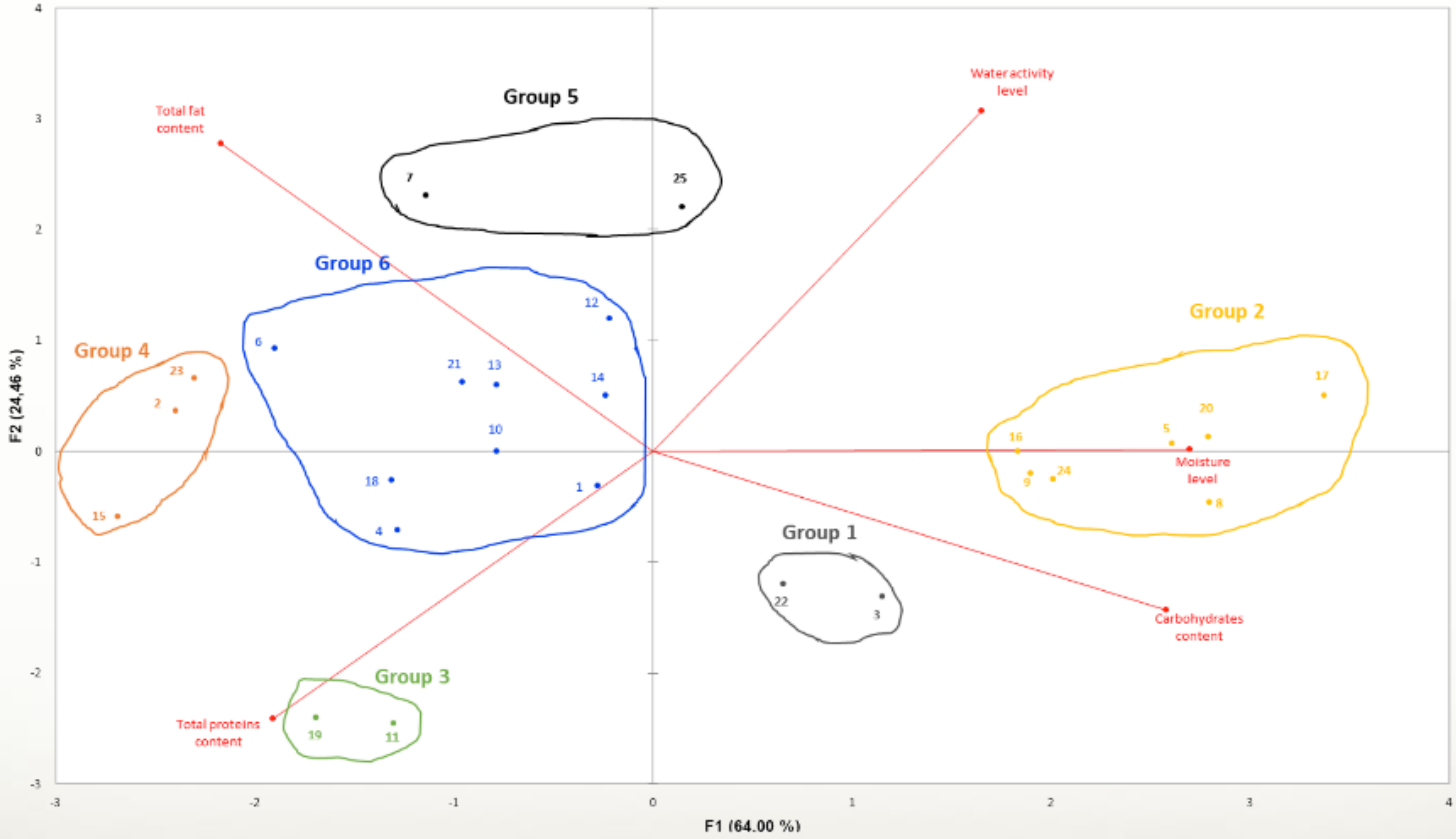
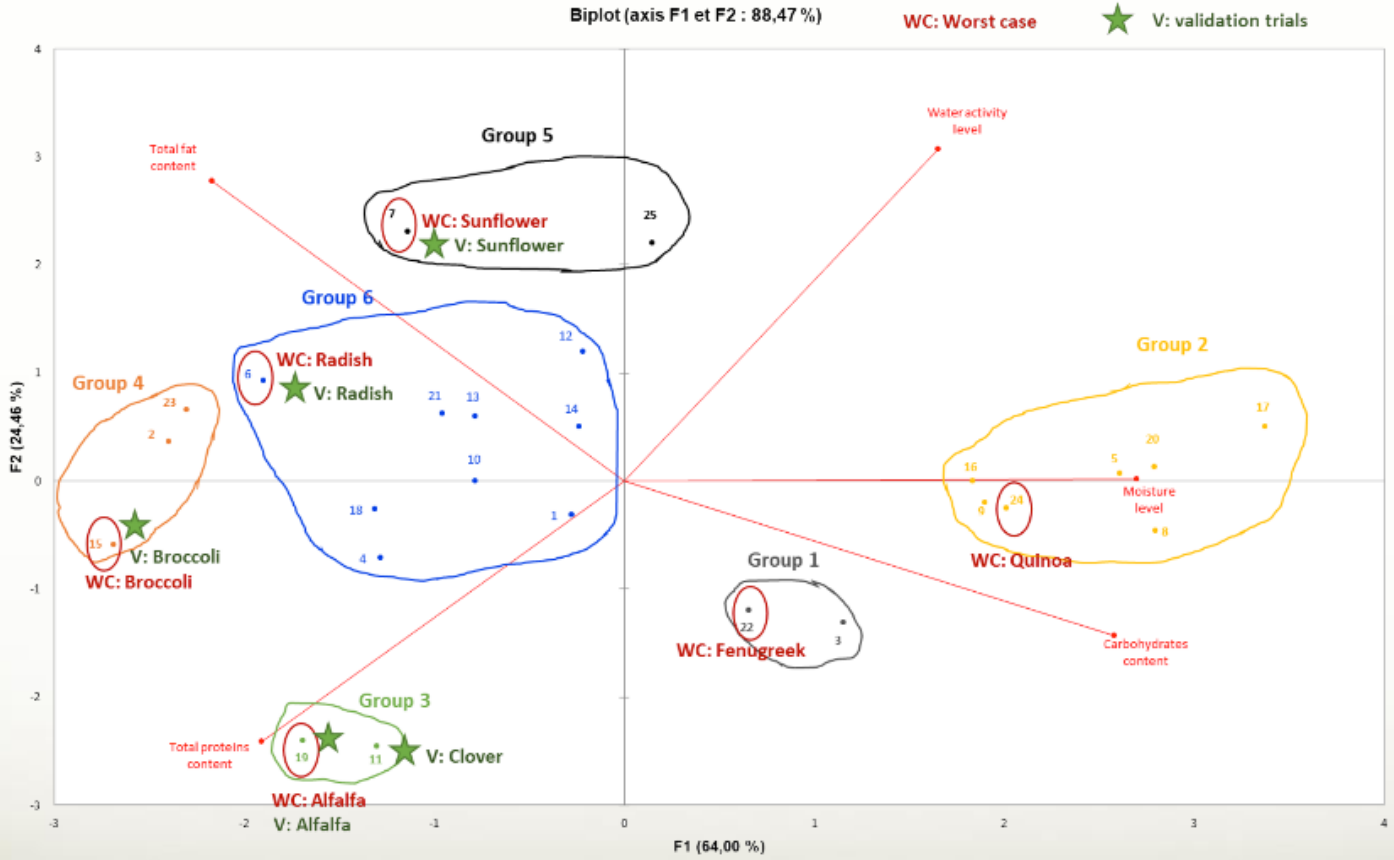
RESULTS

STATISTICAL ANALYSIS



RESULTS

IDENTIFICATION OF WORST CASE PRODUCT



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CONCLUSIONS

- ✓ SunGarden Seed is the first commercially-available seed that meets the January 2017 Proposed Guidance recommendation for a scientifically-valid prior treatment to reduce microorganisms of public health significance.
- ✓ SunGarden Seed is organic, eco-friendly, and can achieve a 5-log to 6-log pathogen reduction without significant impact on germination.
- ✓ Validating our system with Novolyze demonstrates that our process meets the FDA requirement for prior treatment of seed for sprouting.
- ✓ The Categorization Study allowed us to perform a smaller number of validation trials while demonstrating a high standard of efficacy across a range of seeds.

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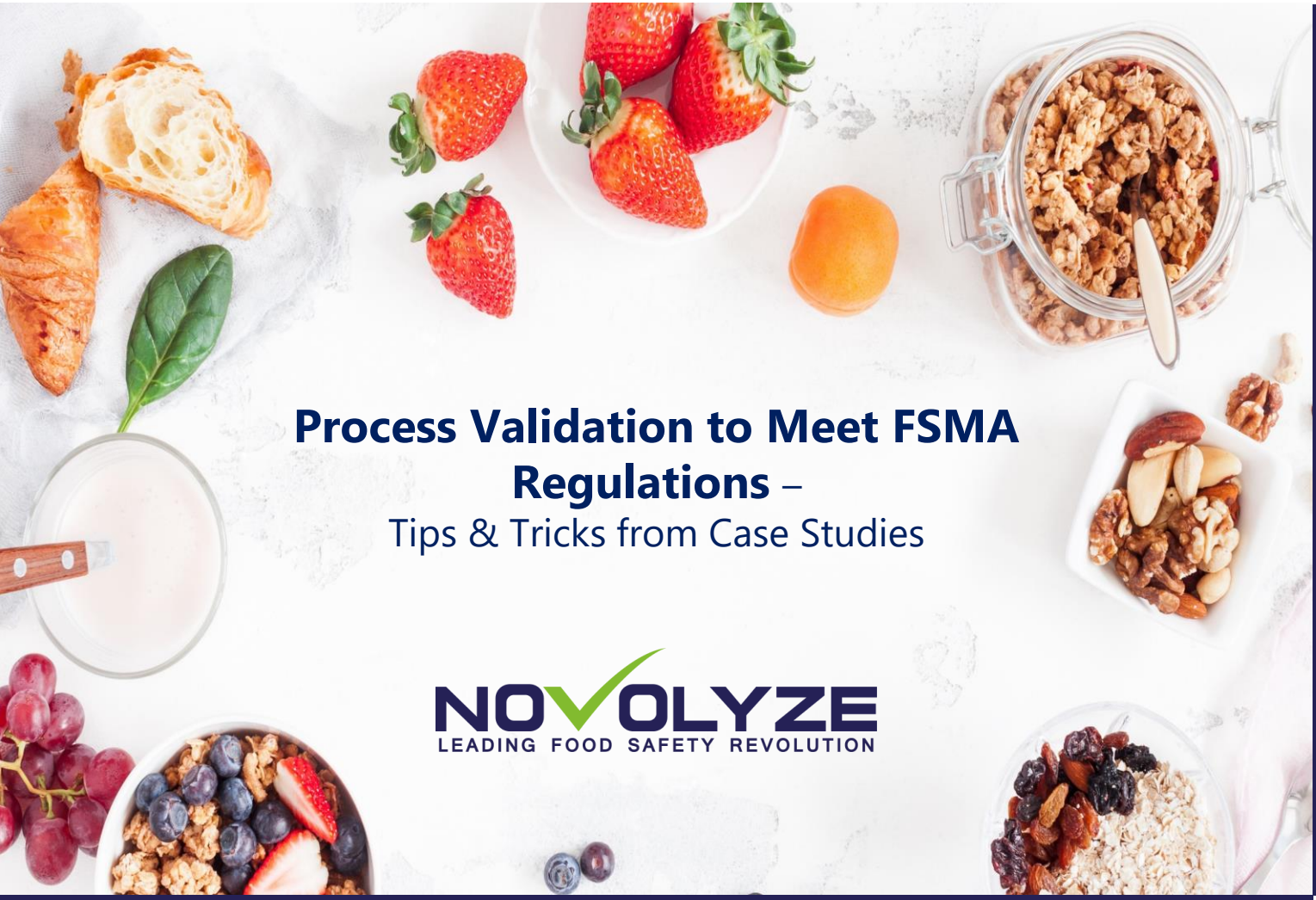

Process Validation to Meet FSMA Regulations –
Tips & Tricks from Case Studies

NOVOLYZE
LEADING FOOD SAFETY REVOLUTION

May 25, 2021

Session 1:

Defining the best strategy for the validation

Laure Pujol
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ABOUT NOVOLYZE

Improving Safety & Quality in Food Production Systems for a Sustainable Future

- Operations in **US** & **France –** Working **Worldwide**
- **Senior Team of Food Safety & Quality Professionals** (microbiologists, software engineers process authorities (PA), food engineers…)

NOVOLYZE
LEADING FOOD SAFETY REVOLUTION

Why validation?

Pathogen testing misses low prevalence bacteria such as *Salmonella*, *Listeria*, *E. Coli*, etc.

Product Pathogen Testing does not Make Food Safe (or Unsafe)

2017-2018 *Salmonella* Crisis
12M boxes recalled in 83 countries

"This recall will cost us several hundred million euros…we don't understand how the 16,000 analyses we did in 2017 didn't prevent the risk"

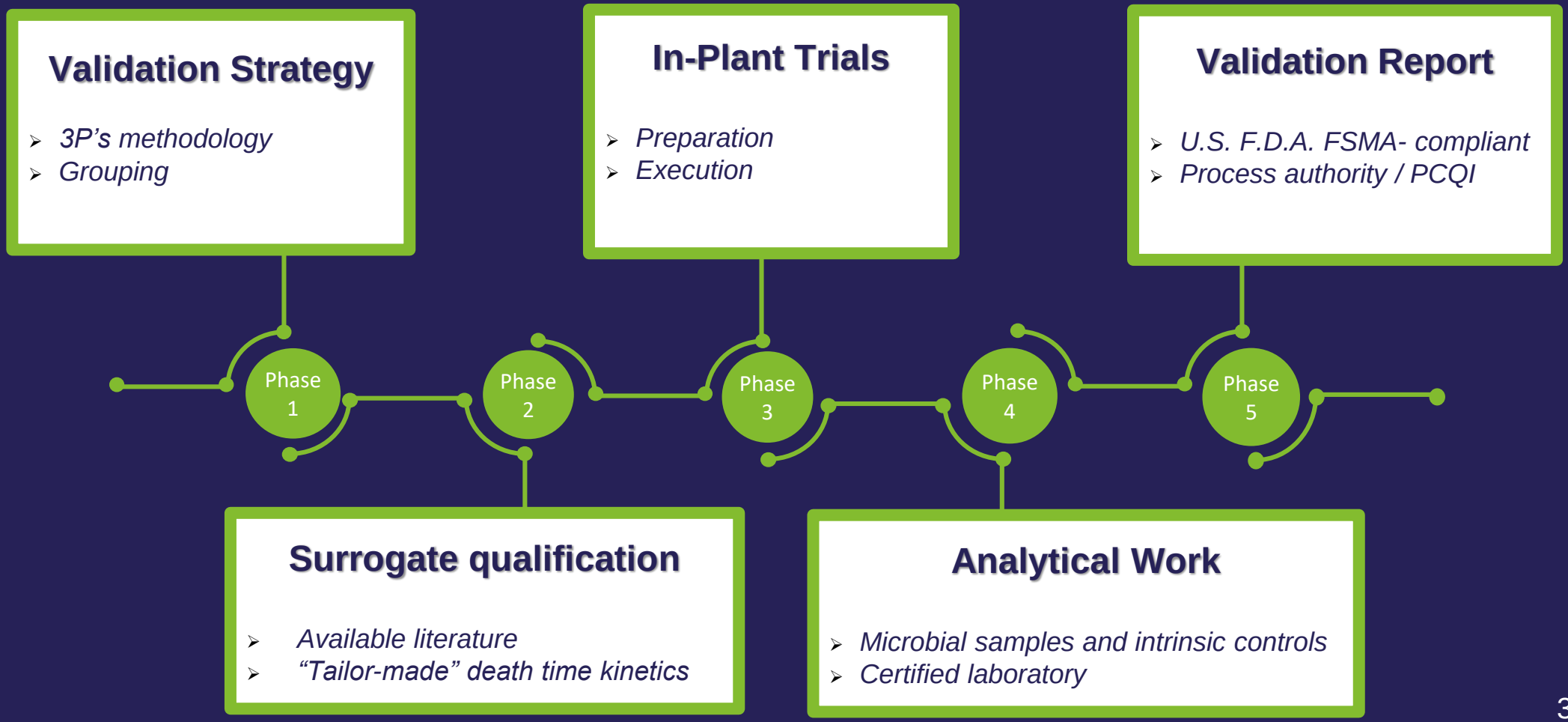
CEO of a Global Food Company

Validation

Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable **of controlling the hazard** to a specified outcome

- Scientific data from publication
- Mathematical modelling
- Benchtop trials at lab/pilot scale
- In plant microbial challenge studies using surrogate

In-Plant Process Validation Studies



VALIDATION STRATEGY

The 3 P's

PATHOGEN

PROCESS
Most conservative recipe

PRODUCT
Worst case

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Grouping kill-steps for the <u>same product</u>:

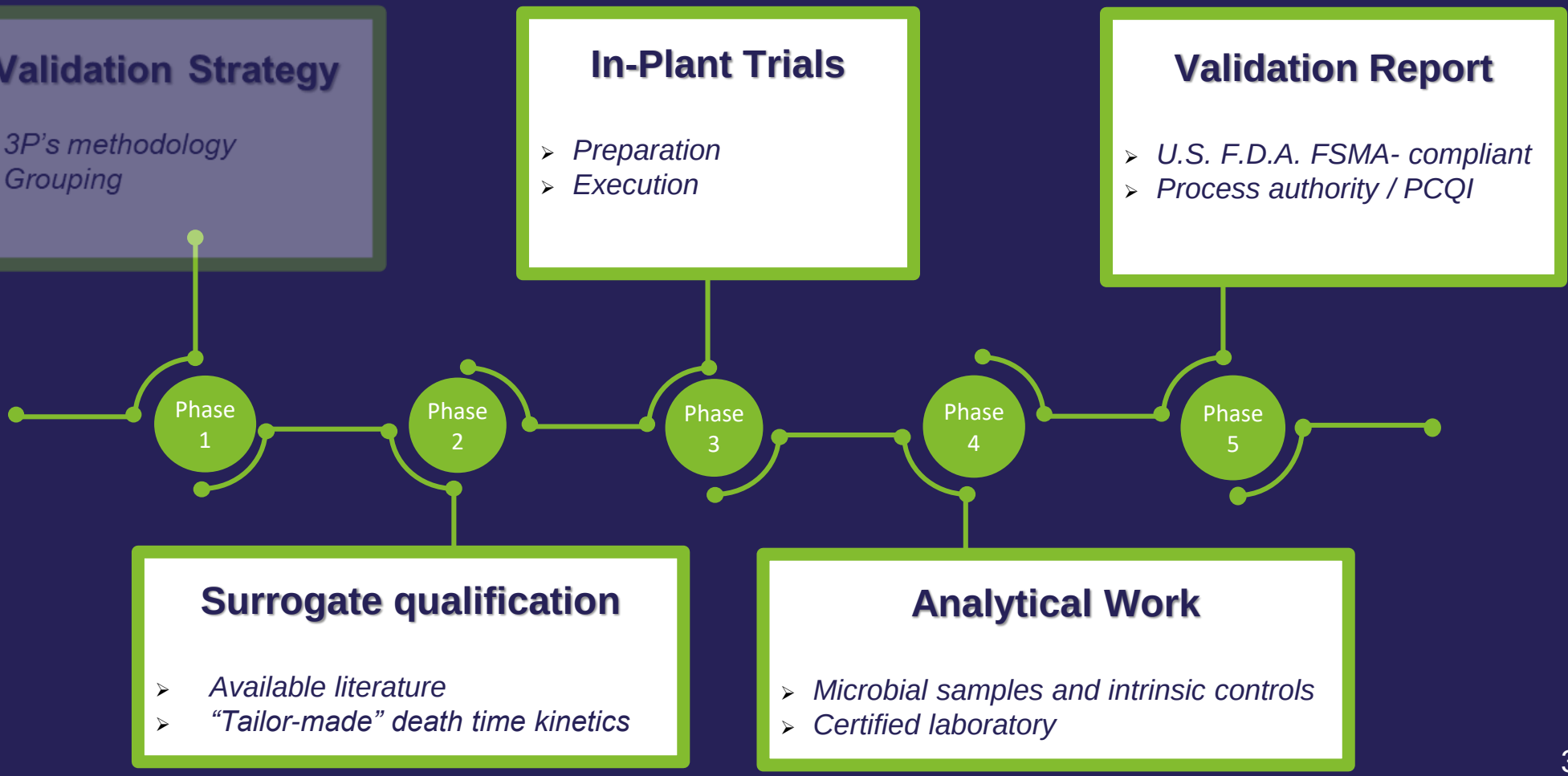
More relevant when the number of products per kill-step is low (e.g. cocoa)

Phase 1

Grouping products for the <u>same kill-step</u>:

More relevant when the number of products per kill-step is high (e.g. spices, herbs)

In-Plant Process Validation Studies



SURROGATE QUALIFICATION

Phase 2

Lots of available literature

Guidelines for Using *Enterococcus faecium* NRRL B-2354 as a Surrogate Microorganism in Almond Process Validation

Use of *Enterococcus faecium* as a Surrogate for *Salmonella enterica* during Extrusion of a Balanced Carbohydrate-Protein Meal

ANDREIA BIANCHINI,[1,2*] JAYNE STRATTON,[1,2] STEVE WEIER,[1] TIMOTHY HARTTER,[3] BRIAN PLATTNER,[3] GALEN ROKEY,[3] GERRY HERTZEL,[3] LAKSHMI GOMPA,[2] BISMARCK MARTINEZ,[2] AND KENT M. ESKRIDGE[4]

Inactivation of *Salmonella enterica* and Surrogate *Enterococcus faecium* on Whole Black Peppercorns and Cumin Seeds Using Vacuum Steam Pasteurization

*Jordan J. Newkirk, Jian Wu, Jennifer C. Acuff, Chris B. Caver, Kumar Mallikarjunan, Brian D. Wiersema, Robert C. Williams and Monica A. Ponder**

Radiofrequency pasteurization process for inactivation of *Salmonella* spp. and *Enterococcus faecium* NRRL B-2354 on ground black pepper

Xinyao Wei[a], Soon Kiat Lau[a], Jayne Stratton[a,b], Sibel Irmak[c,d], Jeyamkondan Subbiah[a,c,*]

ASTA Report on Surrogate Selection and Proposed Spice Groupings for Validation Studies

February 2019

Identification of a surrogate to validate irradiation processing of selected spices

E.V. Arias-Rios[a,d], G.R. Acuff[b], A. Castillo[a], L.M. Lucia[b], S.E. Niebuhr[c], J.S. Dickson[c,*]

INACTIVATION OF *SALMONELLA ENTERICA* AND *ENTEROCOCCUS FAECIUM* ON WHOLE BLACK PEPPERCORNS AND CUMIN SEEDS USING STEAM AND ETHYLENE OXIDE FUMIGATION

Jordan Jean Newkirk

Effect of Oil and Dry Roasting of Peanuts at Various Temperatures and Times on Survival of *Salmonella* and *Enterococcus faecium*

T.H. Sanders and R.S. Calhoun[1*]

Multilaboratory Comparison of Thermal Resistance of *Enterococcus faecium* and *Salmonella enterica* in Peanut Butter

Ian Hildebrandt[1], Shannon Pickens[2], Soon Kiat Lau[3], Jeyamkondan Subbiah[3], Nathan Anderson[4], Bradley Marks[1], Elizabeth Grasso-Kelley[2]

[1]Department of Biosystems and Agricultural Engineering, Michigan State University East Lansing, MI
[2]Illinois Institute of Technology, [4]Food and Drug Administration, Bedford Park, IL
[3]Biological Systems Engineering Department, University of Nebraska-Lincoln, Lincoln NE

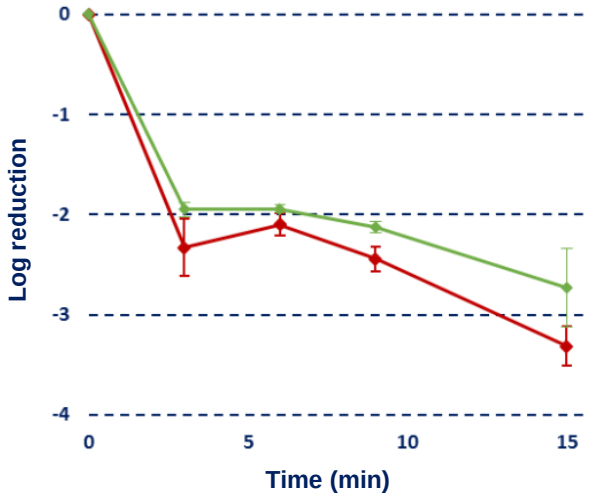
Enterococcus faecium As a Surrogate for _Salmonella_ in Thermal Treatment of Non-Fat Milk Powder

Shuxiang Liu[1], Nurul Ahmad[2], Ian Hildebrandt[2], Jie Xu[1], Elliot Ryser[2], Meijun Zhu[1], Bradley Marks[2], and Juming Tang[1*]
(1)Washington State University, Pullman, WA, (2)Michigan State University, East Lansing, MI

CASE STUDIES: Several Products

Phase 2

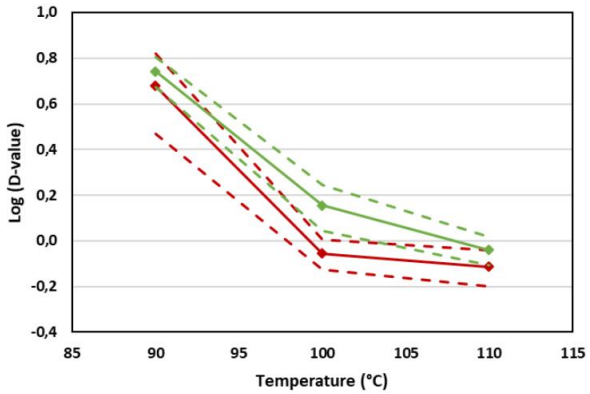
Cereal product



- Very close behavior at one temperature
- App 0.5 log difference

➔ **Appropriate surrogate**

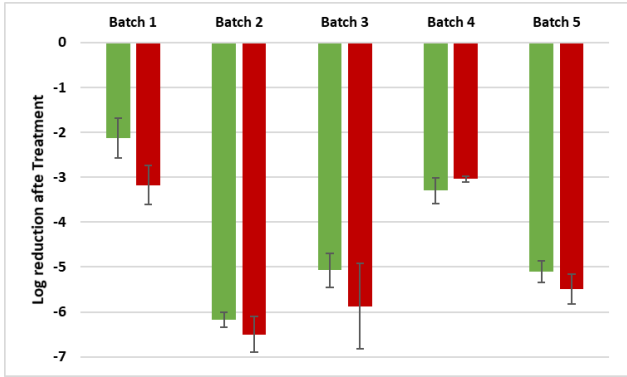
Spice product



- D-values very close at three temperatures

➔ **Appropriate surrogate**

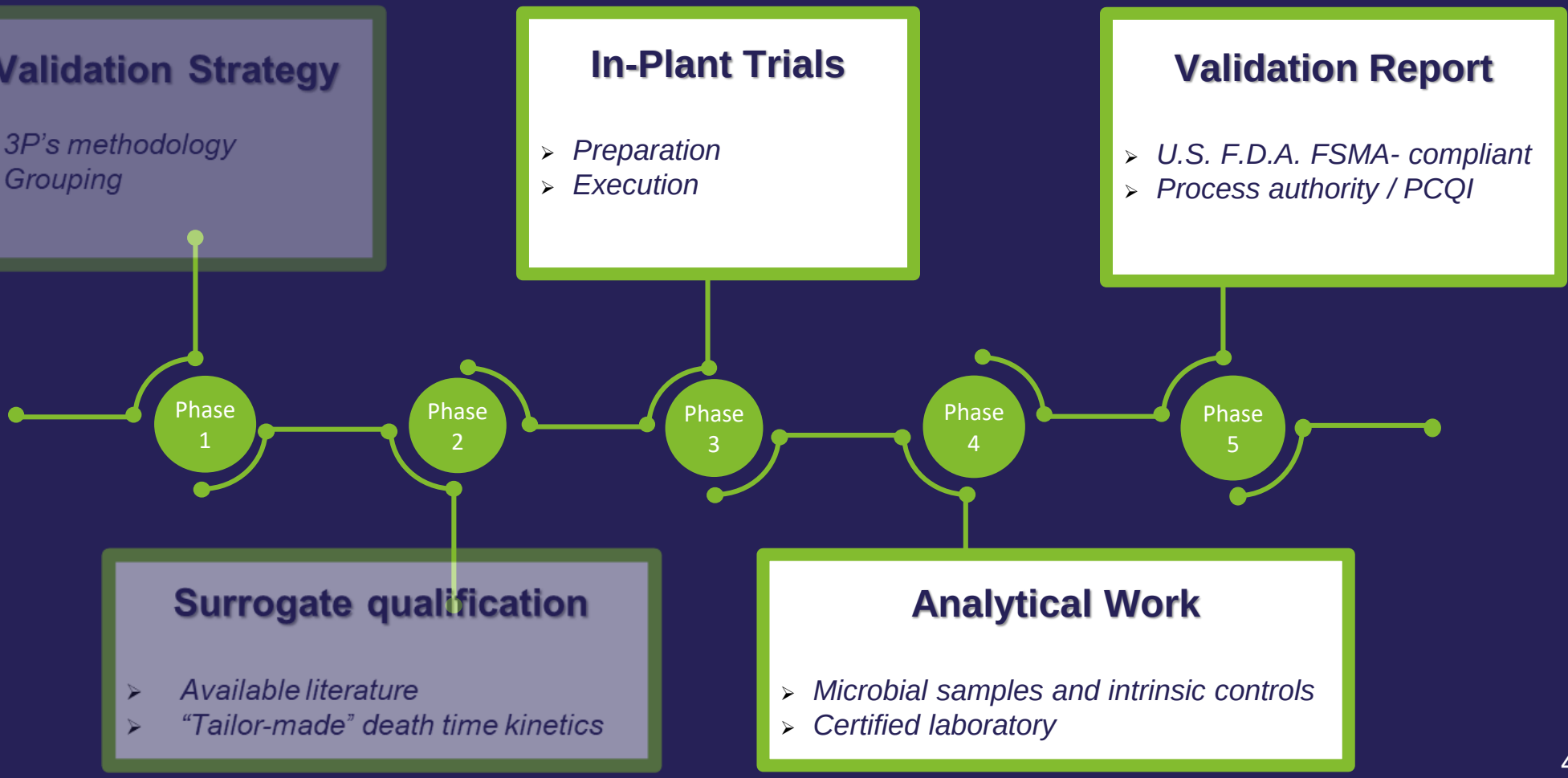
Cocoa product



- Log reduction close for a same treatment for different batch of product

➔ **Appropriate surrogate**

In-Plant Process Validation Studies



PREPARATION OF THE IN-PLANT TRIALS

- Identification of the **validation team**
- Identification of the supplier for all the **materials** needed (e.g. Surrogate)
- Identification of the **external lab** for the analysis
- **Protocol** to conduct the validation
- **Timeline**

An effective validation is a validation well prepared and planned with a dedicated team !!

Protocol to conduct the validation

(question to be answered prior to the execution)

Phase 3

- What is the process step that I need to validate, what are the process parameters that I want to test ?
- What is the product and its intrinsic properties before and after my treatment ?
- What is the inoculation strategy ?
- What are the samples that I need to collect ?
- Where should I place the inoculated product ?
- Where/when should I recover the inoculated samples ?

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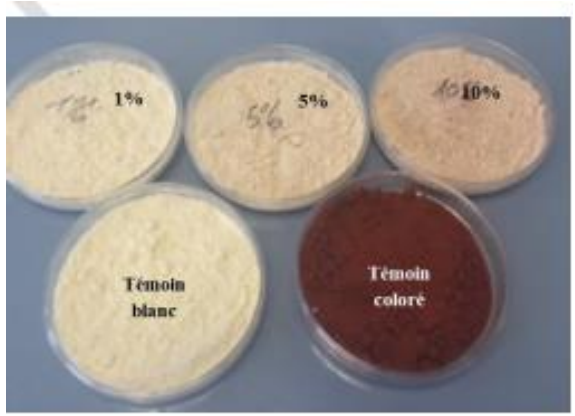
Case study: Residence time determination

Phase 3

Determine the exact time to sample at each stage

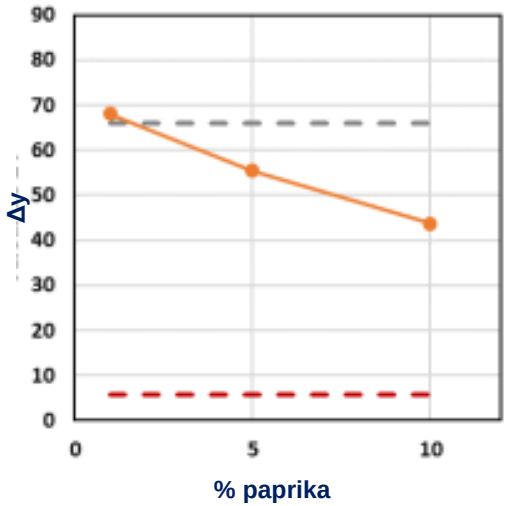
Determine the food matrix to color the flour

Paprika

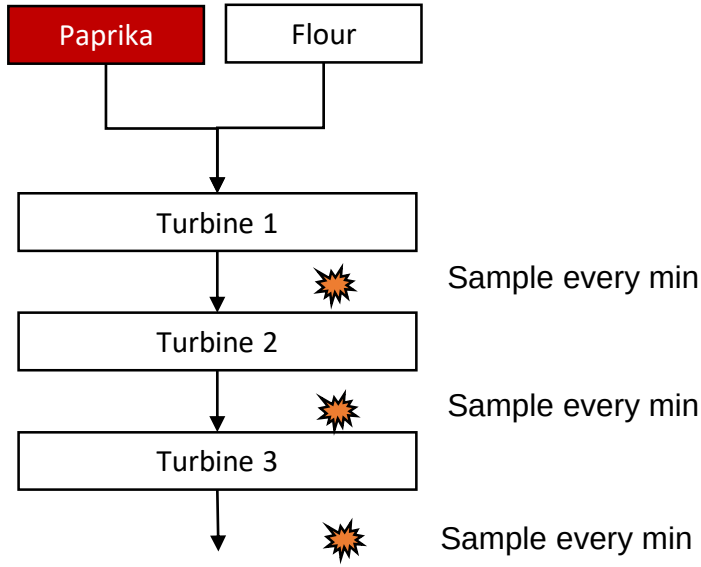


Determine the metric to follow to determine when the color appears

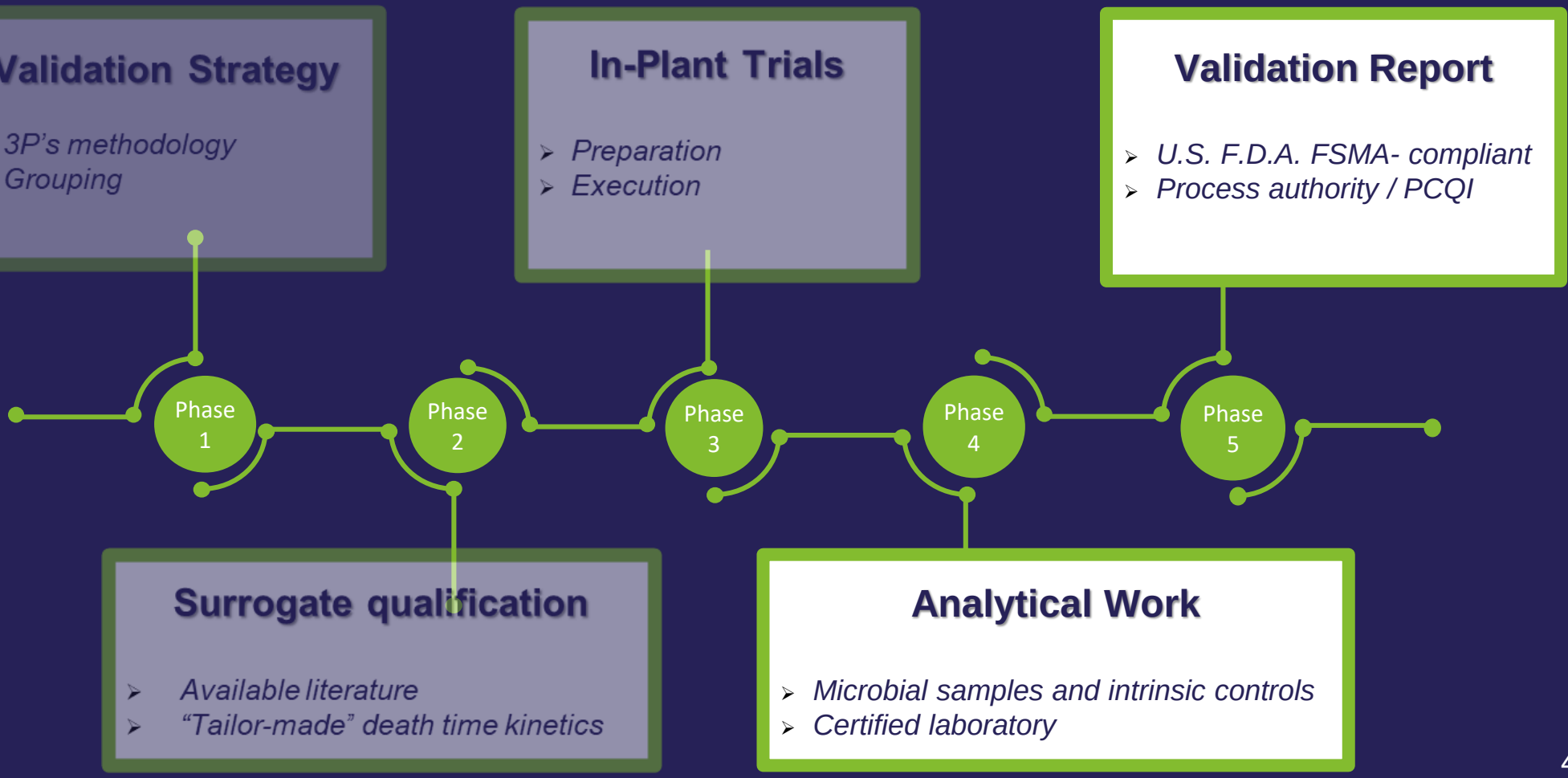
Colorimetry



Set up experimental design



In-Plant Process Validation Studies



ANALYTICAL WORK

- ***Certified Lab***
- ***External Lab***
- ***Transport from the facility at refrigerated temperature***
- **Enumeration to be started within 48h-72h**

Phase 3

STRATEGY

"Clean" Product	"Dirty" Product
TPC ≤ 10cfu/g	**TPC > 10cfu/g**
Non-Selective Enumeration **(Preferred)**	Overlay Enumeration with Selective Media

- 3-5 inoculated, non-treated controls per trial
- 10-20 inoculated, treated controls per trial
- 3 trials

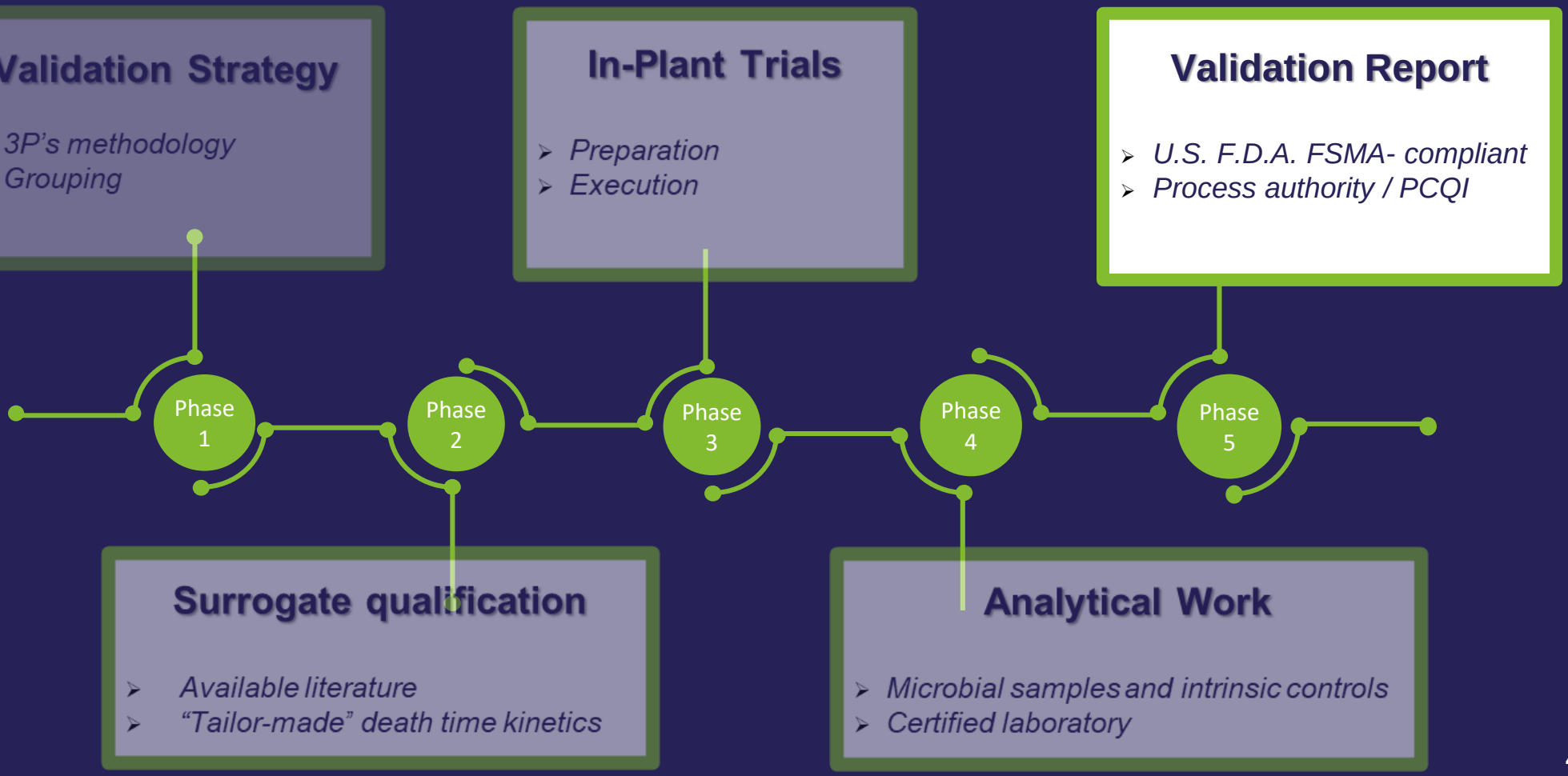
ANALYTICAL CONTROLS

Water Activity | **% Moisture** | **Fat Content**

+ Background Microflora

NOVOLYZE
LEADING FOOD SAFETY REVOLUTION

In-Plant Process Validation Studies



VALIDATION REPORT

- ***Written and reviewed by the validation team***
- ***Dated and signed***
- ***Clear statement of the achievement of the targeted log reduction***

To include

(not exhaustive list)

Phase 5

- Manufacturer information
- Product, process, parameters description
- Validation methodology applied (inoculation method and placement of the samples)
- Calculation of the log lethality
  - Assess the minimum log lethality achieved
  - Consistency of the results
  - Repeatability of the results
- Conclusion and identification of the critical parameters to achieved for further production

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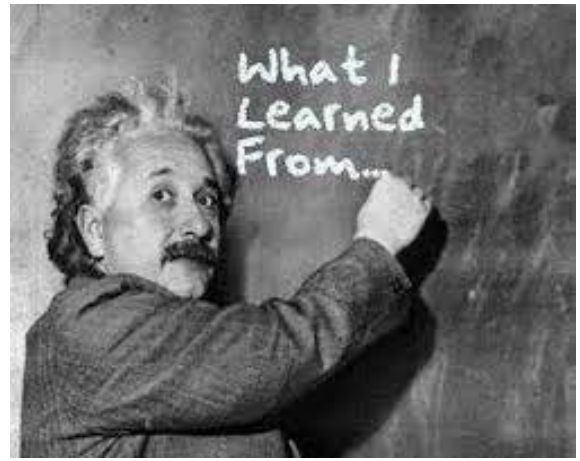
Take home message

- 3Ps' methodology need to be applied
- Each case is different, but the same approach can be applied

An effective validation is a validation well prepared and planned with a dedicated team !!



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Questions?

Questions should be submitted to the presenters via the **Questions section** at the right of the screen.

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