Process Validation to Meet FSMA Regulations – Tips & Tricks from Case Studies Part 2: In-Plant Validation

Moderator: Laure Pujol, Novolyze, France

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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.

Becky Douglas
Tree Top Inc., United States

Becky joined the Tree Top team in 2017 as a Senior Food Scientist. Prior to this, she spent the previous 15 years specialized in engineering solutions for food and nutraceutical manufacturing process and package systems. She holds a bachelor’s degree in Chemical Engineering from Oregon State University. Recently, her career has focused on fruit and the processes used to convert it into safe and delicious products. Becky is serving our industry with innovative solutions by tapping into her diverse processing expertise and scientific approach to all fruit matters. When Becky isn’t pondering the next fruit solution, she enjoys trail running and traveling with her husband.
Greg Sommerville  
*Frontier Co-Op, United States*

Greg has 19 years working in the global herb and spice supply chain and presently leads Frontier Co-op’s purchasing team. His responsibilities include food and flavor, essential oils and packaging along with managing supply chain, supply integrity and sustainability. Since 2017 Greg has been a qualified FSPCA Lead Instructor for FSVP and PC for human foods and over the years has been a Safe Quality Food (SQF) Consultant for high risk category, completed lead auditor training for BRC third party audits, holds a level 4 HACCP certification for food manufacturing from Campden BRI as well as working within several groups for GFSI and their schemes. Greg is presently on the BOD for the American Spice Trade Association and has worked through several committees within the association.

Jennifer Stivers  
*Frontier Co-Op, United States*

Jennifer is the Supply Integrity Manager for Frontier Co-op, and has more than 8 years of laboratory experience and 10 years of food industry experience. She received her BSc. in Microbiology from the University of Iowa, and worked in the field of cancer research before joining the team at Frontier. The first half of her career with Frontier was spent designing and implementing the microbiology lab and testing protocols, and she further worked as a major player on the team that achieved ISO 17025 accreditation for the Frontier quality labs. The second half of her career has been focused on food safety, internal auditing, building quality systems and regulatory compliance, including acting as the company’s SQF practitioner and PCQI, and validating many programs and processes – most notably, leading Frontier’s steam pasteurization process validation.
Process Validation of Steam Pasteurization

Frontier Co-op

June 2021
Mission

“Nourish People and Planet. Always Be Fair.”
Company Background

- Founded 1976
- Headquarters – Norway, IA (Cedar Rapids)
- ~$200 MM in sales
- 5 year Compound Annual Growth Rate → 14%
- 700+ employees
- Cooperative owned by wholesale customers

- Frontier and Simply Organic #1 in US natural products channel, #2 in US grocery organic channel
- Aura Cacia #1 in US natural channel
- Plant Boss new to market
The Beginning - 1970

[Images of a small wooden house and a group of people posing outdoors in the 1970s.]
The Now

Frontier Co-op now has 4 facilities in Iowa
- Norway
- North Liberty
- Urbana
- Belle Plaine

North Liberty
Operate cleaning, blending, grinding
2 Imtech batch sterilizers
The Challenge

- 2735 items purchased
  - 2011 packaging
  - 226 essential
  - 478 herbs, spices, ingredients
  - 20+ co-pack items
- Where possible all items to be processed through a validated kill step
- No chemical treatment allowed
  - No ETO
  - No PPO
  - No irradiation
- Internally 154 items that Frontier

- FDA requires validation (21 CFR 117.160)
  - Guidance for Industry: Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods (Docket No. FDA-2011-D-0091)
    - Validate any treatment or process used to “adequately reduce” Salmonella spp. in a food
      - ...we use the phrase “adequately reduce” to mean reducing the presence of Salmonella spp. to an extent sufficient to prevent illness... determined by the estimated extent to which Salmonella spp. may be present in the food combined with a safety factor... a process adequate to reduce Salmonella spp. would be a process capable of reducing Salmonella spp. by 5 logs per gram of food
• Obtain and evaluate scientific and technical evidence the control measure is capable of effectively controlling the identified hazard

• IQ / OQ / PQ
  – Installation qualification
  – Operational qualification
  – Performance qualification
Validation Planning

• Establish the scope of validation
  – What is being validated?
    • Pathogen
    • Process
    • Products
Worst Case Scenarios

• Establish worst case scenarios to challenge the system
  – What makes a worst case scenario?
    • Low Aw/low moisture;
    • High oil or fat content;
    • Large particle size; and/or
    • Product density
The Additional Challenge

- How to obtain and evaluate scientific and technical evidence our control measure is capable of effectively controlling the identified hazards?
  - Dry, low moisture food challenge
  - In-plant validation is best, cannot use pathogens in that setting
  - Surrogate solution with Novolyze
Product Categorization and Grouping

- Steam pasteurization of >150 various herbs and spices
  - List and categorize products
  - Define properties and characteristics
    - Product type (leaf, seed, root, bark, berry, etc.)
    - Particle size
    - Bulk density
    - Moisture/water activity
    - Oil and/or fat content
    - pH
- Factors which increase heat resistance in *Salmonella* organisms are: low water activity/moisture, high oil/fat content, neutral pH
Thermodynamics

• Consider thermal kinetics and heat transfer in relation to the process and properties of the various herbs and spices
  – Think about how the process interacts with the product
    • Large particle size; and/or
    • Product density
In-plant Validation – Tips and Tricks

- Prior planning prevents poor performance (map it out, start to finish!)
- Work with plant operations, quality and planning teams, etc. to schedule validation activities
- Push the limits to prove that the process will provide the intended outcome
  - Critical limits are the *minimum* for the process pathogen reduction, to be met or exceeded operationally
In-plant Validation – Tips and Tricks

• Inoculation strategy
  – Low microbial material that is not naturally antimicrobial
  – Large particles prove to be a challenge when working with a dry powder
  – Ensure proper temperature controls and avoid delays in holding of samples
• Untreated, inoculated controls must be used to prove the presence of viable organisms to begin with
• Perform process in triplicate, test samples in duplicate
What if in-plant validation is not an option?

- Review of literature and scientific data
- TDT, D- and z-values
- Thermal mapping of process
- Laboratory studies with product/pathogen
- Documented analysis and correlation
Validation Report and Certificate Sharing

• Report should be written by a process authority with knowledge and unbiased analysis of results
  – Objective
  – Diagram of process with temperature mapping details
  – Calibrated equipment certificates
  – References
  – Product grouping decisions
  – Materials and methods
  – Test organism reasoning and type
  – Inoculation process
  – Processing recipes and methods
  – Microbiological analysis
  – Results analysis and conclusions

• Certificate provides option of maintaining confidentiality while also providing documented evidence of process efficacy and validation
Questions?

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Validation of a Legacy Process
Tips for Success

Summer 2021
My Validation Experience

Tree Top dries cut apples to low (2%) and intermediate (18%) moisture products through a consecutive series of forced air ovens. Drying plant was purchased in 1968 and process was rebuilt after a fire in 1976.

A validation study conducted with the National Food Labs (NFL) in 2012 estimated 4.0 log reduction of salmonella pathogens within a single oven.

Starting in 2017 we began the task of revalidating the process controls for our forced air convection ovens.
Tip #1 – Ask a Few Questions

- Who
- What
- When / How long
- Where
- Why
- How Much
- What’s included
- What’s not included
## Tip #2 – Build a Team

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Tip #3 – Ask Many More Questions

- How does the system work
- How does the system not work
- Normal and Extreme Operating Conditions
  - Environment
  - Ingredient
- Settings
  - What is controllable?
  - What is uncontrollable?
- Impact to Process
  - What makes a difference?
  - What does not?
Process Transformation Types

- Heat
- Concentrate
- Mix
- Move
- React

- Cool
- Dilute
- Separate
- Store / Hold
- Preserve
Process Description

Inputs
- Raw Apples
  ~85-86% Moisture
  Micro load
  Acid Concentration
  Sugar Concentration
- Air
- Natural Gas
- Electricity

Variables: Air Temp, Fruit Temp, Gas Flow, Air Flow, Humidity, Time, and many others

Black Box “Process”

Outflows
- Water & VOCs
- Heat
- Air
- Dried Apple Pieces
  ~1-2% Moisture
  Micro load
  Acid Concentration
  Sugar Concentration
Tip #3: and Collect Process Data

• Incoming Micro Load
• Conditions
  – Environment
  – Ingredient
• Settings
  – Controllable
  – Uncontrollable but measurable
• Measurement
  – What is recorded?
  – What will you have to record?
Tip #4 – Test it Out
Tip #5 – Start Small, Then Go Big
Tip #5 – Start Small, Then Go Big

A bench-scale test can sometimes provide you with a reasonable degree of certainty in your scaled up process.
Tip #5 – Start Small, Then Go Big
Review

- Ask a few questions to understand the project at hand
- Build a team that can help you work through the various aspects of the validation
- Ask a lot of questions about the process, product, and challenges faced
- Collect as much process data as you can before you validate
- When in doubt, test it out!
- Start with a small scale, then move to the larger system
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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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