Process Validation and Challenges For Nuts

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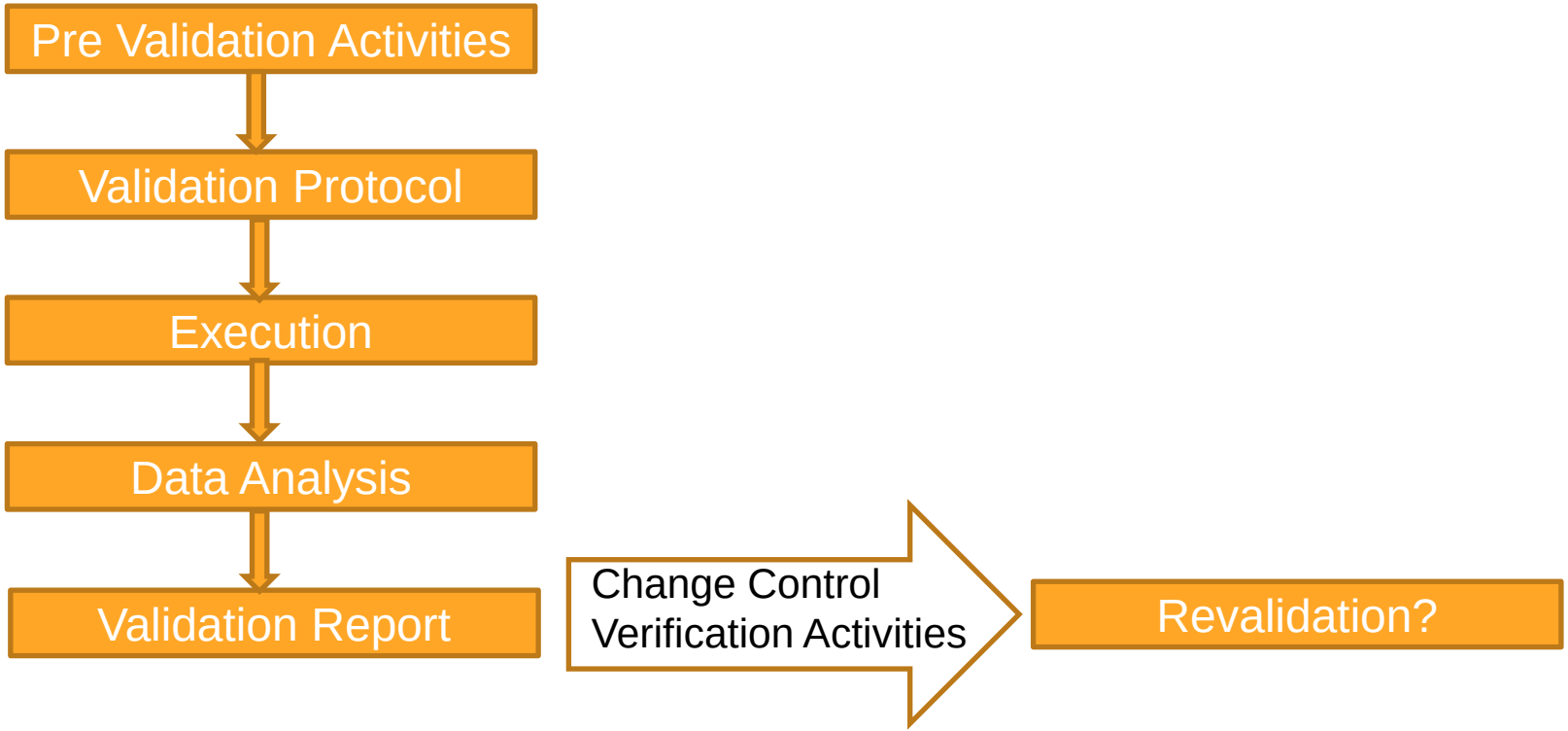
california almonds
Almond Board of California

Validation, Verification and Process Validation

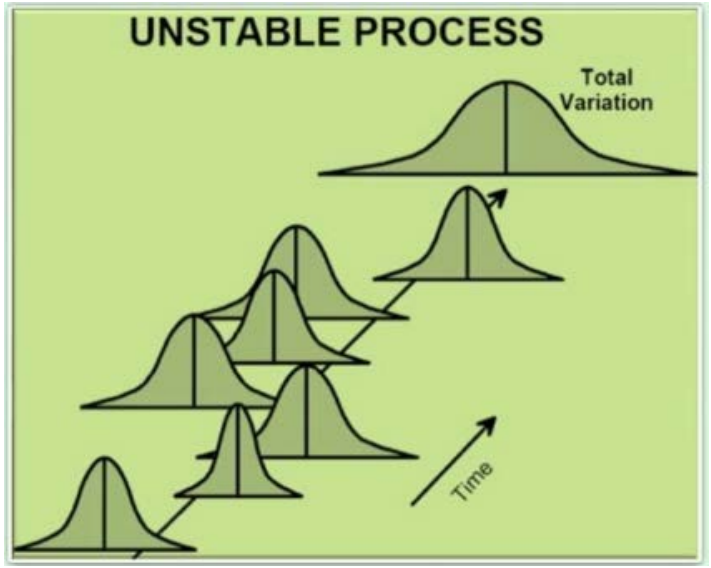
- Validation:
  - obtaining evidence that a control measure or combination of control measures, if properly implemented, it's capable of controlling **the hazard to a specified outcome** (CODEX)
- Verification:
  - Confirmation of whether a control measure has been operating as intended

- Process Validation:
  - **Process validation** is **defined** as the collection and evaluation of data, from the **process** design stage throughout production, which establishes scientific evidence that a **process** is capable of consistently delivering quality/safe products (FDA)

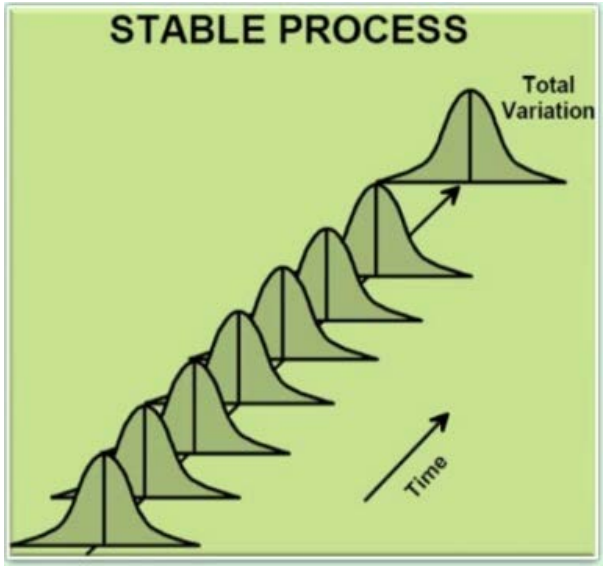
Process Validation Steps



Unstable Process & Stable Process



The process is constantly changing

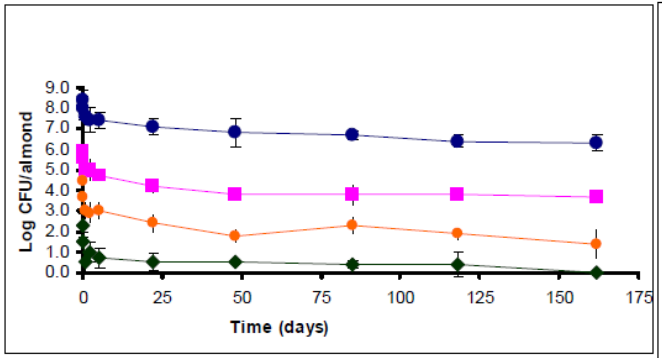


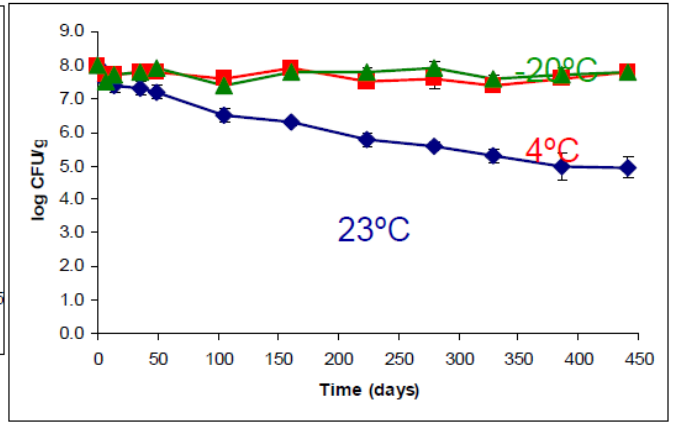
Stable processes produce a consistent level of performance

The Global Harmonization Task Force

Why Do We Need to Validate?

Salmonella doesn't grow on almond/nuts but it can survive for a long time





Uesugi, Danyluk and Harris, 2006 JFP 69: 1851-1857

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 981

[Docket No. FV06–981–1 FR]

Almonds Grown in California; Outgoing Quality Control Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

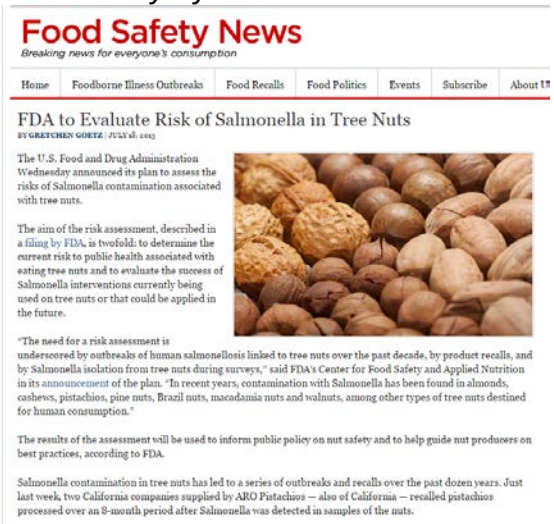
SUMMARY: This rule adds outgoing quality control requirements under the administrative rules and regulations of the California almond marketing order (order). The order regulates the handling of almonds grown in California and is administered locally by the Almond Board of California (Board). This rule provides for a mandatory program under the order to reduce the potential for *Salmonella* bacteria in almonds. This action will help ensure that quality almonds are available for human consumption.

DATES: This rule is effective on March 31, 2007. Handler treatment plans for the 2007–08 crop year must be submitted by May 31, 2007. Mandatory compliance with this rule begins September 1, 2007.

Food Safety Success Criteria

- What level of protection is needed
  - Risk assessment studies show that a minimum 4 log reduction is required for almonds
  - Minimum 5 log reduction is required for product to be called ‘pasteurized’

- For other nut types
  - No standard is available as of now
  - FDA ‘suggests’ minimum 5 log reductions for peanuts and pistachios
  - Risk assessment studies for tree nuts are under way by the FDA



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FDA to Evaluate Risk of Salmonella in Tree Nuts

BY GRETCHEN GOETZ / JULY 28, 2013

The U.S. Food and Drug Administration Wednesday announced its plan to assess the risks of Salmonella contamination associated with tree nuts.

The aim of the risk assessment, described in a filing by FDA, is twofold: to determine the current risk to public health associated with eating tree nuts and to evaluate the success of Salmonella interventions currently being used on tree nuts or that could be applied in the future.

"The need for a risk assessment is underscored by outbreaks of human salmonellosis linked to tree nuts over the past decade, by product recalls, and by Salmonella isolation from tree nuts during surveys," said FDA's Center for Food Safety and Applied Nutrition in its announcement of the plan. "In recent years, contamination with Salmonella has been found in almonds, cashews, pistachios, pine nuts, Brazil nuts, macadamia nuts and walnuts, among other types of tree nuts destined for human consumption."

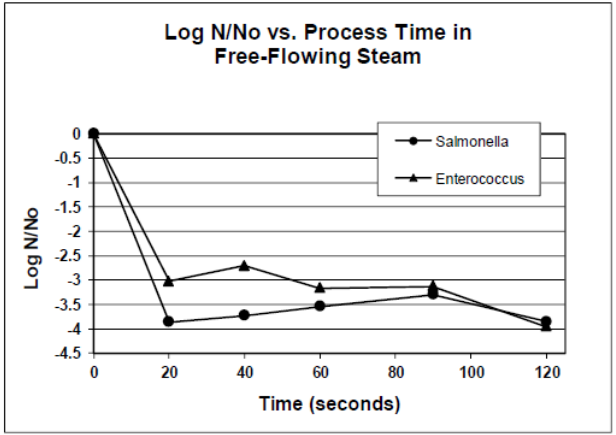
The results of the assessment will be used to inform public policy on nut safety and to help guide nut producers on best practices, according to FDA.

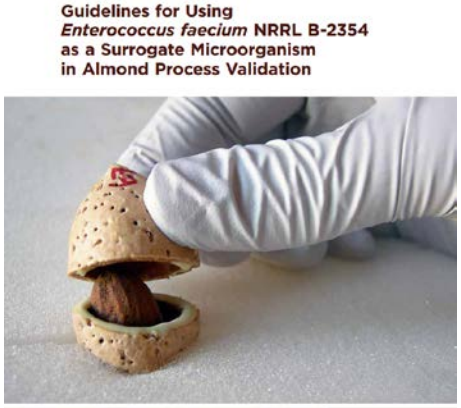
Salmonella contamination in tree nuts has led to a series of outbreaks and recalls over the past dozen years. Just last week, two California companies supplied by ARO Pistachios — also of California — recalled pistachios processed over an 8-month period after Salmonella was detected in samples of the nuts.

Surrogate Selection

- *Enterococcus faecium* NRRL B 2354 is confirmed as a surrogate for S*almonella* Enteritidis PT 30 both in dry and moist heat conditions for almonds, **for other nut types the surrogate should be evaluated case by case.**

Moist heat





Dry heat processes for 4 log reductions of Salmonella Enteritidis PT 30

Time (min)	Temperature (°F)
100	250
23	280
9	300

ABC Study z= 47°F

Do not extrapolate over 300°F!

Traditional Liquid vs Dry Nut Validations

- Liquid systems
  - Straight forward transition of TDT work from bench top to commercial scale
  - D and z values are low or manageable

- Dry systems
  - Transition of TDT work from bench top to commercial scale needs careful considerations
  - D and z values are extremely high or not manageable

PATHOGEN INACTIVATION IN FULLY COOKED CHICKEN

TABLE 4. D-values of *Salmonella* and *Listeria innocua* in fully cooked chicken breast meat products (N = 90 per temperature)

Temperature (C)	*Salmonella*			*Listeria innocua*		
	D (min)	SD	R^2	D (min)	SD	R^2
55	24.071	1.852	0.902	56.169	4.016	0.896
57.5	9.600	1.556	0.920	20.355	1.031	0.883
60	3.828	0.750	0.907	7.362	0.833	0.923
62.5	1.527	0.299	0.893	2.665	0.424	0.921
65	0.609	0.135	0.890	0.965	0.185	0.871
67.5	0.243	0.027	0.862	0.349	0.028	0.912
70	0.097	0.034	0.876	0.126	0.038	0.888

	Temp(°F)	Time(min) 4-log	Time(min) 5-log	z-value (°F)	Reference
DRY ROASTING Peanuts	284	16	19.3	77.5F	Goodfellow (2009)
DRY ROASTING Almonds	250 265 280 295 300	100 50 23 12 9		47F	Max temp of process is 300F using aluminum almond or equivalent device ABC Dry roasting validation Guidelines (ABC, 2007)
OIL ROASTING Almonds	260	1.6	2.0	NA	ABC Guidelines; Harris and Du (2005)
BLANCHING Almonds	190 185 180	1.6 1.99 2.47	2.0 2.49 3.09		ABC, 2007b)

Validation Study Criteria

- Challenge study vs Temperature profiling
  - Both are complementary to each other
  - Microbial challenge study alone is not sufficient
  - Temperature profiling method can be used for processes with well established D and z values

Common Validation Types by Process (GMA-PTNA Safe Nut Book)

Process Type	Validation Type		Validation Objective	Process Critical Factors Examples
	Inoculation Challenge Study	Measurement of Physical Delivery of Process		
[*1] Oil Roasting		X	Demonstrate that the nut is exposed to a minimum required oil temperature for a specific amount of time (e.g. 260F for 2 minutes for almond 5-log process)	Throughput (residence time, i.e., belt/chain speed; bed depth,); temperature; product incoming moisture, product immersion
[*2] Dry Roasting	X	X	Demonstrate controllable operating conditions which will deliver a minimum required log-reduction of target microorganism	Throughput (belt/chain speed;bed depth); air temperature; air flow; incoming nut temperature & moisture; cooling flow & temperature;
[*1] Blanching		X	Demonstrate that the nut is exposed to a minimum required water temperature for a specific amount of time (e.g. 190°F for 2 minutes for almond 5-log process)	Throughput (feed rate setting); Blanch water temperature
Steam / Moist Heat	X	X	Demonstrate controllable operating conditions which will deliver a minimum required log-reduction of target microorganism	Throughput / Product loading; steam temperature; chamber temperature; air temperature, initial product temperature
[*1] PPO		X	Demonstrate that defined parameters are met during pasteurization cycle	Initial product temperature; chamber temperature; chamber vacuum; PPO volume / concentration / vaporization temperature; exposure time; post ventilation tempering/ initial product temp

Building Worst Case Validation Conditions

- Product properties
  - Initial Temperature
  - Moisture level
  - Shelled vs In-shell
- Process conditions
  - Lowest possible set temperature
  - Fastest belt speed/min residence time
  - Heat Source (Boiler, Heat exchangers
  - Damper settings/Airflow
  - Max capacity
  - Product bed depth

- Considerations for challenge (inoculated samples) study
  - Ensure control is traveling with samples (traveling control)
  - Ensure moisture level for inoculated samples is comparable to incoming raw product moisture
  - Ensure inoculated samples are exposed to the same treatment as product

Yugo vs Ferrari

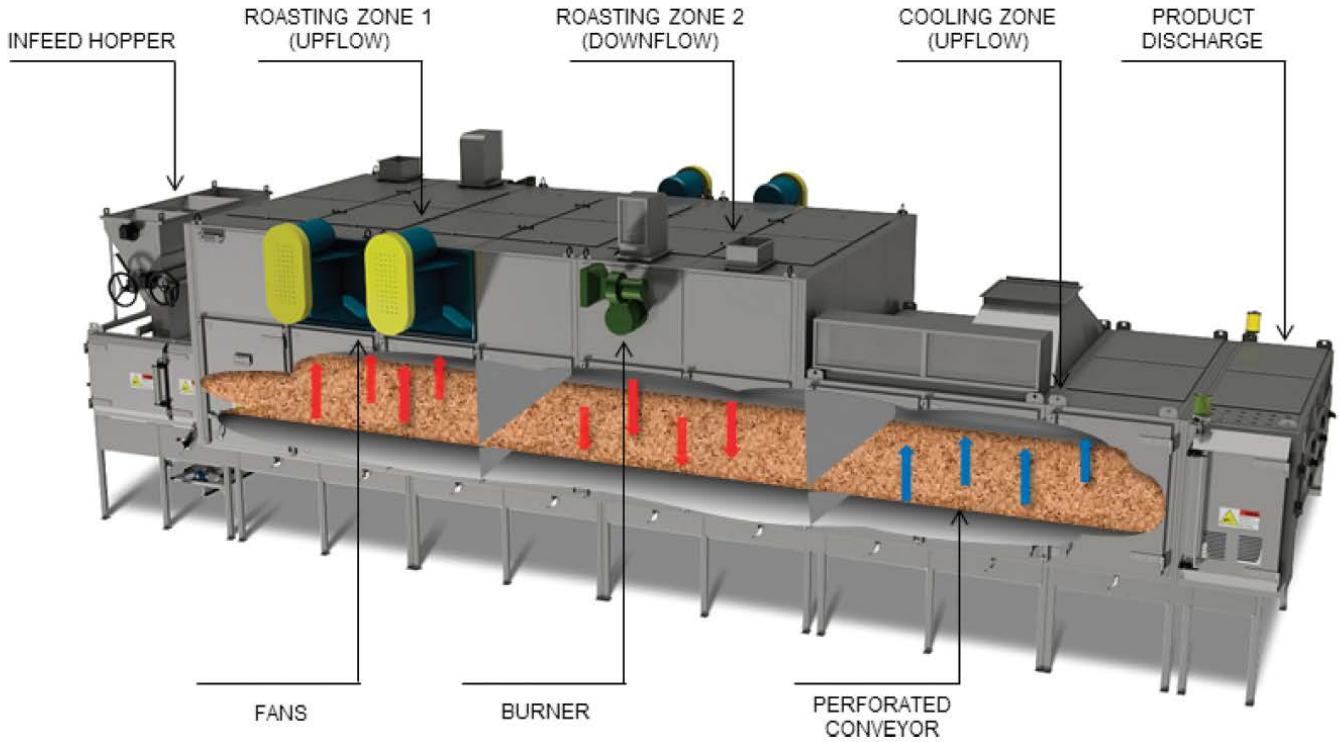
My dream

Reality! What I find in the plants!

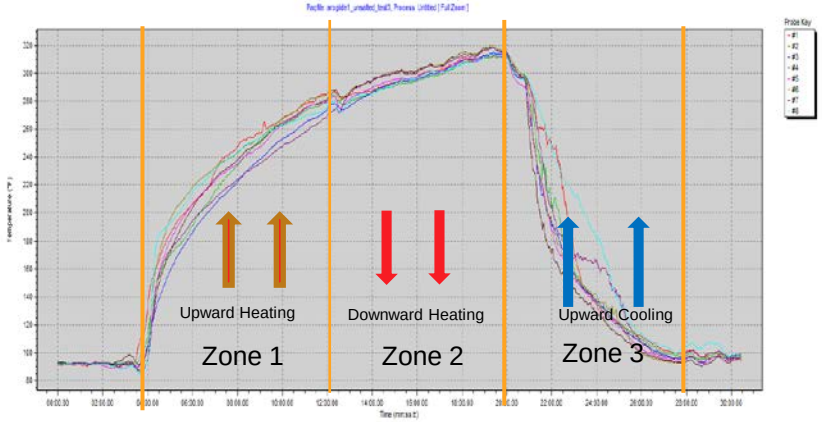
Challenges in Plant Environments

- Lack of design specifications
- Lack of control systems
- Lack of proper equipment qualification
- Lack of proper maintenance program
- Lack of change management
- Lack documentations
  - No diagrams
  - No P&IDs
  - No Manufacturer information, Good luck with model and serial numbers
- Lack of proper cooling capacity

Dry Roaster Validations



Dry Roaster Validation



Probe	Estimated Log reduction in Salmonella spp.
#1	4.74
#2	4.28
#3	4.14
#4	4.91
#5	4.39
#6	5.17
#7	4.68
#8	4.51

$$L = 10^{\frac{T-T_R}{z}} \qquad F = \sum_{0}^{t} \Delta t * L$$

Lethality computation was done using D_{300} = 2.25 min and z=47°F

Damper Settings and Circulation Fan Speed

- Damper settings controls moisture level which should be monitored and recorded, Circulation fan speed controls the airflow.

Burner damper setting

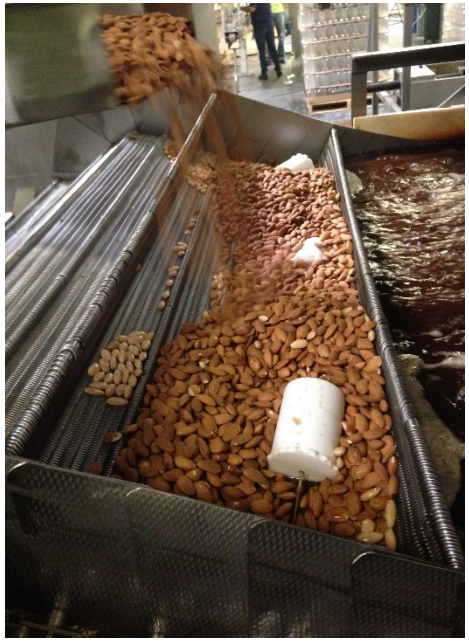
Exhaust damper setting

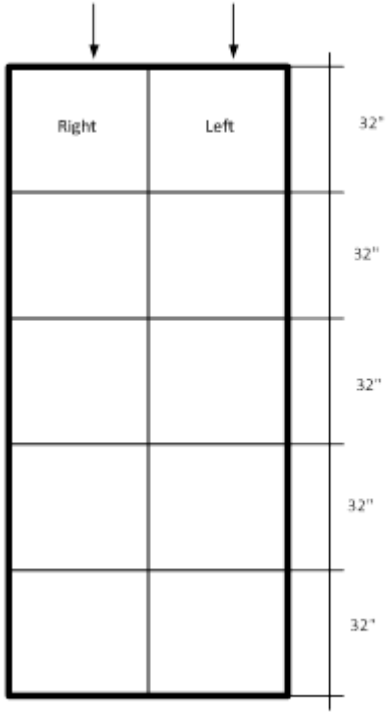
Effects of airflow and air flow directions on inactivation of E. faecium. D. Poirier, T.H. Sanders, and J.P. Davis-Peanut Science (2014) 41:72–84

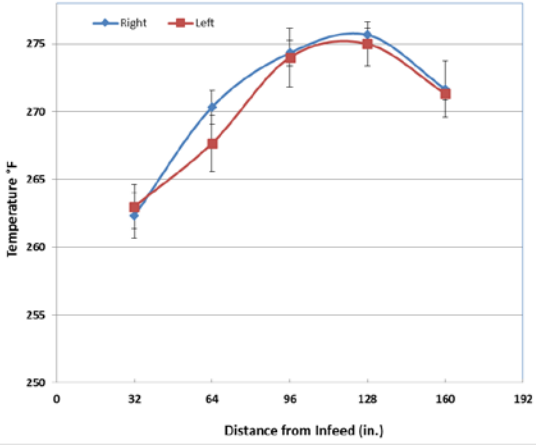
Oil Roaster Validation

- Hazard: Salmonella- minimum 4 log reduction
- Validation success criteria (ABC):
  - **In-between nut** temperature shall be at or above
    - For 4 log reduction: 260°F for 1.6 min (96 sec)
    - For 5 log reduction: 260°F for 2.0 min
  - The nuts shall be **fully immersed** in oil

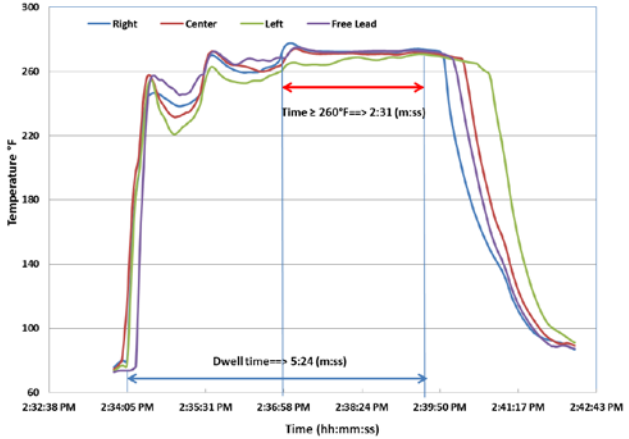
Oil Roaster Validation

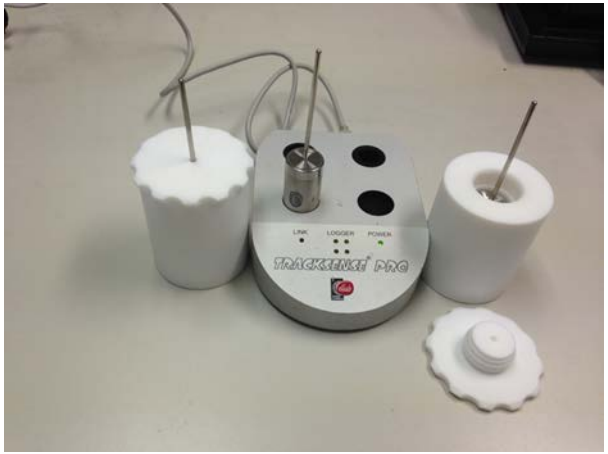






Oil Roaster Validation





Trial Date and Time	Status	Right	Center	Left
12/15/2014 02:34: pm	Time in oil (m:ss)	0:00	0:00	0:00
	Dwell time (m:ss)	5:24	5:24	5:24
	Time out of the oil (m:ss)	5:24	5:24	5:24
	Time reached at 260°F (m:ss)	2:30	2:35	2:53
	Total time ≥260°F (m:ss)	2:54	2:49	2:31

Heat source

Ensure proper conditions selected for validations

Drum Roaster Validation Candied Nuts

- No temperature devices
- No controls
- Hand held infrared temperature measurement
- Artisan process
- Direct flame

- Process total time is 15 min
- Nuts are added to a sugar solution
- Solution is boiled until all water evaporated (7-8 mins)
- Flavorings added until desired quality is reached

- **Validation Approach I**
  - Design a bench challenge study in sugar solution
  - Collect the samples at certain time interval (2, 4, and 6 min)
  - Evaluate lethality
  - If a desired lethality is achieved, the process maybe considered as OPR
- **Validation Approach II**
  - Equip the system with temperature probes and controller
  - Design a challenge study for the complete process using colored inoculated samples
  - Collect the colored inoculated samples
  - Evaluate lethality

Validation Study Report Requirements

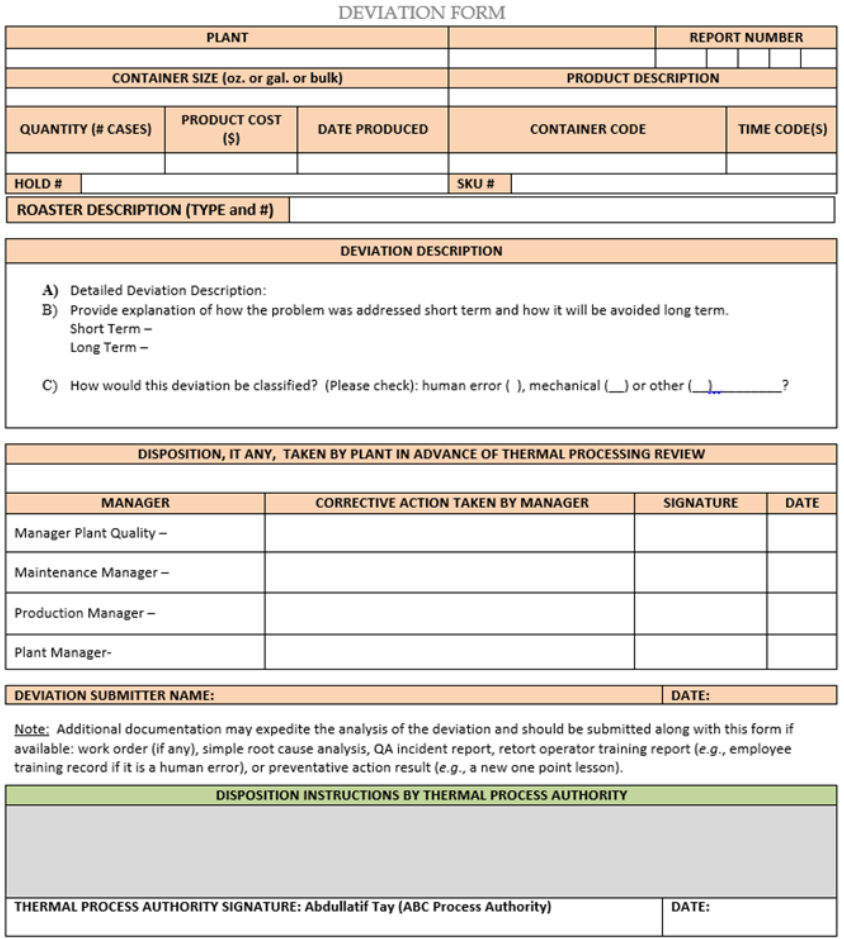
- Process Description
  - Survey of system
  - PI&Ds showing locations of critical control devices
  - Heating medium
  - Type and location of temperature sensors
  - Divert or shutdown features
  - Air source
  - Calibration practices/schedule
  - Belt speed settings (Residence time)
  - Throughput
  - Copy of chart recorder
  - Calibration records of all critical devices

					Dry Roaster
Equipment Information					
Description	**Equipment Manufacturer**	**Model #**		**Serial #**	**Validation #**	**ID#**
Dry Roaster 1		N/A		N/A		
Scheduled Process					
Process	**Process Lethality**	**Minimum Roaster Temperature (Chart Recorder - °F)**			**Minimum Time (minutes)**
Nuts	4-log reduction of SE PT-30	315 °F			17.0 min
Operating Critical Parameters (To ensure the scheduled process is reached)					
Process	Product Initial Temp	Minimum Dry Roaster Temperature		Min Process Time in Heat Zone	Max Bed depth
		Zone 1	Zone 2		
Nuts	65°F	315 °F	315°F	17.0 min	3.0 inch
Monitor Frequency	Initial Temperature shall be measured and recorded per hour	Continuous. Operator must verify Recorder temperature every hour		Operator must verify the belt speed and record on production sheet every hour	Operator shall measure the product depth and verify the uniform product distribution every hour
Comments		QA Process Forms Roaster Production Sheets Weight Bin Tickets with Temperature and time. The roaster is equipped with an audible/visual alarm to prevent the temperature falling below the minimum CCP.		Roaster operator shall confirm dwell time in heat zone time for every shift	Adjusted by the bed depth setting on the gravity feeder. The feeder setting shall be recorded every hour.
Product Identification: Dry roasted Nuts					
Product Segregation: All wet sanitation of bins and equipment is conducted in a separate room away from production. Raw nuts stored in segregated cool room. Employees on the roasted or processed side of the operation wear plastic gloves and are restricted to roasted areas. Roasted product is segregated from non-roasted and conveyed in sealed boxes or covered sanitized steel to mixing and packaging.					
Product Packing: Retail packaging					
Protocol for Handling Process Deviations **- Recording charts and all other CCPs shall be reviewed daily in order to confirm that all CCPs are met. The review shall be done by a qualified representative of firm. The product shall be released only after a record review.** **- Recording chart reviews shall verify that a minimum temperature of 290 °F** **- Should a review of written record or chart records show that any of CCPs are not met, the product shall be put on hold and appropriate records review by HACCP Team and/or Quality for disposition. The evaluation and disposition of the product shall be documented.**					

Process Deviation

Any departure from an established validated conditions. It requires evaluating, investigation, response and control by PA, QA and Engineering team.

- Human error
  - Operator selected the wrong recipe
  - No chart
- Mechanical failure
  - Heat exchanger/Boiler out
  - Circulation fans out



DEVIATION FORM

PLANT		REPORT NUMBER

CONTAINER SIZE (oz. or gal. or bulk)	PRODUCT DESCRIPTION

QUANTITY (# CASES)	PRODUCT COST ($)	DATE PRODUCED	CONTAINER CODE	TIME CODE(S)

HOLD #		SKU #	

ROASTER DESCRIPTION (TYPE and #)	

DEVIATION DESCRIPTION

A) Detailed Deviation Description:
B) Provide explanation of how the problem was addressed short term and how it will be avoided long term.
Short Term –
Long Term –

C) How would this deviation be classified? (Please check): human error ( ), mechanical (__) or other (__)_____?

DISPOSITION, IT ANY, TAKEN BY PLANT IN ADVANCE OF THERMAL PROCESSING REVIEW

MANAGER	CORRECTIVE ACTION TAKEN BY MANAGER	SIGNATURE	DATE
Manager Plant Quality –			
Maintenance Manager –			
Production Manager –			
Plant Manager-			

DEVIATION SUBMITTER NAME:	DATE:

Note: Additional documentation may expedite the analysis of the deviation and should be submitted along with this form if available: work order (if any), simple root cause analysis, QA incident report, retort operator training report (*e.g.*, employee training record if it is a human error), or preventative action result (*e.g.*, a new one point lesson).

DISPOSITION INSTRUCTIONS BY THERMAL PROCESS AUTHORITY

THERMAL PROCESS AUTHORITY SIGNATURE: Abdullatif Tay (ABC Process Authority)	DATE:

Reasons for Revalidation

- Revalidation can be considered where cumulative minor changes to process and raw products may eventually affect the process
- Change in process that may affect the safety or validation status
  - Heat source- Boilers, Heat exchangers
  - Belt change
  - Fans and dampers
  - Controls
- Change in raw product specs that may affect the process
  - Moisture level
  - Type, size and density of nuts
- Process is moved within facility or transferred from one location to another
- Change in the application of the process