


International Association for Food Protection®

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

Moderator: Laure Pujol, Novolyze, France

Sponsored by the IAFP FOUNDATION

Please consider making a contribution

This webinar is being recorded and will be available to IAFP members within one week.

International Association for Food Protection® WEBINAR


International Association for Food Protection®

Webinar Housekeeping

- For best viewing of the presentation material, please click on ‘maximize’ in the upper right corner of the ‘Slide’ window, then click ‘Escape’ to return to normal view.

- 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.

International Association for Food Protection® WEBINAR


International Association for Food Protection®

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.

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

International Association for Food Protection® WEBINAR

Today's Participants

Laure Pujol, Novolyze, France
Novolyze, United States

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.

Today's Participants

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

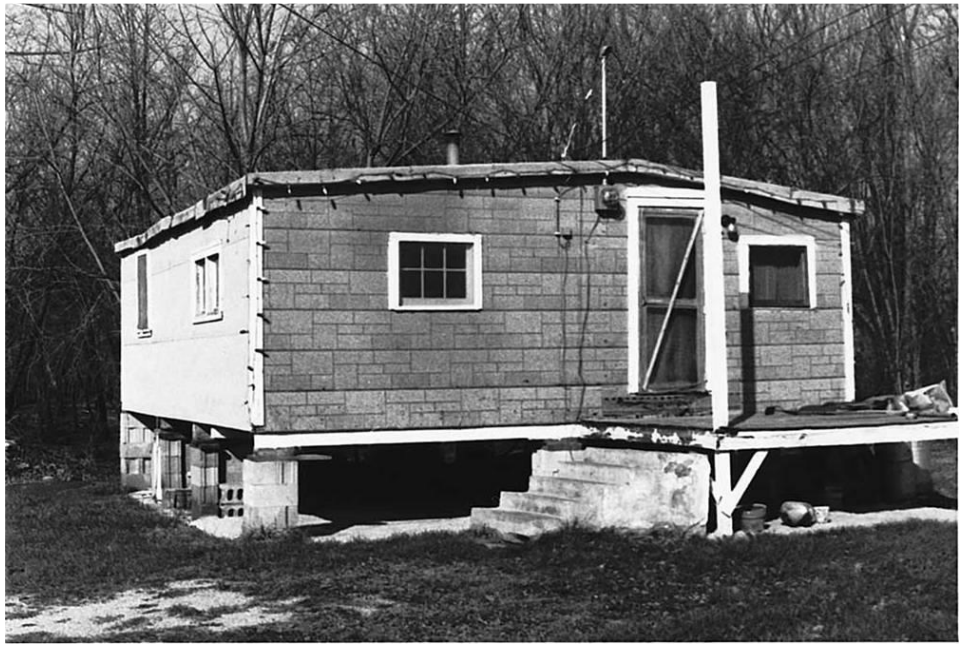
"Nourish People and Planet. Always Be Fair."

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



The Now

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

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

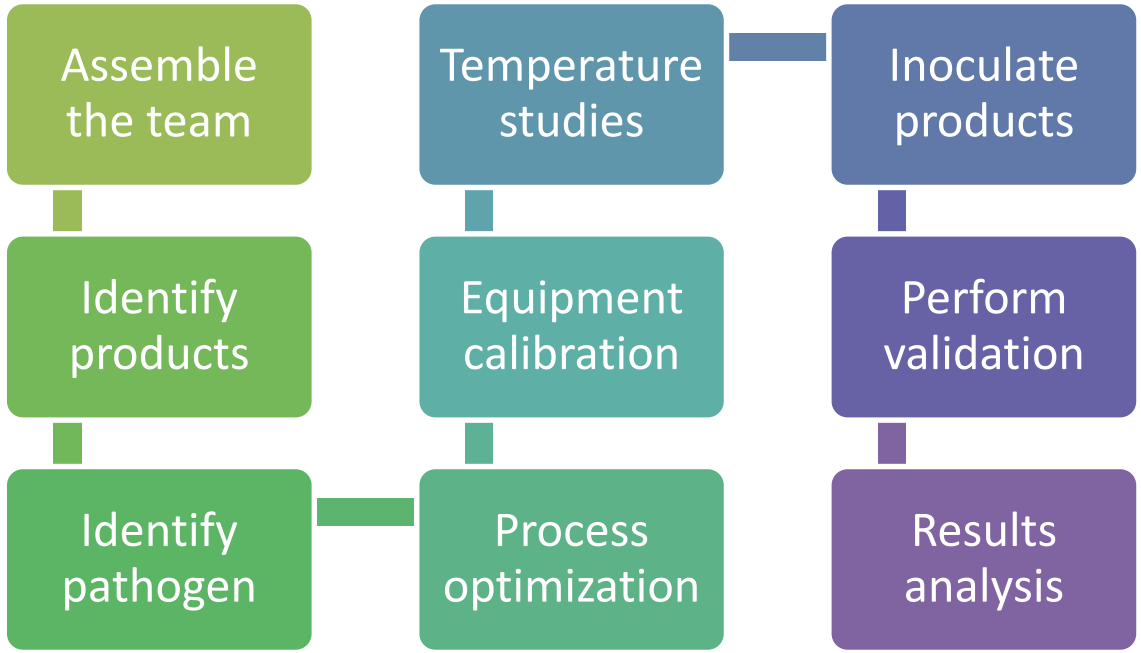
The Challenge

- 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

Process Validation

- 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

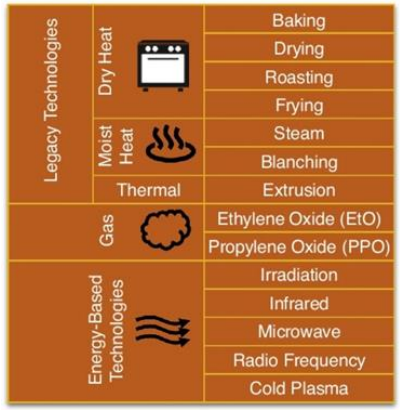


Validation Planning

- Establish the scope of validation
  - What is being validated?
    - Pathogen
    - Process
    - Products

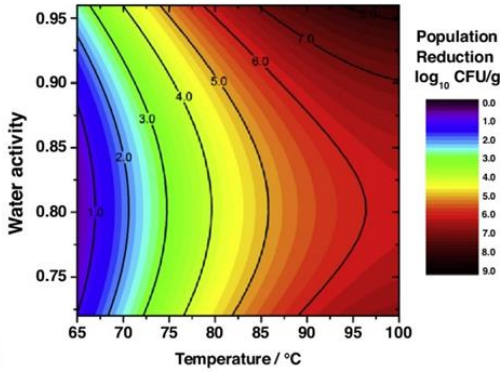
Initial number of the most resistant microorganism of public health significance per gram of food	Log reduction (also known as D)	Decrease in most resistant microorganism of public health significance per gram of food	Percent of change	Final number of bacteria per gram of food
10,000 or log 4[1]	1	10-fold	90%	1,000 or log 3
10,000 or log 4	2	10 X 10 = 100 fold	99%	100 or log 2
10,000 or log 4	3	10 X 10 X 10 = 1000-fold	99.9%	10 or log 1
10,000 or log 4	4	10 X 10 X 10 X 10 = 10,000-fold	99.99%	1 or log 0

Pasteurization Processes



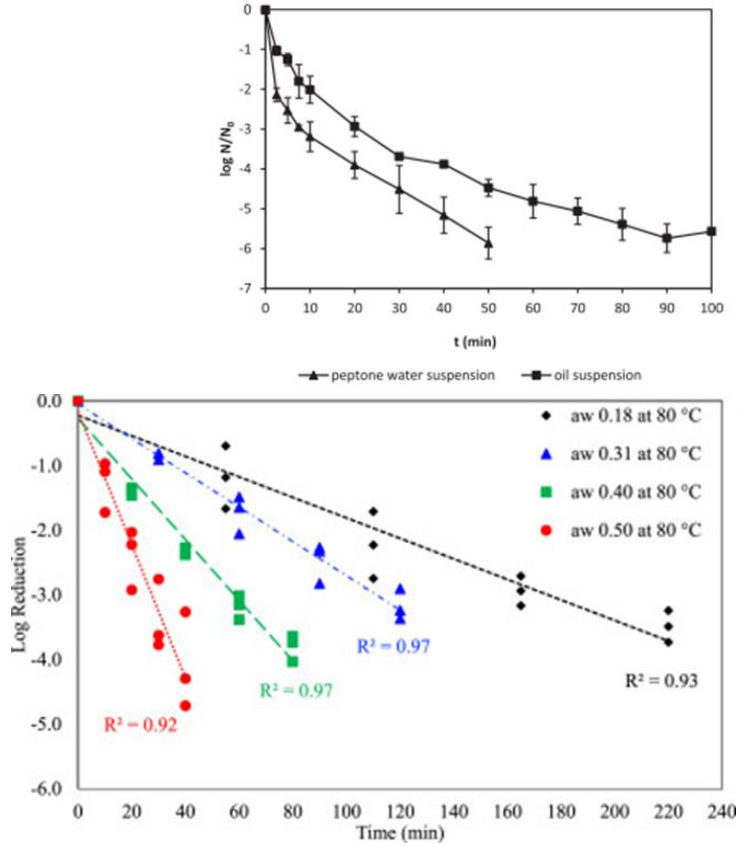
Low-Moisture Foods + Ingredients

Pathogen Reduction



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

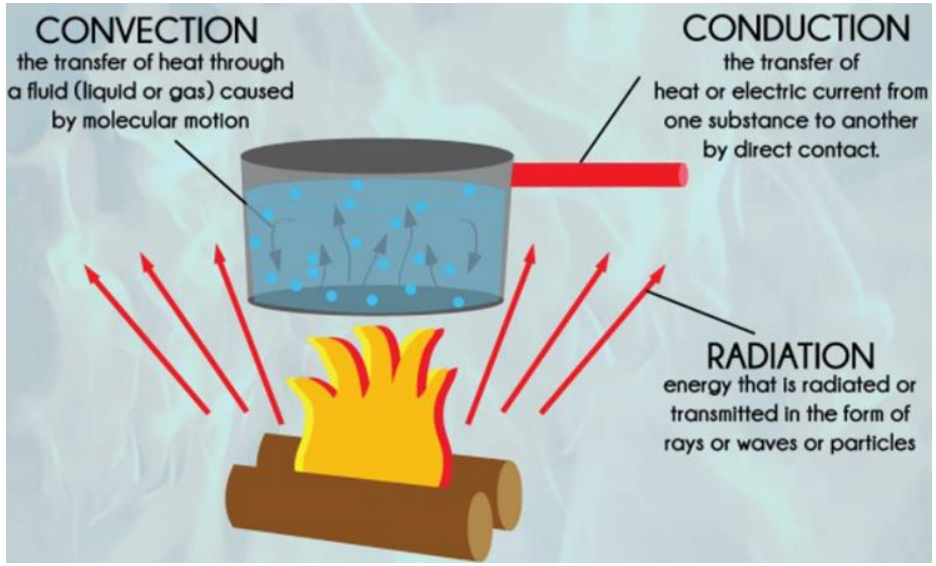
- How to obtain and evaluate scientific and technical evidence our control measure is capable of effectively controlling the identified hazards?
  - Dry, low moisture food challenge
  - In-plant validation is best, cannot use pathogens in that setting
  - Surrogate solution with Novolyze

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

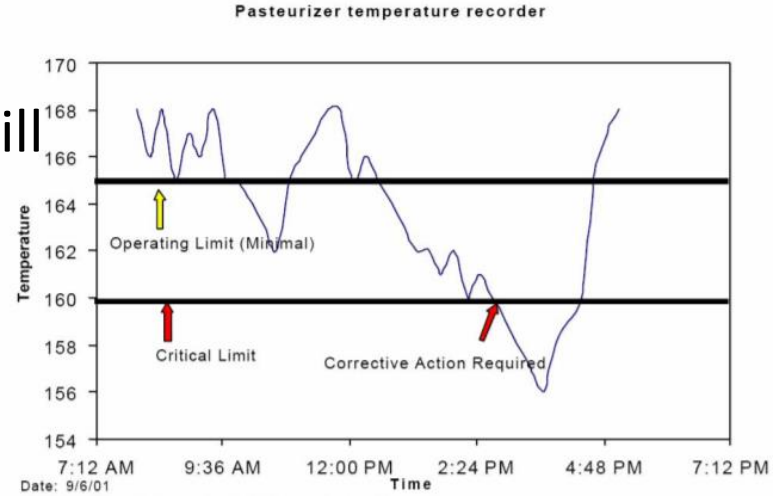
Thermodynamics

- 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?

Greg Sommerville

VP Global Procurement

Frontier Co-op

3021 78th St. Norway, IA 52318

+ 1 319-227-7996 ext. 5457

Whatsapp: +1 345-547-7444

www.linkedin.com/in/greg-sommerville-29a412a/

Jennifer Stivers

Supply Integrity Manager

Frontier Co-op

3021 78th St. Norway, IA 52318

+ 1 319-227-7996 ext. 1195

Mobile: +1 319-640-5831

www.linkedin.com/in/jennifer-stivers-13907695/

www.auracacia.com

Aura Cacia. pure essential oils

www.frontiercoop.com

FRONTIER® CO-OP MEMBER OWNED SINCE 1976

www.simplyorganic.com

Simply Organic.

www.plantboss.com

PLANT BOSS™

TREE TOP®

Grower Owned Since 1960

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

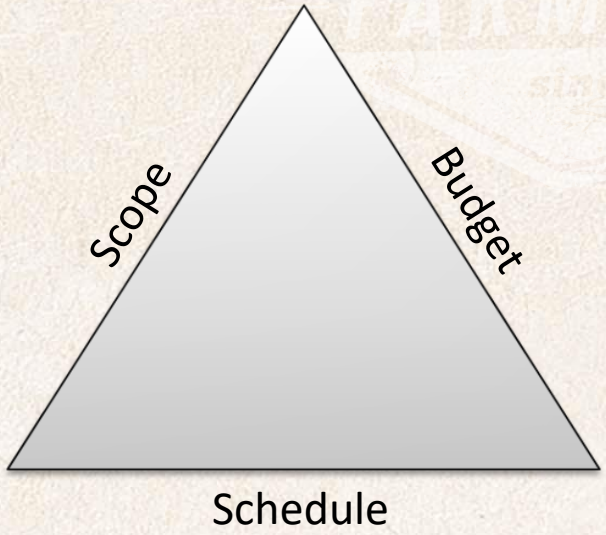
A validation study conducted with the National Food Labs (NFL) in 2012 estimated 4.0 log reduction of salmonella pathogens within a single oven.

Starting in 2017 we began the task of revalidating the process controls for our forced air convection ovens.

TREE TOP Grower Owned Since 1960

Tip #1 – Ask a Few Questions

- Who
- What
- When / How long
- Where
- Why
- How Much
- What's included
- What's not included



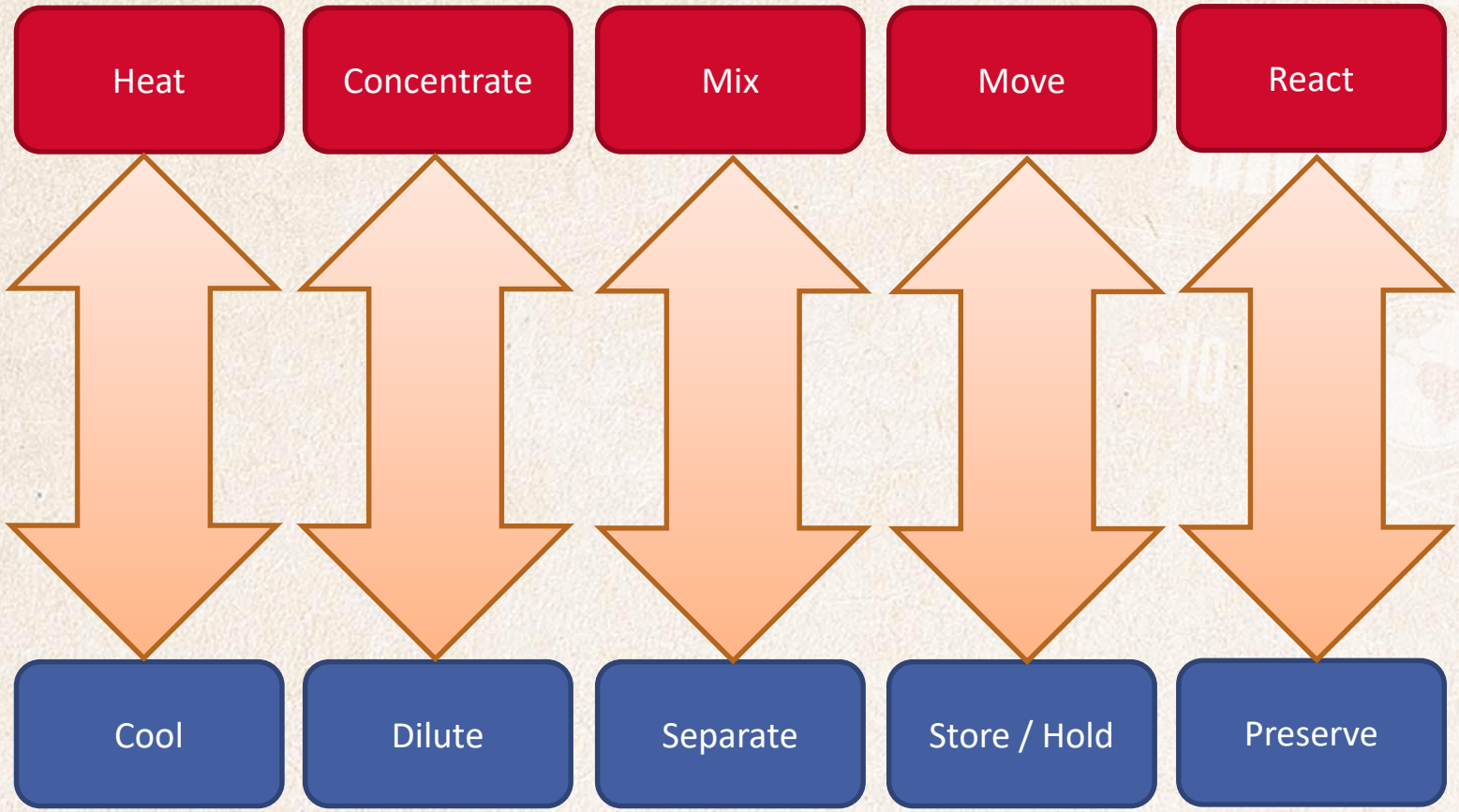
Tip #2 – Build a Team

Published Guidance	Research Institutions	External Partners	Internal Gang
• OpX • IAFP, IFT • USDA FSIS, FDA • White papers	• Institute for Food Safety and Health (IFSH) • Agricultural University Food Programs	• Novolyze / Microbe Supplier • Original Equipment Mfg • Customer Resources	• Quality Control / Assurance, Operations, Maintenance, Sanitation, Scheduling, Planning, Shipping • Regulatory, Engineering, Management, R&D

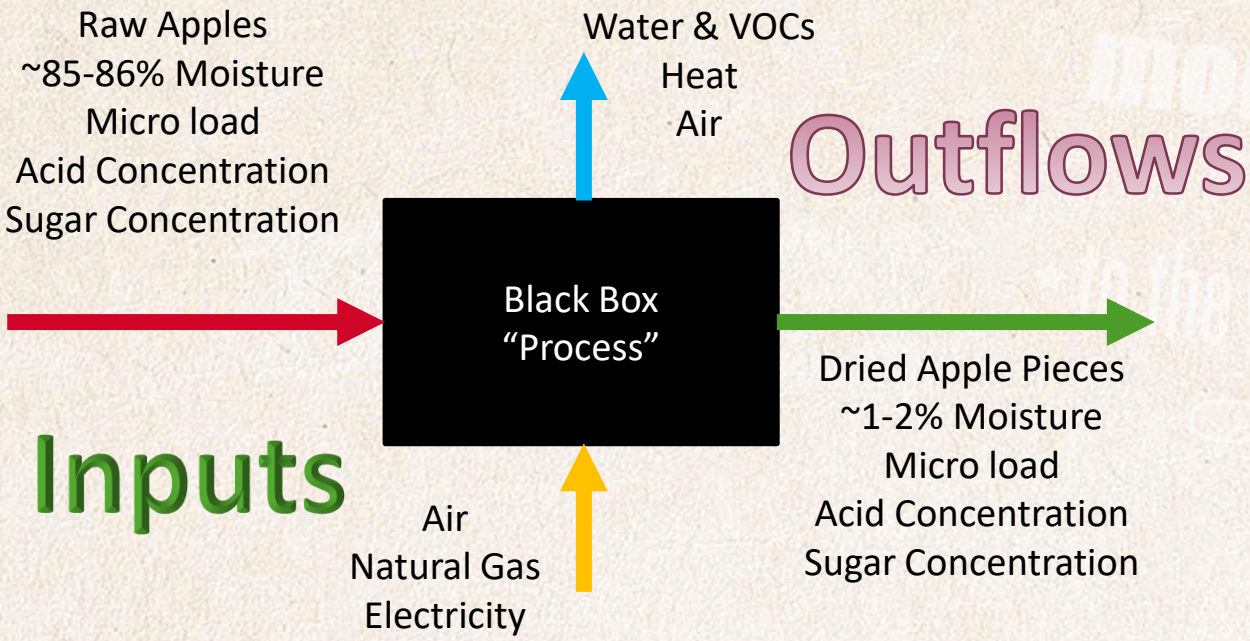
Tip #3 – Ask Many More Questions

- 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



Process Description

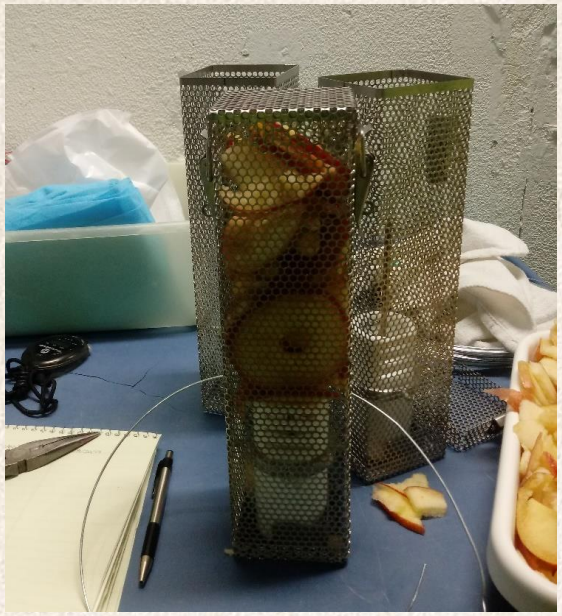


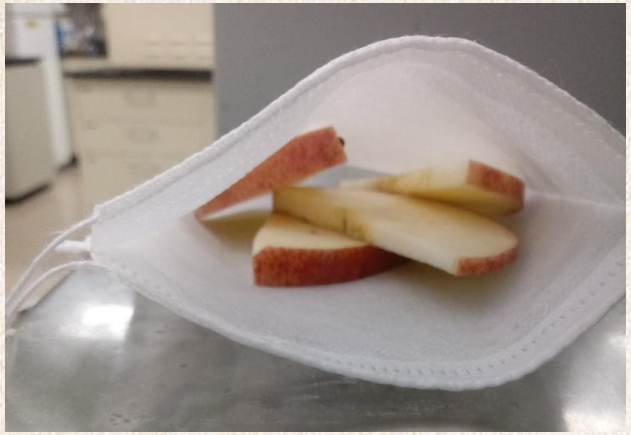
Variables: Air Temp, Fruit Temp, Gas Flow, Air Flow, Humidity, Time, and many others

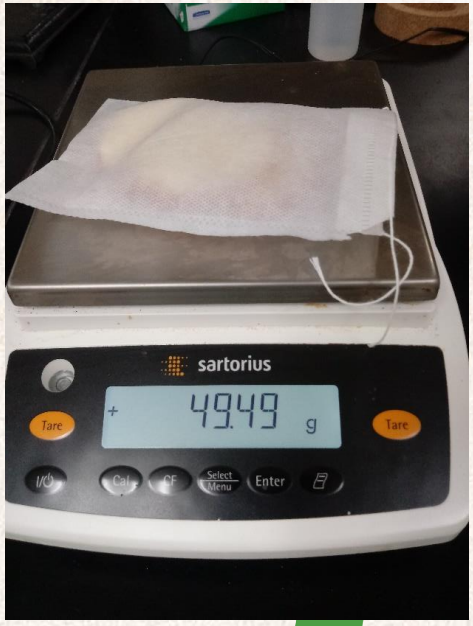
Tip#3: and Collect Process Data

- 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







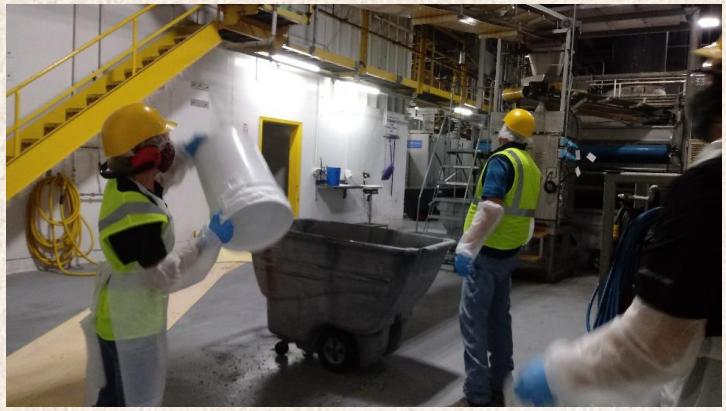
Tip #5 – Start Small, Then Go Big

TREE TOP
Grower Owned Since 1960

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



TREE TOP® Grower Owned Since 1960

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

Contact: Becky.Douglas@treetop.com

TREE TOP
Grower Owned Since 1960


International Association for Food Protection®

Questions?

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

International Association for Food Protection® WEBINAR


International Association for Food Protection®

Contact Information

- becky.douglas@treetop.com
- greg.sommerville@frontiercoop.com
- jennifer.stivers@frontiercoop.com
- laure.pujol@novolyze.com

International Association for Food Protection WEBINAR


International Association for Food Protection®

Join us for these upcoming webinars

June 29 Connecting Processing Systems to Optimize Productivity and Reduce Waste While Achieving Higher Compliance

July 7 GFSI Race to the TOP- Feature 1 Auditor Training and Professional Development

July 8 Using Assessment Data to Make Effective Risk Based Food Safety Decisions

International Association for Food Protection® WEBINAR


International Association for Food Protection®

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

Not a Member? We encourage you to join today.
For more information go to:
www.FoodProtection.org/membership/

All **IAFP webinars** are supported by the IAFP Foundation with no charge to participants.

Please consider making a donation to the **IAFP Foundation** so we can continue to provide quality information to food safety professionals.

IAFP FOUNDATION

International Association for Food Protection® WEBINAR