

Process Validation for Low-Water Activity Foods



IAFP: *Salmonella* in Peanut Products
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Outline

- Validation and verification
 - Factors to consider

- Case studies almonds
 - Oil roasting
 - Blanching
 - Propylene Oxide

- Application to peanuts/peanut butter

Establishing Processes

- Process Validation
 - Collect and evaluate scientific evidence that the process is effective to achieve desired lethality

 - Determine critical limits

 - Confirm individual equipment is capable of consistently delivering for given product

In-plant process validation

- Almond Board of California
 - Detailed procedures for in-plant validation
 - Blanching
 - Oil roasting
 - PPO
 - Other processes
 - Good starting point for other nuts and other low water activity foods
 - <http://www.almondboard.com/About/content.cfm?ItemNumber=25135&token=58482&userID=>
 - Experienced thermal process authority

Verification

- Review of records
 - Applying and achieving validated process
- Calibration of instruments
- Periodic microbiological analysis

FDA Guidelines (March 2009)

- Manufacturers of foods containing a peanut-derived product as an ingredient obtain peanut-derived product only from suppliers with validated processes in place to adequately reduce the presence of *Salmonella* spp. (e.g., by 5 logs).
- <http://www.cfsan.fda.gov/~dms/pnutguid.html>
- <http://www.cfsan.fda.gov/~dms/pnutbull.html>

FDA Guidelines (March 2009)

- If peanut-ingredient has not received a validated process
 - Determine adequacy of final product process for reduction of *Salmonella* (e.g. 5 log)
 - Challenge study

Definitions – thermal processing

- D-value
 - Time required for a 1-log reduction in population
 - *First order kinetics assumed*
 - *Do not apply to non-linear data*
- F-value
 - Time to achieve a defined process at a given temperature
- z-value
 - Temperature required for a 1-log (10-fold) change in D-value

Collecting scientific data

- When time and temperature profiles can be mimicked in the laboratory
 - E.g., oil roast, water blanch
 - *Salmonella* is the test organism
- In-plant studies usually involve surrogates



Challenges

- Choosing test strain or strains
 - Most resistant pertinent pathogen
 - *Salmonella enterica*
 - *Salmonella* Enteritidis PT30 ATCC BAA-1045
 - 2000/2001 almond outbreak strain
 - *Salmonella* isolated from peanut outbreaks?
 - Using marked strains (background) (e.g., antibiotic resistance)

Challenges

- Validating microbiological methods
 - Inoculation methods
 - Culture conditions
 - Collecting culture from petri dishes vs. broth
 - Inoculation and drying procedure
 - Moisture in inoculated product
 - Stability of population during storage
 - Establish storage time/temperature
 - Heat resistance during storage



Challenges

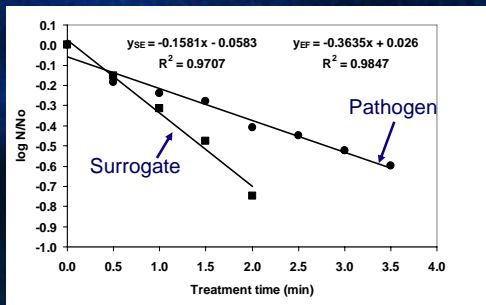
- Recovery methods
 - Diluent
 - Cooling mechanism
 - Homogenization methods
 - Plating media (injury)
 - Enrichment methods
 - Incubation



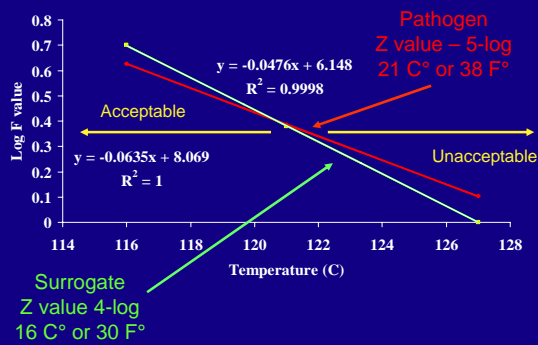
Surrogates

- Non-pathogen
 - Avirulent pathogen
 - Other organism
- Inactivation characteristics (process specific)
 - Similar to the target organism (more robust)
 - Similarly susceptible to injury
 - Reproducible growth, ease of preparation, ease of enumeration, enrichment method available, genetically stable

Example Unacceptable Surrogate



Example of a Surrogate Acceptable Over Limited Temperature Range Surrogate vs. Pathogen Z value



Salmonella surrogate for almonds

- *Enterococcus faecium* NRRL B-2354
 - Labeled as *Pediococcus* sp.
 - <http://www.almondboard.com/files/Enterococcus%20Validation102407.pdf>
- Stated as applicable for validation studies of heat processes for almonds
 - Dry roast, Moist air
- Reasonable to apply to peanuts/peanut butter under conditions specified for almonds but should be validated on peanuts and against peanut-specific *Salmonella* first

Using Salmonella for in-plant

- High risk venture
- Do not assume that your process will eliminate *Salmonella*

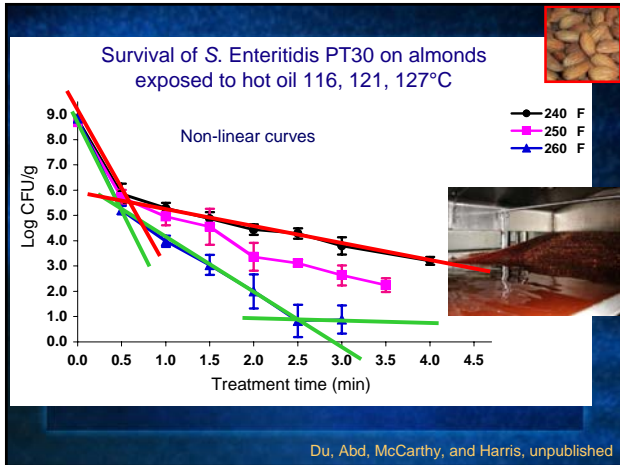


Measuring Temperature

- Surface temperature?
 - Surface contamination with *Salmonella* is assumed in whole nuts
 - For validation – uniform distribution of *Salmonella* in nut butters is assumed
- Oil or water temperature
 - Easier to measure
- Identification of process cold spot critical



Aluminum almond



Treatment of almonds inoculated at 5 log CFU/g

Enrichment of 1-g sub-samples of almonds from 50 g of treated almonds. Three sub-samples were taken from each 50 g of treated almonds.

Temperature	Treatment time (min)				
	0.5	1.0	1.5	2.5	3.5
121°C/250°F (5.1 log CFU/g)			2/9	0/9	0/9
127°C/260°F (5.3 log CFU/g)	8/9	2/9	0/9		

Assumes a 5 to 6 log kill:
250°F - 1.5 to 2.5 min
260°F - 1 to 1.5 min

ABC recommendation:
minimum 260°F, minimum 2 minutes

Du, Abd, McCarthy, and Harris, unpublished

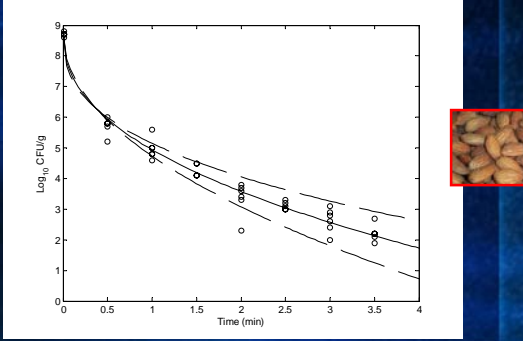
- ### Critical limits for almonds
- Operational Limits for Oil Roasting:
 - 138°C/280°F to 149°C/300°F
 - 3 to 10 minutes (processor dependent)
 - Critical Limits for Oil Roasting
 - Oil temperature at cold spot of at least 127°C/260°F
 - Almond exposure of at least 2 minutes

Weibull Model

$$\log_{10}(S) = \log_{10} \frac{N}{N_o} = -bt^n$$

S = survival ratio at time t
 b = shape parameter
 n = scale parameter

Best fit (—) and 99% confidence intervals for the coefficient estimates (---) of the Weibull model to experimental data of *Salmonella* Enteritidis PT 30 on inoculated almonds after exposure to 121°C oil. Enumeration on TSA.



Du, Abd, McCarthy, and Harris, unpublished

Time to 4- or 5-log reduction of *Salmonella* Enteritidis PT 30 on almonds exposed to hot oil, according to the Weibull model

Temperature (°C/°F)	99% CI	Time required for reduction (s)		
		4- log	5-log	
116/240	99% CI	125	255	2X
121/250	99% CI	82	145	1.8X
127/260	99% CI	44	76	1.7X

Du, Abd, McCarthy, and Harris, unpublished

Dry Roasting

- Significantly greater challenge
 - Equipment variability
 - Air, drum
 - Heat distribution
 - Can be highly variable across bed
 - Difficult to identify cold spot
 - Air flow/temperature/bed depth/product moisture
 - More difficult for lab-based studies
- ABC recommendations for 4-log
 - 100 min at 121°C/250°F to 9 min at 149°C/300°F
 - Or surrogate testing over wide range of conditions

Validating commercial PPO treatment in almonds

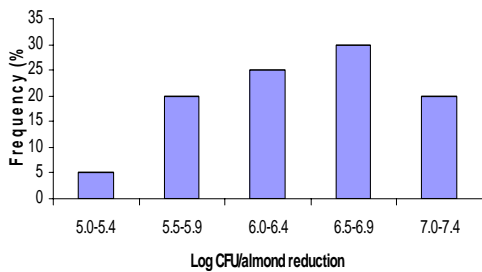
Inoculated almonds are prewarmed inside 900-kg bins or 22.5-kg boxes

Almonds commercially treated with PPO

Salmonella recovered and enumerated from treated almonds



SE PT30 reduction on almonds treated with PPO



Danyluk, Uesugi and Harris. 2005. JFP 68:1613- 1622



Critical limits for almonds



- <http://www.almondboard.com/files/PPO%20Pasteurization%20Validation%20Guidelines%20and%20SOPs.pdf>
- Initial product temperature
 - Not less than 30°C/86°F
- 0.5 oz PPO/cubic foot
- 4 hours
- Post PPO treatment
 - 38-43°C (100-110°F) for 2 days
 - Above 15°C/59°F for 5 days

Are these data applicable to peanuts?

- Reasonable to assume that oil/ Blanch data applies to other whole nuts
 - However, assumption should be validated
 - With other nuts
 - Other nut-associated *Salmonella*
- Assumes surface contamination
 - Applicable to whole nuts
- Peanut butter processing lines?
 - Application of whole nut data not valid
 - Hot oil sanitation
 - "fresh" vs. dried peanut butter on wall of pipe
 - Heat transfer properties?
 - *Salmonella* not located on "surface" of peanut butter

Summary

- Thermal resistance of *Salmonella* is greatly increased in low water activity foods
- Survivor curves can be non-linear
 - "D" values do not apply
 - Significant tailing often observed
 - This can significantly impact the efficacy of some processes
 - z values may also be impacted and are often high
- Expert microbiologists and thermal process authorities with low water activity food experience should be consulted for process validation
