A SAFE PROCESS THROUGH VALIDATION

NPSA SHELLERS FORUM

ORLANDO,FLORIDA

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PRESENTED BY

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A Brief Look Into History

2001 OUTBREAK IN CANADA

PHAGE TYPE 30

SALMONELLA entriditis

PHAGE TYPE 9C

2004 OUTBREAK IN OREGON

What Is A Process Authority

- Demonstrate educational requirements and experience to evaluate the effectiveness of a process to reduce the levels of salmonella.
- Apply standardized inoculation and testing procedures.
- Understand the process, develop temperature profiles.
- Submit detailed report to TERP.
- Obtain validation certificate.

Processes Almonds and Pecans Have In Common

- Hot water treatment---2 minutes @190°F.
- Oil Roasting --- 2 minutes @260°F.
- Propylene Oxide (PPO) treatment ---.5 ounces/ft^3

What is 4-Log & 5-log

- What is a Log? Count the zeros (10=1 log,100= 2 logs)
- 4 -log ⟶ 10,000 fold ABC requirement
- 5 –log ⟶100,000 fold to label as pasteurized(FDA)
- Importance of “Risk Assessment” based on the pathogen contamination level of pecans.
  - For example, almond contamination averaged .85% and the Risk Assessment suggested a 4-log would be safe.
  - If pecans have a lower level of contamination ,the Risk Assessment may suggest something lower than a 4-log.

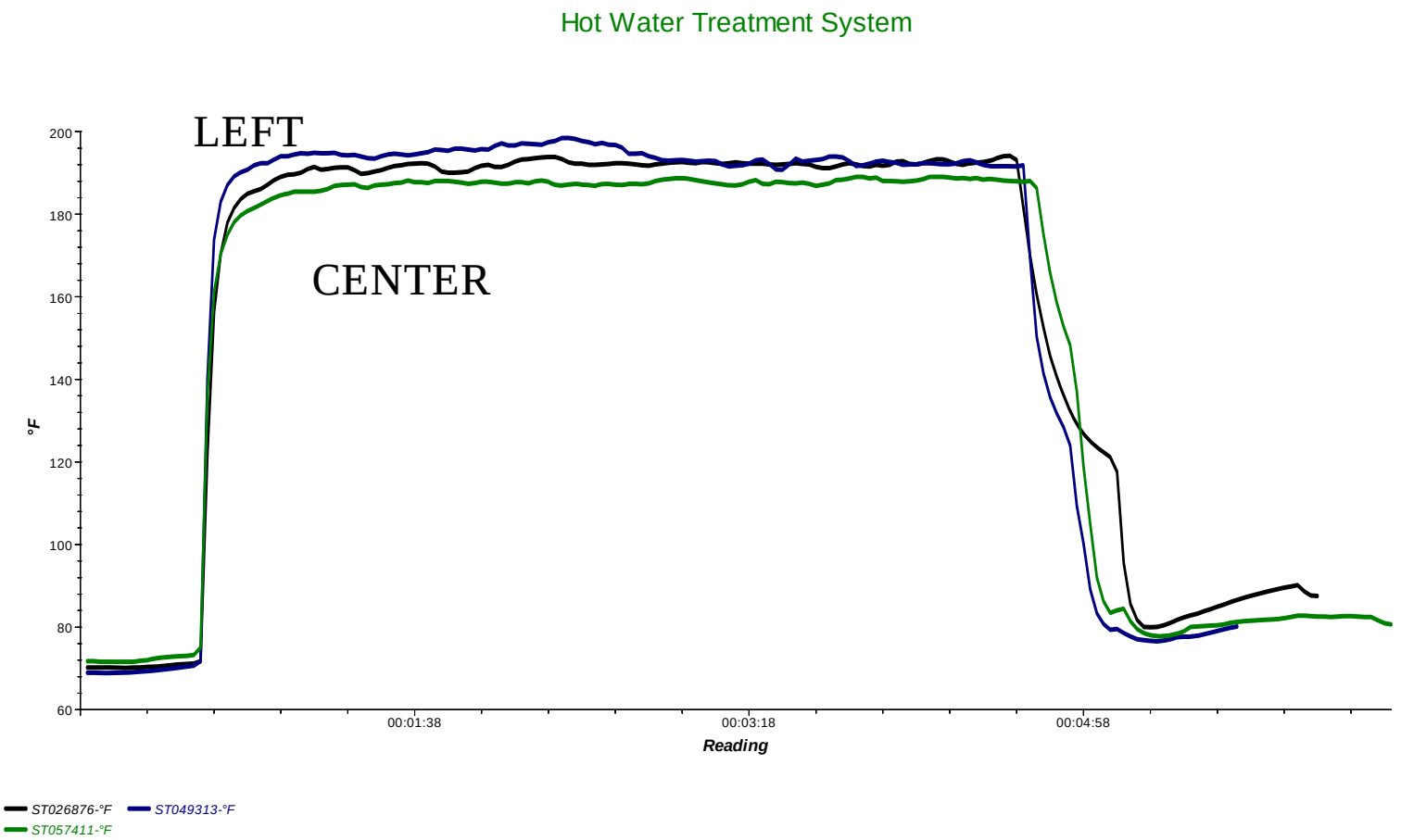
Validation By Temperature Profile

- By using Temperature Data recorders, develop temperature profile of hot water/oil system.
- If it has 2 minutes @190°F water it meets FDA 5-log approval.
- If it has 2 minutes @ 260°F oil it meets FDA 5-log approval.

Validation By Time & Dosage

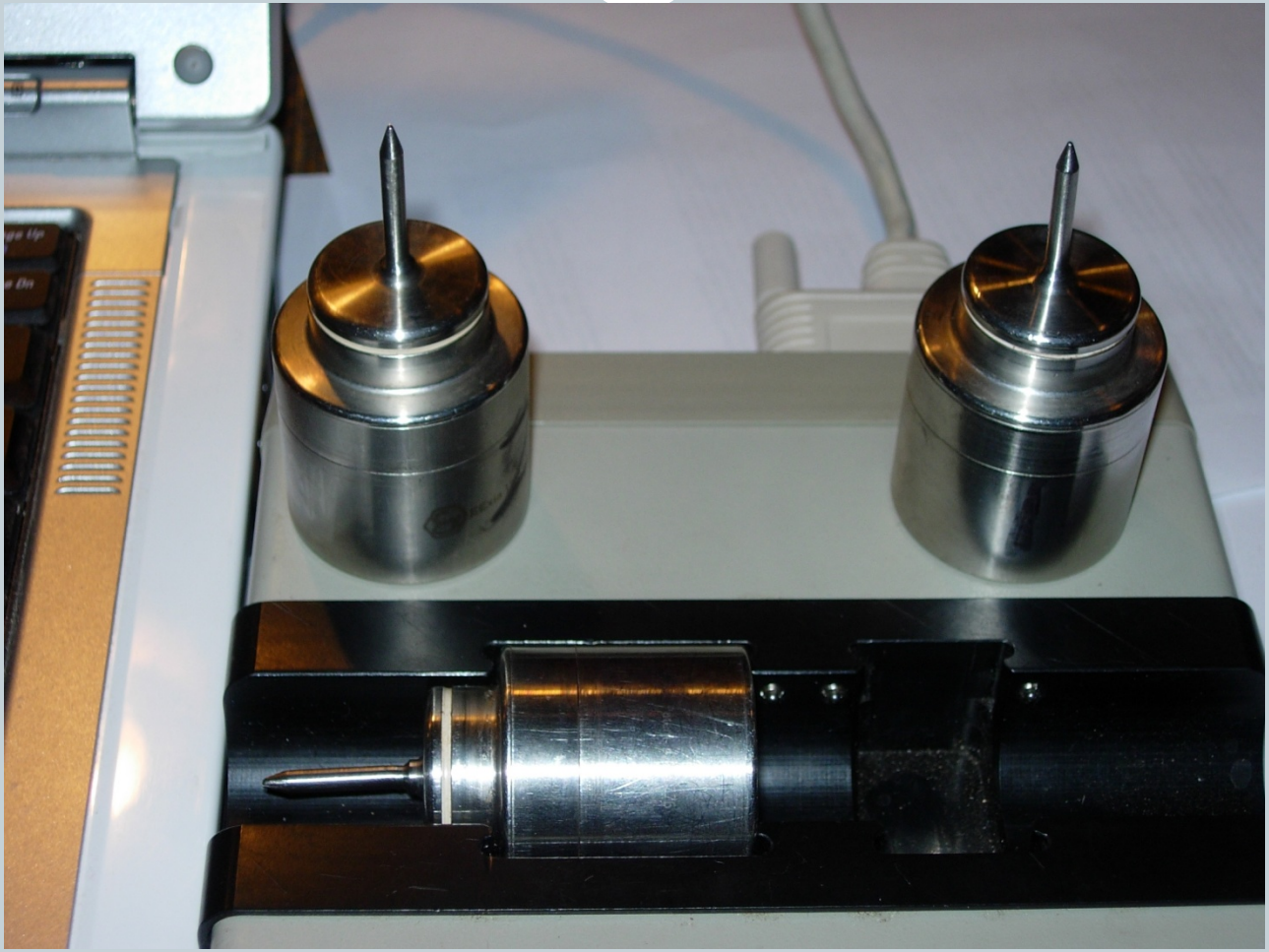
- If chamber has 4 hours @.5 ounces/ft^3 it meet FDA 5- log approval for almonds.
  - Needs to be verified for pecans
  - Label restricts some of the earlier research done with PPO

Almond Hot Water System



DataTrace Temperature Recorders

DataTrace Temperature and Reader



PPO Chamber

Validation by Surrogate

Enterococcus faecium

What About Chlorine as a Validation Method?

- Chlorine has many advantages and disadvantages.
- Low cost, broad activity, effective at low concentrations.
- Difficult to retain ppm chlorine in solution due to the organic load which depletes chlorine concentration.
- More effective at low PH, promotes rancidity
- Method of control
- Example of alfalfa
- More research needed to determine effectiveness

What About Dryers To Get 4-Log Reduction?

- This would have to be tested with surrogate inoculation.
- Typically, dryers in the 200°F for 45 minutes will deliver 1-2 logs. Generally, 24o°F for one hour will deliver 4-logs but this would roast the pecan.
  - Risk Assessment could change level of log destruction

Validation Before Shelling, Caution is Needed

- The best pasteurization system is right before packaging
- After shelling downstream sanitation is important to prevent pathogen contamination.
- Equipment and floors should be swabbed to guarantee pathogen free contact points.
- Air ventilation, untreated storage areas blowing into treated areas.
- Separation of product untreated from treated.

What Can We Learn from the Peanut Recall?

- DO NOT RETEST for pathogens (obs #1,FDA report 1/9/09)
- Dry roaster not validated (obs #3)
- Finished totes stored next to raw peanuts (obs#4). Two floor swabs were positive for salmonella
- Using equipment materials that were not cleanable (obs #6)
- Improper air ventilation between raw areas and finished areas (obs #7)
- Multiple use of sink for hand-washing(obs #8)
- Inadequate cleanup of equipment and support structures (obs #9)
- Inadequate pest control, live cockroaches found next to packaging area (obs #10)

Next Steps

- Set up research budget through NPSA
- Update research on hot water systems, oil/dry roasting, PPO & chlorine dip
- Survey to determine level of contamination for in-shell pecans and meats
- Research appropriate surrogate for pecans, develop testing laboratories
- Develop minimum standards for PA's and recruit expertise
- Complete Risk Assessment based on survey results
- Establish Validation Authority
  - * Review reports and issue validation
- Work with NPSA to validate processing systems