

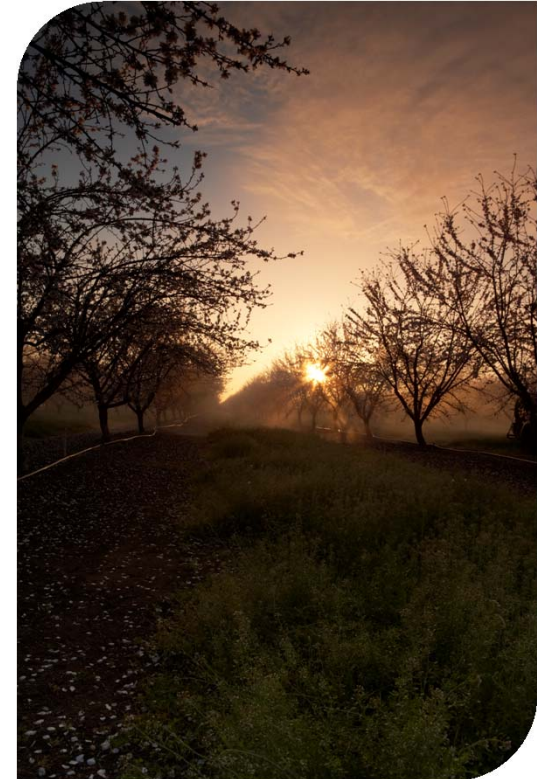
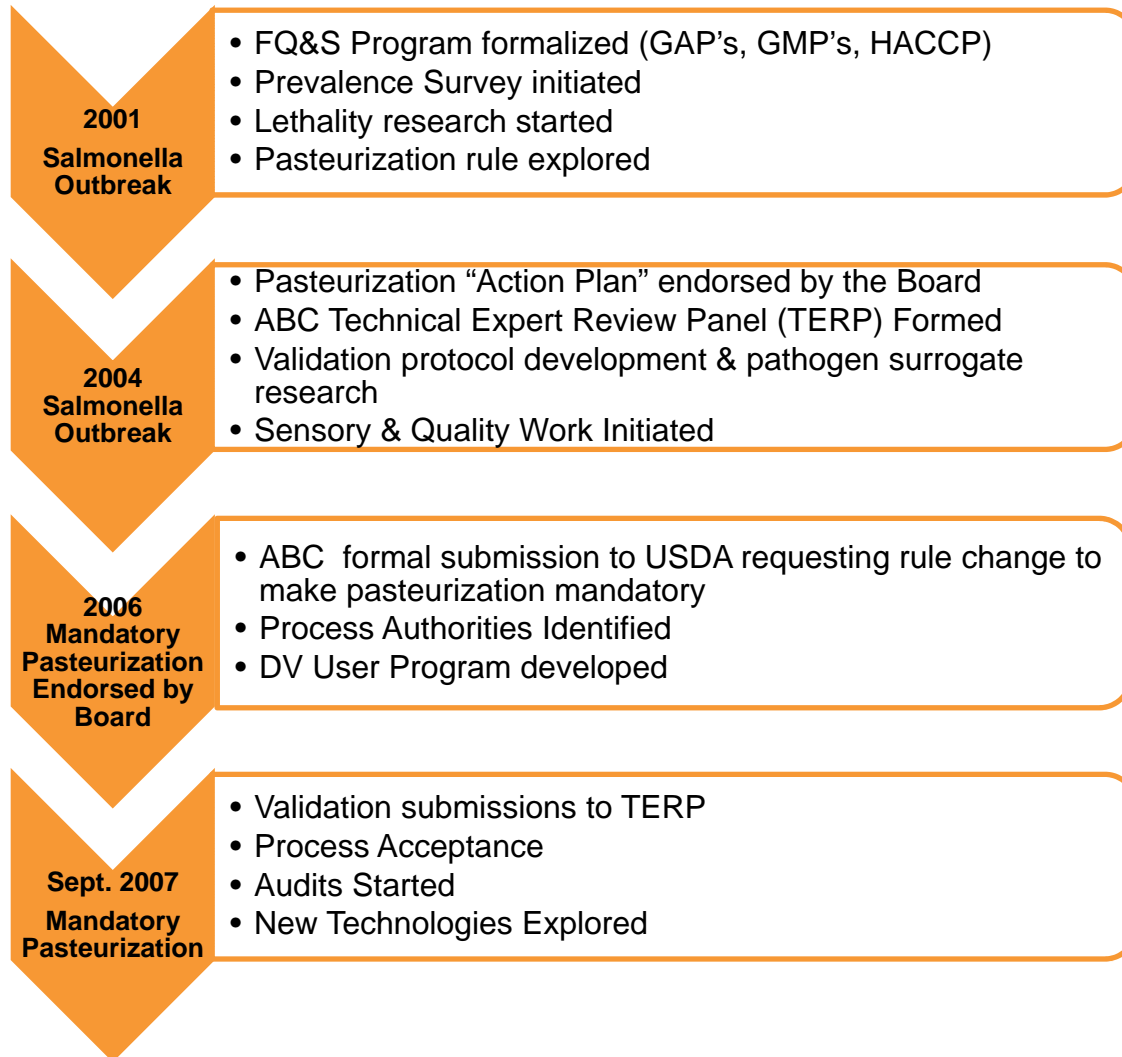


American Spice Trade Association

Almond Industry Pasteurization Initiatives

Tim Birmingham,
Director, Quality Assurance and Industry Services

Almond Pasteurization Program Timeline



ABC Pasteurization Program: 3 Keys to Building Credibility

1. Research

- Microbial surveys
- Pathogen / Surrogate research studies
- Risk Assessment
- Validation research / Protocols / Guidelines

2. Formal (Independent) Validation & Review Process

- ABC Process Authorities (PA's)
- ABC Technical Expert Review Panel (TERP)

3. Verification of Performance

- ABC managed audits



Some of the things we studied:

1. What are the levels of *Salmonella* contamination in almonds?

Survey of Almonds from Huller/Shellers
(100 g)

Year	Number Positive	% Positive
2001	12 of 2003	0.60
2002	24 of 2012	1.2
2003	15 of 1764	0.80
2004	12 of 1643	0.73
2005	18 of 1852	0.97
2006	30 of 1899	1.6
2007	15 of 1799	0.83

Average 0.97% positive samples per year

Levels less than 3 to 15.5 MPN/100 g



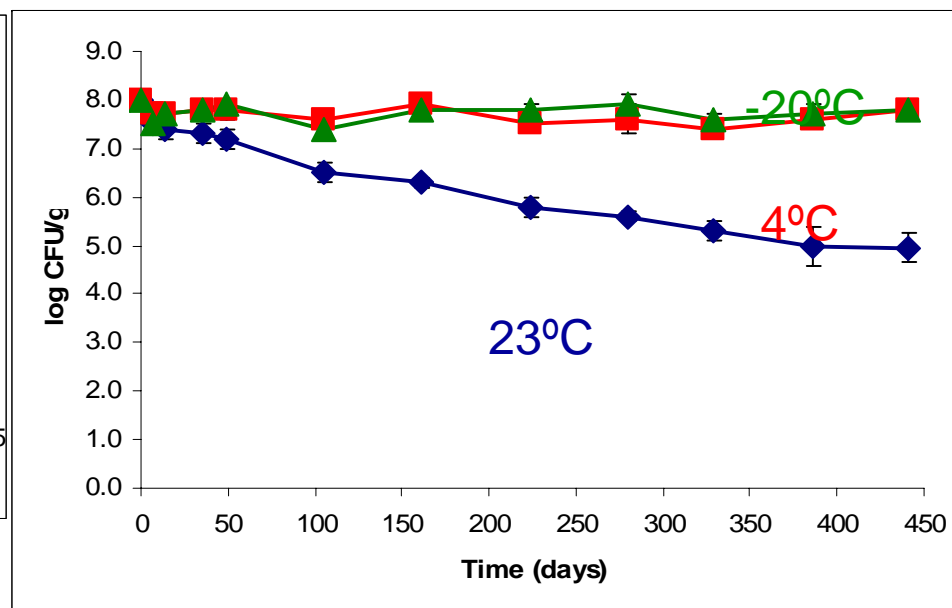
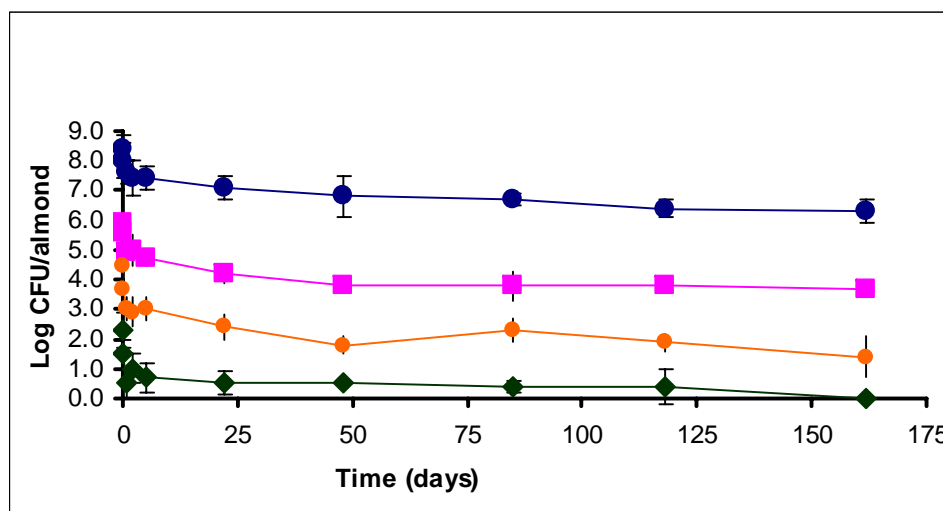
Salmonella serotypes (2001 through 2006 almond samples)
characterized by antimicrobial susceptibility profiling and PFGE

Serotype	No. of Times Isolated from Different Almond Lots	No. of Unique Strains Identified
Agona	4	4
Enteritidis	11	7
Montevideo	12	9
Muenchen	10	7
Newport	7	7
Typhimurium	9	6
Total	53	40

Singla and Harris, unpublished

Some of the things we studied

2. Will *Salmonella* grow in almonds or dried foods?



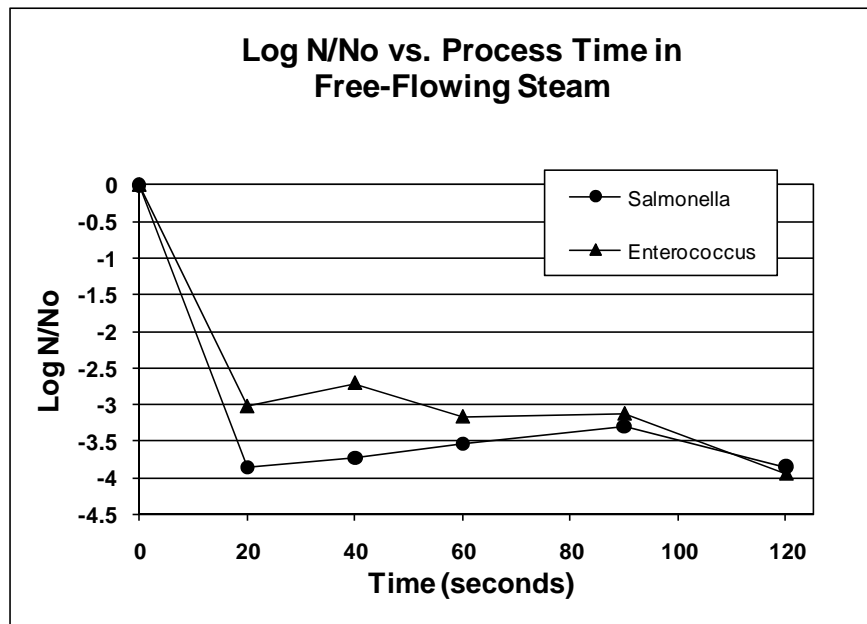
The answer is no, *Salmonella* does not grow in almonds. However, it does survive a really long time!

Infective dose *Salmonella* can be: VERY LOW
10 to 1000 cells per serving

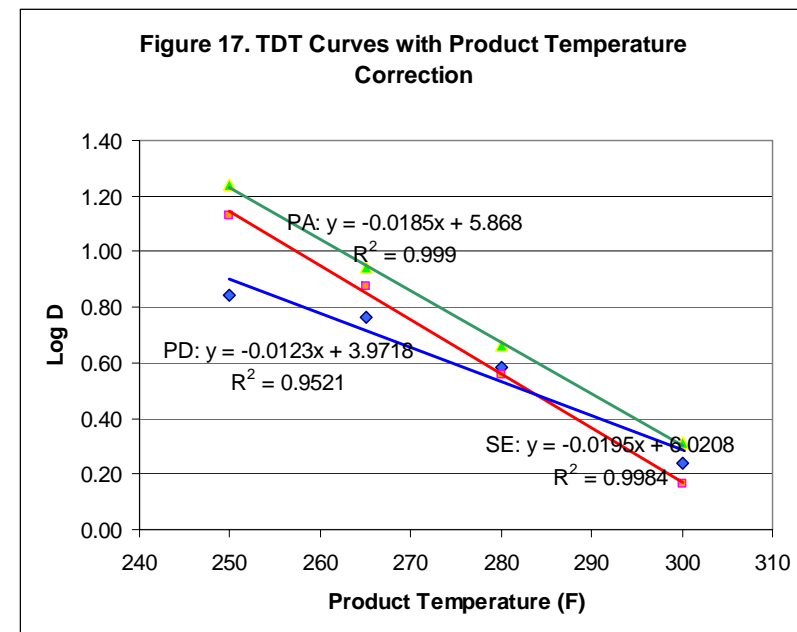
Some of the things we studied:

3. What are appropriate microbial surrogates for validation testing?

Moist Heat: Log reduction *S. enteritidis* vs. *E. faecium*



Dry Heat: TDT Curves *S. enteritidis* vs. *P. agglomerans* vs. *E. faecium*



Some of the things we studied:

4. What is the risk of illness from consumption of raw almonds?

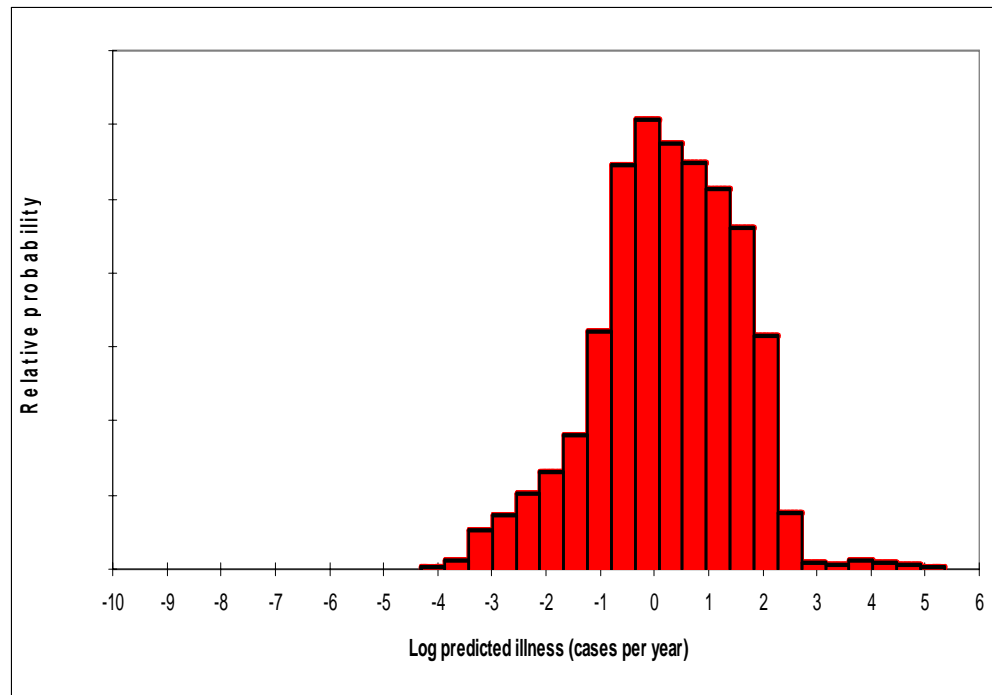
Survey Work – Backbone of Risk Assessment (RA)

- Showed us that *Salmonella* is present in low levels in 1% of the 100g samples tested
- Doesn't quantify level of risk - helps to define where focus should be

Risk Assessment

- Numerous variables and distributions affecting *Salmonella* survival modeled to predict risk of illness
 - Levels of contamination per serving, survival characteristics over time, consumption patterns, storage time and conditions, etc.
- RA is a tool to help understand the risk of illness and make informed decisions on how a specific process will reduce that risk
- Helps to define target lethality required to achieve an appropriate level of protection – e.g. 4 log vs. 5 log

*2005 Risk Assessment Predicted annual illness from consumption of raw almonds.



RA predicted 78% chance of >1 case of salmonellosis per year associated with consumption of raw almonds in the U.S.

Mean predicted cases of 8 per year

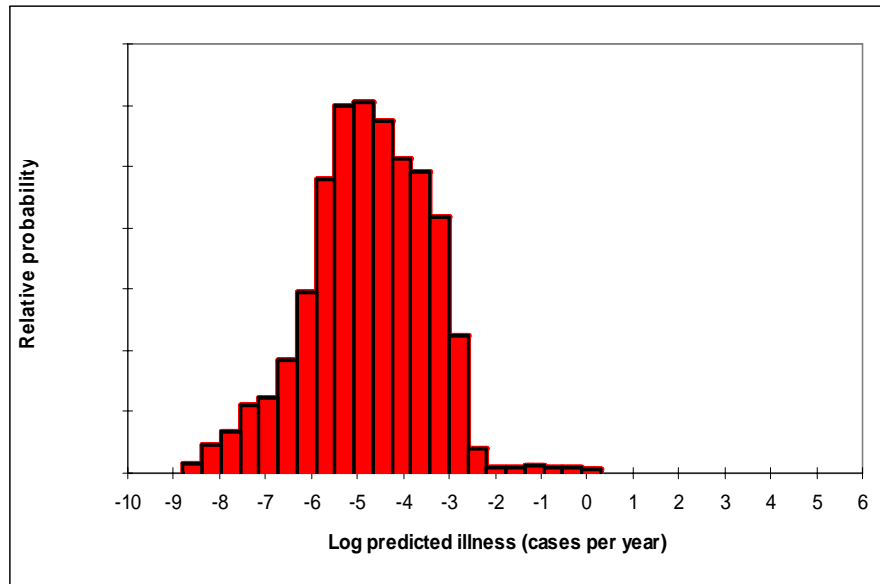
*Monte Carlo simulations assessing the risk of salmonellosis from consumption of raw almonds

Michelle D. Danyluk¹, Linda J. Harris¹ and Donald W. Schaffner²

¹ Department of Food Science and Technology, University of California, Davis

² Food Risk Analysis Initiative, Rutgers University

*Predicted annual illness from consumption of almonds treated with a process achieving a 5 ± 1 -log reduction



Application of a 5 ± 1 log process reduced that predicted risk to less than 0.69%)

Probability of >1 case/year = $<.69\%$
with mean cases per year of 7×10^{-5} per year

*Monte Carlo simulations assessing the risk of salmonellosis from consumption of raw almonds

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Some of the things we studied:

5. Inoculation protocols – Inshell vs. Kernels



Validation Studies / Protocols

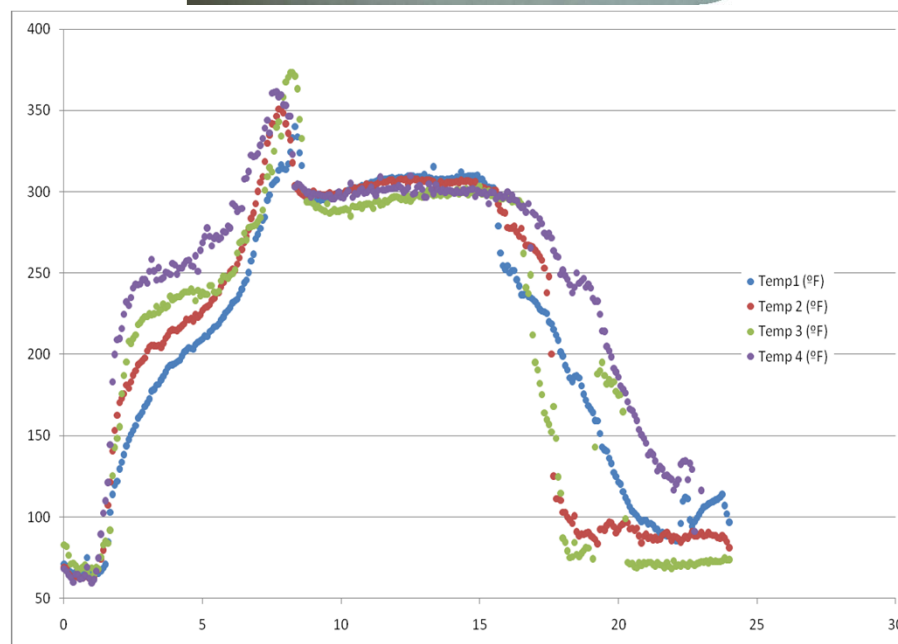
Hot Air Roasters

Hot air roasting may achieve a ≥ 4 -log destruction of SE PT30 under certain conditions

- Aluminum almond temperatures that are equal to general method calculations
 - 100 min at 250 F
 - 50 min at 265 F
 - 23 min at 295 F
 - 9 min at 300 F

Critical factors for hot air roasters will vary depending upon the specific equipment used

- Time / Speed
- Air temperature
- Air flow
- Product loading
- Initial product temperature

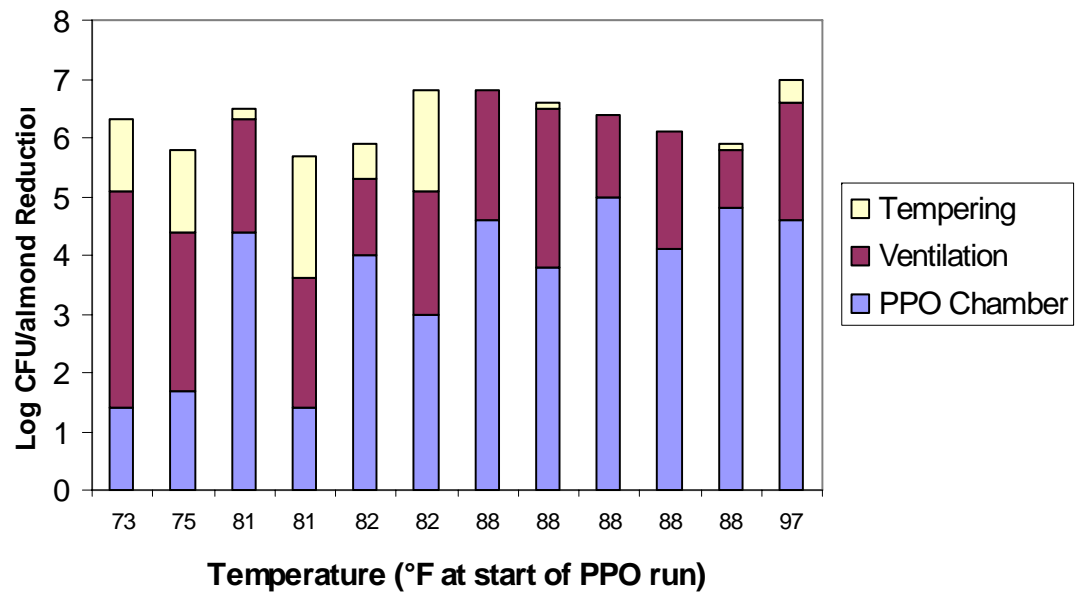


Validation Studies / Protocols

Propylene Oxide (PPO)

Critical Factors Include:

- Initial Product Temperature
- PPO Chamber temperature at start
- Initial Chamber Vacuum
- PPO Chamber Vaporization Temperature
- Initial Product Temperature
- PPO Chamber temperature at start
- Chamber Vacuum post gas injection
- PPO Chamber Exposure
- Post Ventilation time / temperature



Validation Studies / Protocols

Hot Water Blanching

Minimum Critical Factors

- Time: Minimum 2 minutes
 - Critical factor will be speed setting
- Temperature: 190 F
 - Temperature must remain at or above 190 F at entrance and exit of blancher



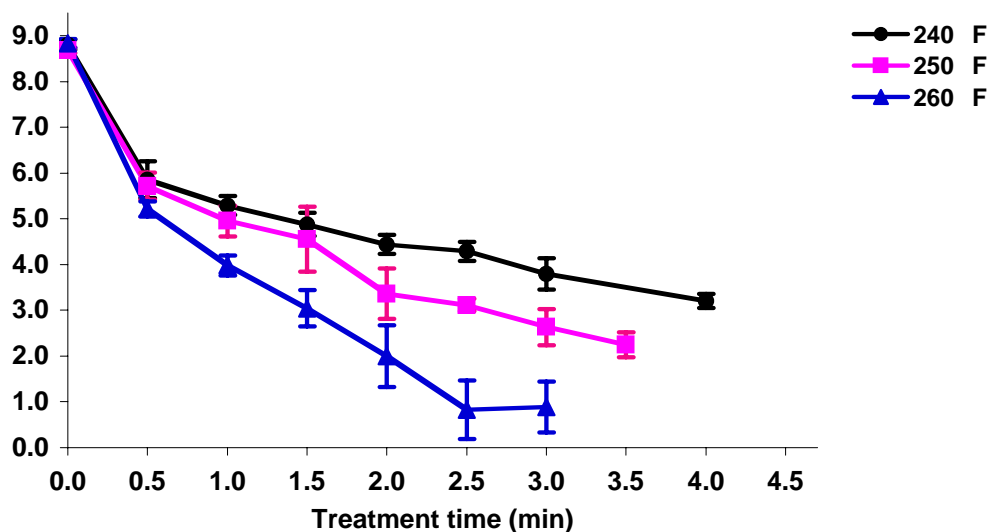
Validation Studies / Protocols

Oil Roasting

Minimum Critical Factors

- Time: Minimum 2 minutes
 - Critical factor will be speed setting
- Temperature: 260 F
 - Temperature must remain at or above 260 F throughout roaster

Survival of *Salmonella* Enteritidis PT 30 on inoculated almonds after exposure to oil heated to 240, 250 and 260 F (116, 121, and 127 C). TSA, n=6.



Validation Studies / Protocols

Steam and Moist Air

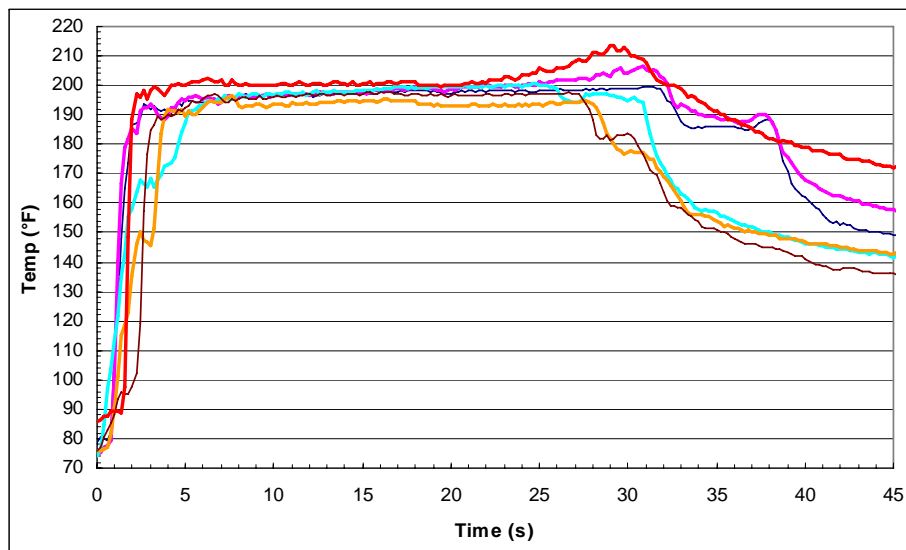
A number of steam processes have been studied and validated

- Ambient Steam continuous product flow
- Moist heat
- Vacuum Steam
- Combination Steam / Drying

Critical factors are specific to the equipment

- Time
- Steam temperature
- Air temperature
- Drying time/temp exposure
- Vacuum
- Product loading
- Type of container

Typical Ambient Steam Pasteurization Process- Average Almond Surface Temperatures



Pasteurization Approved Processes

Process	Accepted
Blanching	24
Oil Roasting	81
PPO	19
Dry Roasting	17
Pasteurizer (Steam or Moist Heat)	12
Steam Plasticizer	3
Others	11
Total of 167 units at 156 Locations	

7 CFR Part 981.442b Mandatory Pasteurization Program Rule for Almonds– Effective Sept 2007

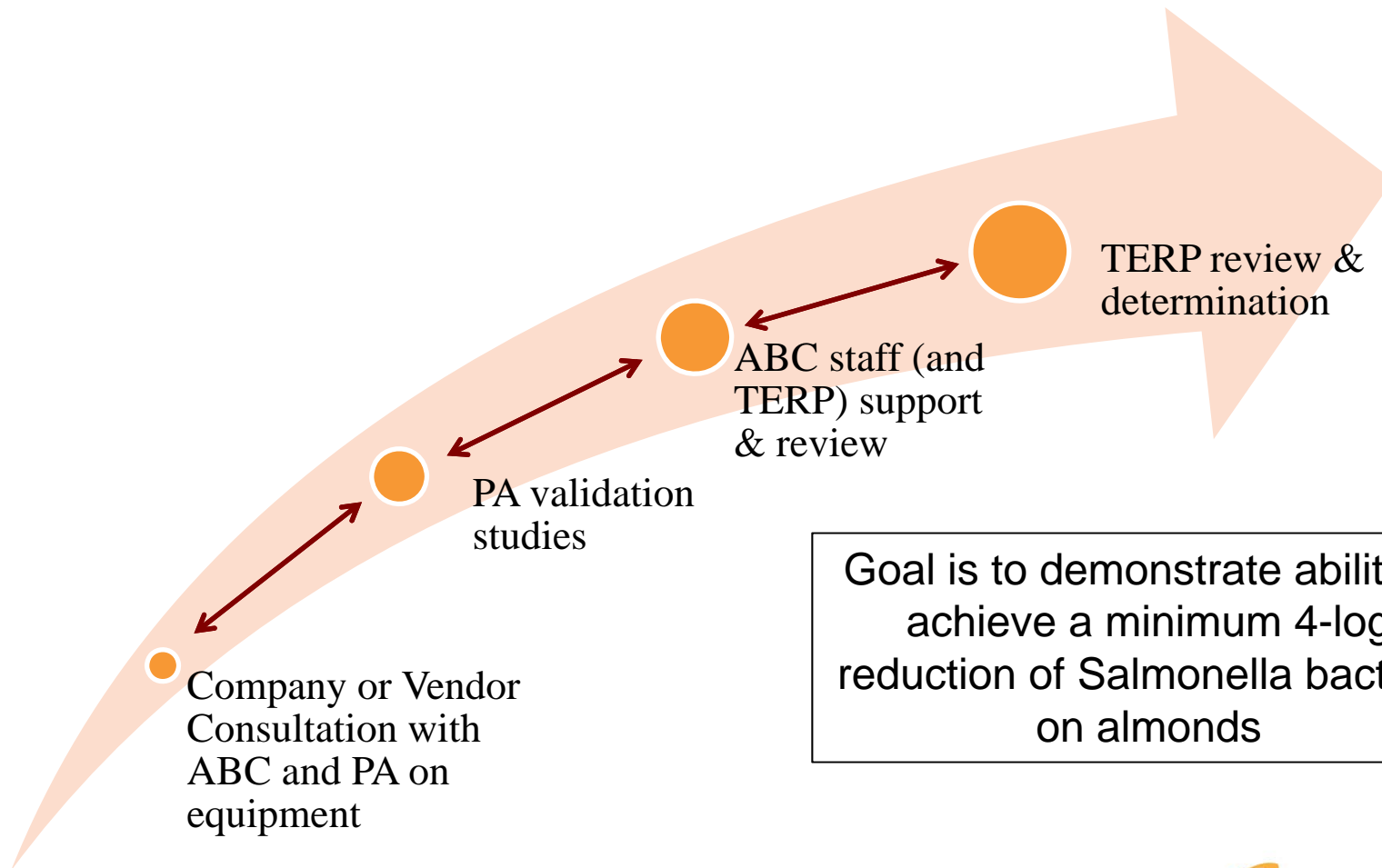
Requires all Handlers to utilize technologies that have been determined to achieve a minimum 4-log reduction of *Salmonella* bacteria in almonds

- Equipment must be validated by a Board approved Process Authority
- Data must be reviewed and accepted pursuant to a letter of determination by the FDA or ABC Technical Expert Review Panel (TERP)

Exemptions currently exist for shipments to DV Users and for shipments outside of North America

- DV Users are manufacturers with pasteurization equipment that has been subjected to the same validation and review process through the ABC TERP
- Typical DV users are treating product with dry roasting, oil roasting, or blanching processes to deliver a minimum 4-log reduction of *Salmonella*
- Any product shipped under exemption must be labeled as “unpasteurized”

The Validation Process



Technical Expert Review Panel Established – Oct. 2004

ABC Technical Expert Review Panel (TERP)

- Experts in microbiology, process engineering, pasteurization, process validation, and regulatory food safety requirements
- Conduct technical reviews of equipment and validation reports to determine ability to deliver a minimum 4-log reduction of *Salmonella* bacteria on almonds
 - Provide written reports outlining the Panel's determination that a process has or has not met the established criteria

Panel Members

- Dr. Ken Stevenson (Chairman)
- Dr. Larry Beuchat
- Dr. Brad Marks
- Mr. Keith Ito
- Dr. Dave Ashton
- Mr. Rick Stier
- Dr. John Larkin – FDA Ex-Officio
- Tim Birmingham – ABC Staff Liaison

7 CFR Part 981.442b - Validation by Process Authority (PA)

Handlers shall only use or ship their almonds to off-site treatment facilities that use treatment processes that have been validated by a Board-approved process authority.

Process Authorities (PA's)

- Experts in almond treatment processes
- Experience in conducting appropriate studies to determine ability of the equipment to deliver the appropriate treatment
- PA's conduct microbiological challenge testing and/or thermal temperature mapping to determine ability of equipment to deliver an appropriate log reduction
- 17 Board approved PA's

Wrapping it All Up

- Low water activity foods & ingredients such as spices serve as ideal survival hosts for pathogens such as *Salmonella*
- Decisions regarding definitive control steps should be rooted in research
 - Where research is lacking get started now!
 - Data from other industries can be used as a starting point but, One Size Doesn't Fit All!
 - Engage partners in research – Equipment manufacturers, Universities, Private labs, etc.
- Establishing well defined protocols adds credibility
- Establishing a review panel keeps the playing field equal and adds credibility
- Don't forget about Post Process – Recontamination control





Thank-You!

