





- •1st Salmonella Outbreak (2000/2001)
- Engaged with Experts
- Began Salmonella survey (Now have 10 years of data)
- Began exploring microbial reduction processes
- July 1<sup>st</sup> Food Quality & Safety Symposium
- PPO Validation submitted to FDA

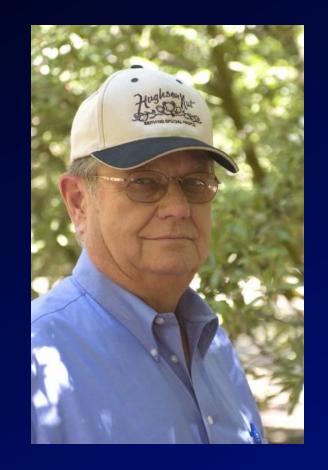
- •Lethality Research Expanded (2002-2007)
- •Surrogate Development Work Initiated (2002-2007
- •Almond GAP's Launched

- •2nd Salmonella Outbreak
- •ABC Approves "Action Plan" calling for 4-log reduction of *Salmonella*
- •First Risk Assessment (2005) – Supported 4-log performance criteria
- •Regulatory language drafted



"Unless we move quickly to process all raw almonds with approved pasteurization technologies, we run the very real risk of committing inexcusable injury to our product and our consumers, and will inevitably invite the forced regulation of our industry, precisely what the Action Plan strives to avoid."

Martin Pohl – Sept. 22, 2005





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- •Regulatory language drafted

- •Mandatory pasteurization rule submitted to USDA – referendum passed (2006)
- Continued lethality / surrogate research
- •DV User Program Developed
- Stakeholder outreach / Program requirements developed
- •September 2007 Effective date of Almond Mandatory Treatment Program for Salmonella Reduction



### Process Validations— 2007 to Present

Process	Active	Since Program Start (2007)
Blanching	20	49
Dry Roast	25	83
Oil Roast	62	139
PPO	13	25
Moist Heat	49	95
Other	1	9
Total	170	400





# From Past to Present: The Evolution of Food Safety Management and Food Safety Culture in the California Almond Industry

Han Chen<sup>1</sup>, Tim Birmingham<sup>2</sup>, Guangwei Huang<sup>2</sup>, Linda J. Harris<sup>3</sup>, Yaohua Feng<sup>1\*</sup>







<sup>&</sup>lt;sup>1</sup> Department of Food Science, Purdue University, West Lafayette, IN 47906, USA

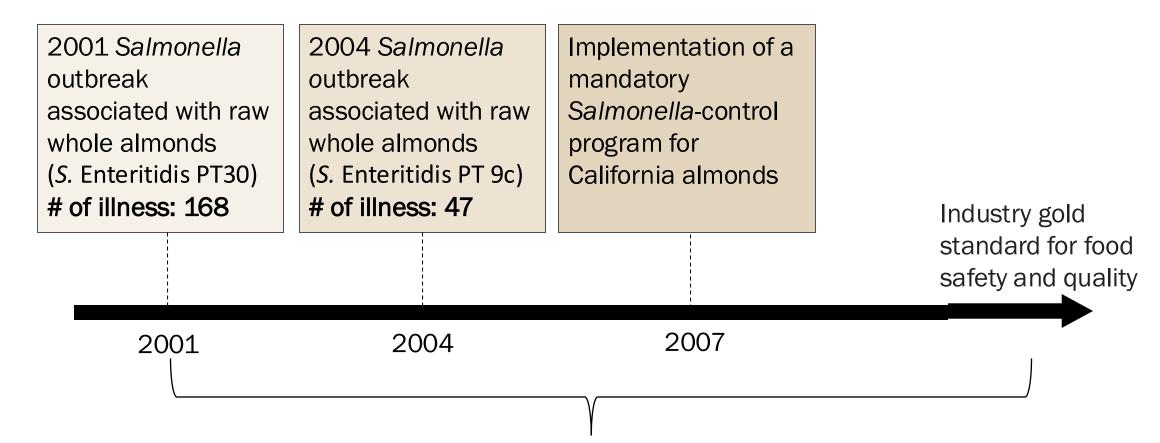
<sup>&</sup>lt;sup>2</sup> The Almond Board of California, Modesto, CA 95354, USA

<sup>&</sup>lt;sup>3</sup> Department of Food Science and Technology, University of California, Davis, CA 95616, USA

# Background



Case study with California almond industry





Developing and implementing various food safety controls for the almond industry

## **Objectives**

Showcase the evolution of food safety management and culture in the California almond industry and identify key factors contributing to these changes.



## Multifaceted methods

This project encompassed four studies

ABC's discussions and actions in addressing food safety issues



Study 1: ABC food safety committee meeting minutes and action plan updates review (N=134) Study 3: Interviews
with experienced
individuals who were
involved in the almond
industry in the early
2000s (N=11)



Individuals'
experiences and
perspectives on the
food safety culture
evolution

Real-time public discussions and comments surrounding the two outbreaks and the mandatory Salmonella-control program



Study 2: News article analysis (N=100)

Study 4: Interviews with current food safety managers from almond processors (N=15)

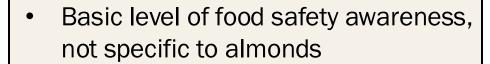


Current food safety
landscape in the
almond industry and
assess the impact of
previous efforts



## Prior to 2001: The uncharted land

The microbial food safety landscape for almonds remained largely unexplored.



 Basic food safety practices implemented to meet federal regulations "

"At that point in time, it was a **quality mentality**, not a food safety mentality. Generally, there wasn't the mindset that you could eat almonds and get sick."

(Study 3, Process Authority)





# The first outbreak in 2001: The first sign of microbial risk

2001 Salmonella outbreak associated with raw whole almonds (S. Enteritidis PT30) # of illness: 168

Outbreak traced back to one almond processor, one huller and sheller, and three growers <sup>1</sup>



2001 2004 2007

Full Text | Newspaper

Recall of nuts and snacks: [Final Edition]

Daily News; Prince Rupert, B.C.. 20 Apr 2001: 16.

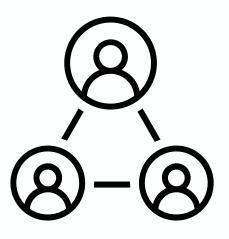


university, (Source: 1. Isaacs et al. 2005)

## Varied reactions to the 2001 outbreak expressed

by most Study 3 participants





66

"It **scared** the bejesus out of me, you know, Salmonella, I need to get educated on that."

(Study 3, Industry Member)

Shocked

Concerned

- Risks and sources of Salmonella
  - Industry reputational damage

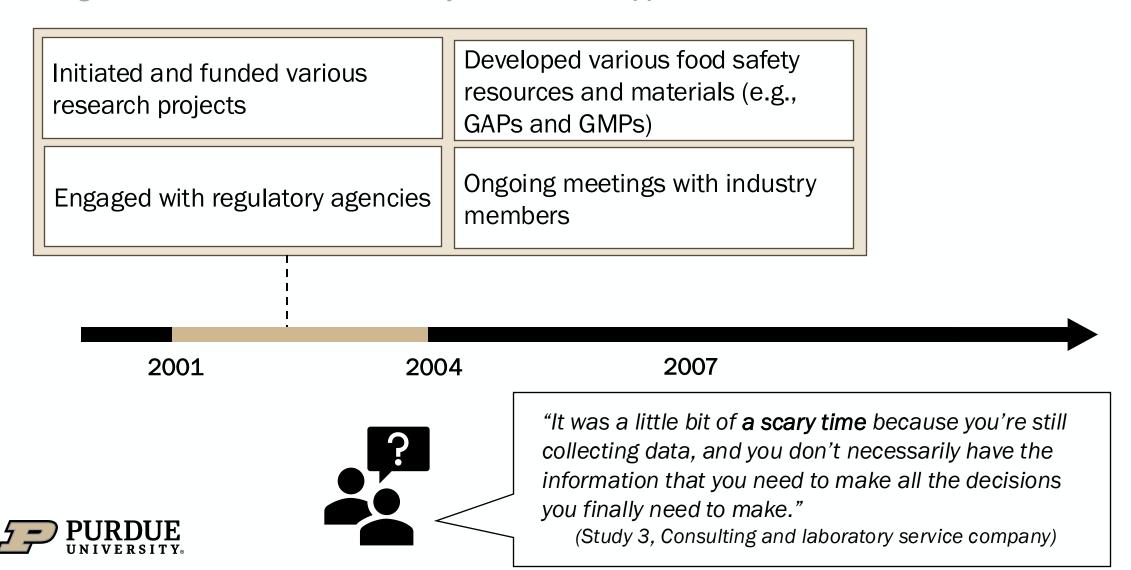


## Different views within the industry

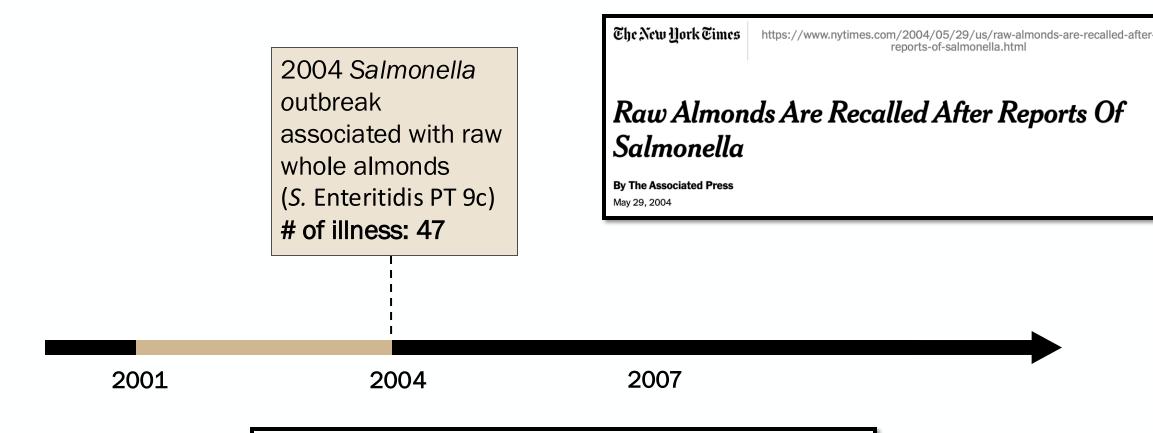
In response to the outbreak "People were kind of like, 'well, that's their problem." (Study 3, ABC) The industry should act on the issue Is it necessary? "The industry kind of looked at the Almond Board and said, 'fix this.'" (Study 3, Process Authority)

# Almond Board of California took the lead in responding

Looking for information to understand why the outbreak happened and how to minimize the risks



## The second outbreak in 2004: The confirmed threat



Outbreak of Salmonella Serotype Enteritidis Infections Associated with Raw Almonds --- United States and Canada, 2003--2004

On June 4, this report was posted as an MMWR Dispatch on the MMWR website (<u>http://www.cdc.gov/mmwr</u>).

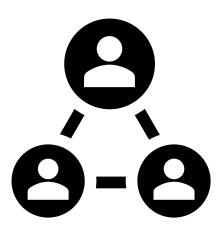


## The outbreak gave a sense of urgency to take actions

"There were a lot of the **smaller** handlers and growers that aren't in tune with all this. They really didn't understand that this was for real."

(Study 3, Process Authority)

Perceived the urgency to act



can put something in place."

(Study 3, Regulator)

"If there are two outbreaks with

the same commodity, they are

likely to be **another** until we

"When the second one happened," we were much more prepared."

(Study 3, ABC)

Still in doubt

Less surprised



## ABC pushed for industry-specific food safety programs



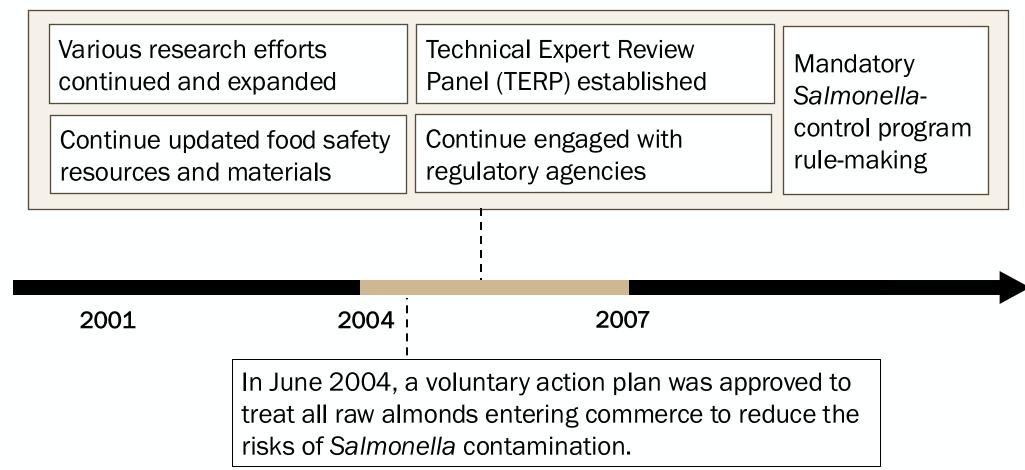


"It was a matter of **stepping up the work we were doing** with other companies, manufacturers, as well as researchers, and government authorities to really start determining what steps and procedures we could put in place to avoid a third outbreak."

(Study 3, ABC)



## ABC increased efforts to improve food safety





## Developing a mandatory Salmonella-control program

Extensive
discussions and
debates throughout
the rule-making
process

Capacity and availability of proper treatment technologies

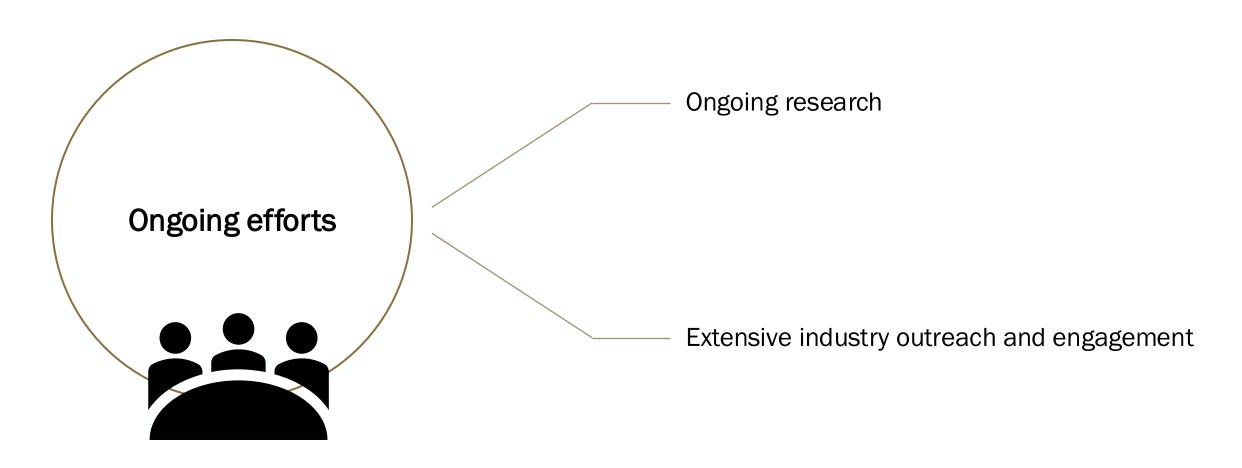
Getting industry members on board and prepared

"I think the challenge with any industry group is getting widespread buy-in and commitment to do something different.... It just requires a little more effort, extra time, extra information, and extra data."

(Study 3, Regulator)



# Efforts brought more industry members on board





## Efforts brought more industry members on board

Ongoing research

Extensive industry outreach and engagement

#### The two most influential activities highlighted

Public meeting involving regulator and epidemiologist

"He scared me. But I think he woke us all up. We needed to have that awakening...he said, 'if you don't fix this problem, we'll fix it for you, and you likely won't like it.'"

(Study 3, Industry Member)

#### Video of affected processors of the first outbreak

"There was a video taken of the processor talking about the whole experience of the outbreak, and the lessons that were learned along the way. I think that's what convinced a number of the people in the industry that this is a problem we all have to face now."

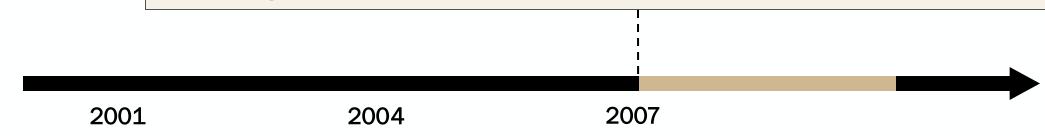
(Study 3, ABC)



# A mandatory Salmonella-control program went into effect on September 1<sup>st</sup>, 2007

Implementation of a mandatory Salmonella-control program for California almonds:

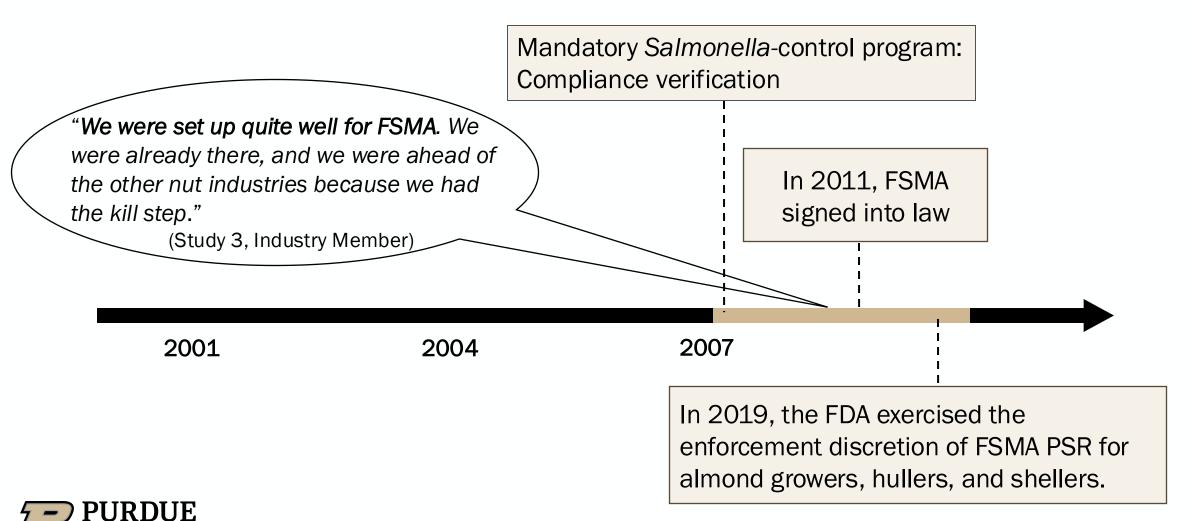
"All almonds sold in the U.S., Canada, or Mexico are required to be treated to achieve a minimum 4-log reduction in Salmonella before shipment, unless they are sold to a board-approved manufacturer who has validated treatment to achieve the desired log reduction."





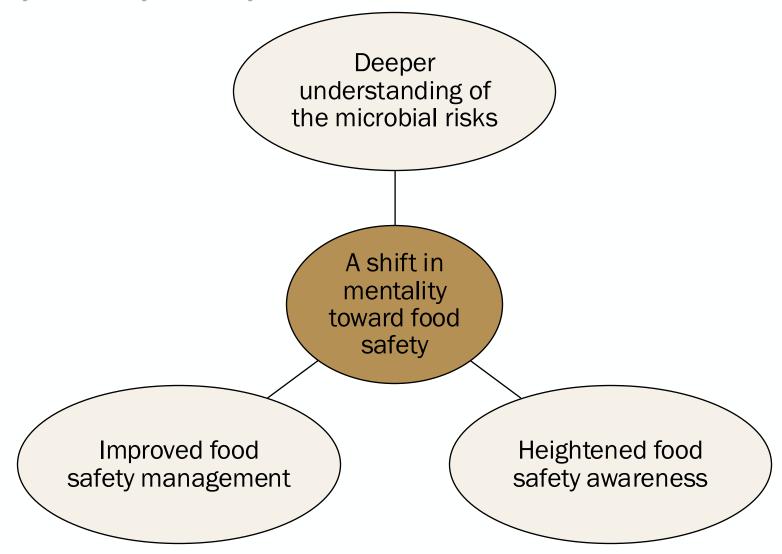
## Post-2007: Program compliance

The almond industry was prepared for the new regulations



# Industry mentality change towards food safety

From "quality mentality" to "safety mentality"





# Two most significant contributing factors driving improvements in food safety management systems

The two outbreaks

"Certainly repeated outbreaks, large numbers of illnesses, increased scrutiny by government regulators, the industries shifted in how they viewed food safety as a priority."

(Study 3, Regulator)

ABC's leadership in taking proactive actions

"All the work that the Almond Board has done has been outstanding. I've seen the industry change the attitude on food safety."

(Study 3, Process Authority)



## Remembering the journey

It wasn't easy, and that's why it needs to continue





"A lot of the people who were involved in this initial process are getting towards retirement age. So, hopefully, that awareness of what happens if you don't keep the food safety practices in mind is there and is continued in future generations."

(Study 3, Consulting and laboratory service company)



## **Significance**

Future generations of almond growers and producers

• Preserve the remarkable history and keep the lessons from past outbreaks

Other industry sectors

 Provide example for industry-driven food safety improvements and self-regulation

Researchers and government agencies

Demonstrate the dynamics and complexity of cultural transformation



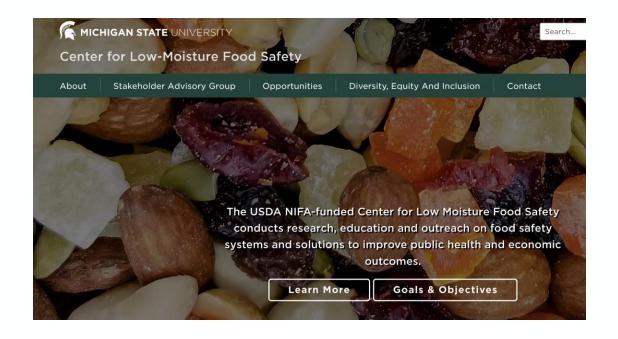
## Acknowledgment

This work is supported by the Agriculture and Food Research Initiative, Sustainable Agricultural Systems Program grant no. 2020-68012-31822 from the USDA National Institute of Food and Agriculture





United States Department of Agriculture National Institute of Food and Agriculture





## References

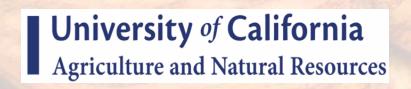
- 1. Isaacs, S., Aramini, J., Ciebin, B., Farrar, J. A., Ahmed, R., Middleton, D., Chandran, A. U., Harris, L. J., Howes, M., Chan, E., Pichette, A. S., Campbell, K., Gupta, A., Lior, L. Y., Pearce, M., Clark, C., Rodgers, F., Jamieson, F., Brophy, I., & Ellis, A. (2005). An international outbreak of salmonellosis associated with raw almonds contaminated with a rare phage type of Salmonella Enteritidis. *Journal of Food Protection*, 68(1), 191–198. <a href="https://doi.org/10.4315/0362-028x-68.1.191">https://doi.org/10.4315/0362-028x-68.1.191</a>
- 2. Centers for Disease Control and Prevention. 2004. "Outbreak of Salmonella serotype Enteritidis infections associated with raw almonds United States and Canada, 2003--2004." Retrieved September 24, 2024, from https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5322a8.htm





# 25 Years of Food Safety: How a foodborne outbreak serendipitously shaped a career

Linda J. Harris, Ph.D., Professor of Cooperative Extension Emeritus December 10, 2025, Sacramento, CA

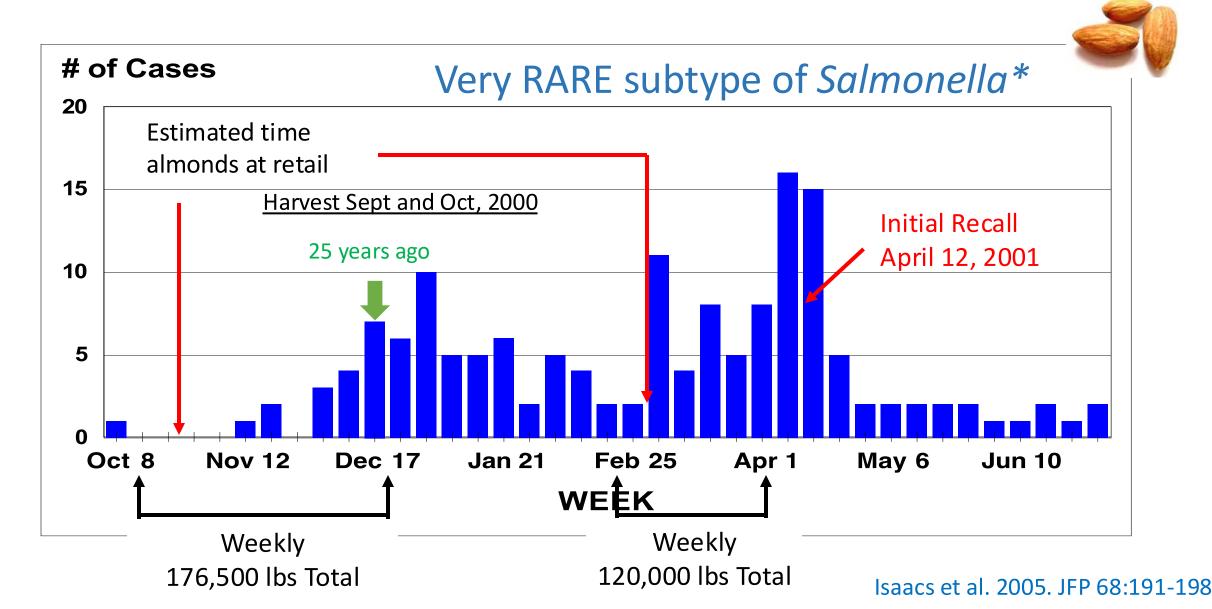








### 2001 almond outbreak: Onset Dates of <u>Salmonella Enteritidis Phage Type (PT) 30</u> Cases in Canada/Raw\* Almond Shipments from California



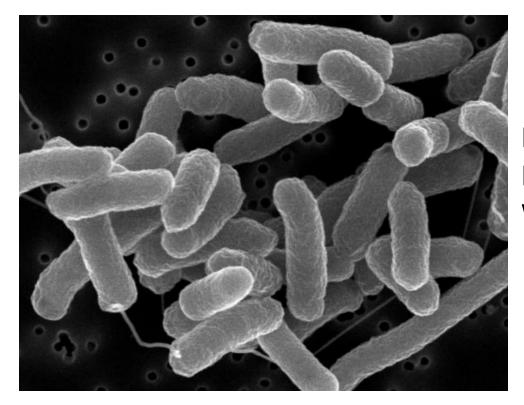
# Pre-2001 nut-adjacent Salmonella outbreaks

- 1953, 1960-61, 1999
  - desiccated coconut (Australia/England)
- 1994-1995
  - peanuts in a savory snack (UK)
- 1996
  - peanut butter Australia
- 2001
  - peanuts UK, Australia, Canada









Before:
Pulsenet fingerprinting
Whole Genome Sequencing

Salmonella Enteritidis Phage Type 30







**UC Davis Lab** 

UCD Lab
San Bernardino

USDA Lab

Nebraska

## 2000-2001 Almond Outbreak Investigation

Growers



Huller/ Sheller(s)



Handler/ Processor





Retail/ Distributor



Consumer

Farm A +

Farm B +

Farm C +

Farm D



Salmonella Enteritidis PT 30

Positive Drag Swabs (6/01 – 7/01)

Facility A +

Facility B Facility C Facility D

4 of 8 Environmental Samples (6/01)



2 of 8 Environmental Samples (6/01)



7 of 11 Lots (5/01 – 8/01)

168 Cases of salmonellosis

(10/00 - 7/01)





Salmonella Enteritidis PT 30



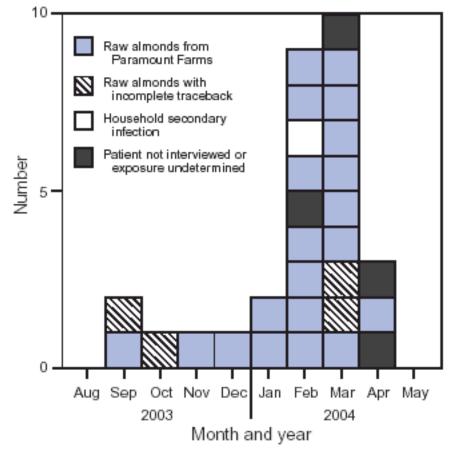
Salmonella Enteritidis PT 30

## RAW Almond Outbreaks 04, 06

- 9/2003 6/2004
  - Salmonella Enteritidis PT 9c
    - Very rare phage type
    - 47 cases in U.S. and Canada
  - Handler (processor) unrelated to 2001 outbreak
- 12/2005 8/2006
   (raw almond-link suspected)
  - Salmonella Enteritidis PT 30
    - 15 cases Sweden



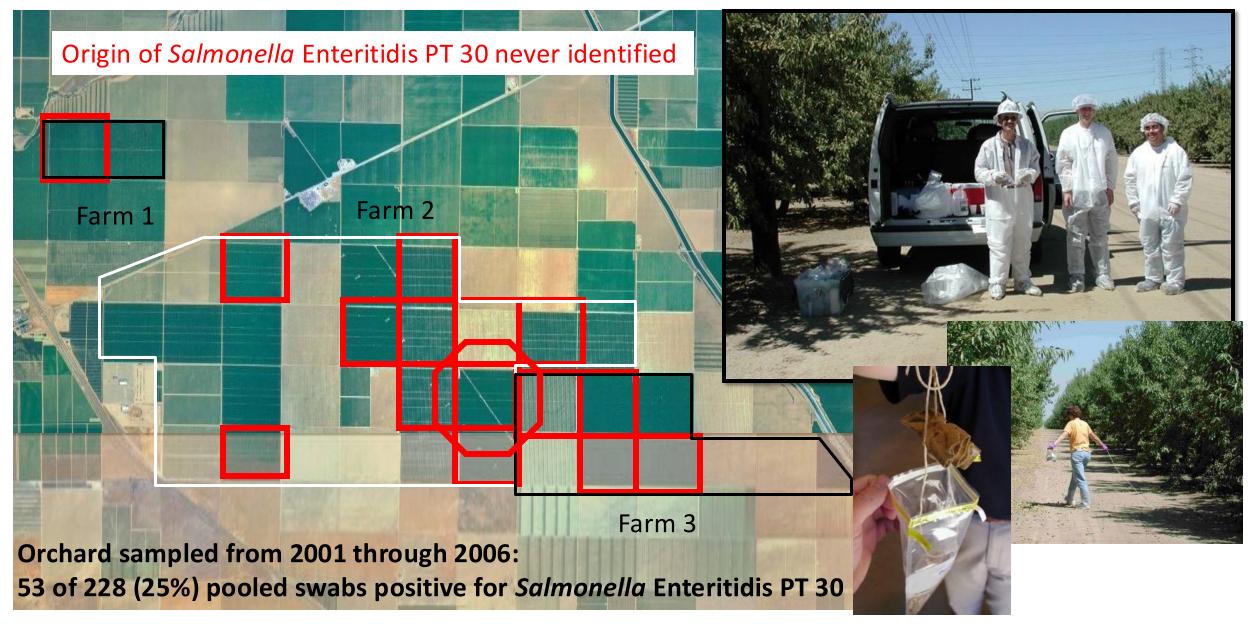
FIGURE. Number\* of PFGE<sup>†</sup>-matched cases of salmonellosis associated with raw almonds, by date of illness onset and mode of exposure — United States and Canada, September 2003–April 2004



<sup>\*</sup>N = 29.

<sup>&</sup>lt;sup>†</sup>Pulsed-field gel electrophoresis.

2001 15/32 - 150 acre orchards positive *Salmonella* Enteritidis PT 30 (10 sq miles/26 sq km)



### Possible Factor Contributing to Outbreak:

Questionnaire revealed: almonds on ground OR swept into windrows

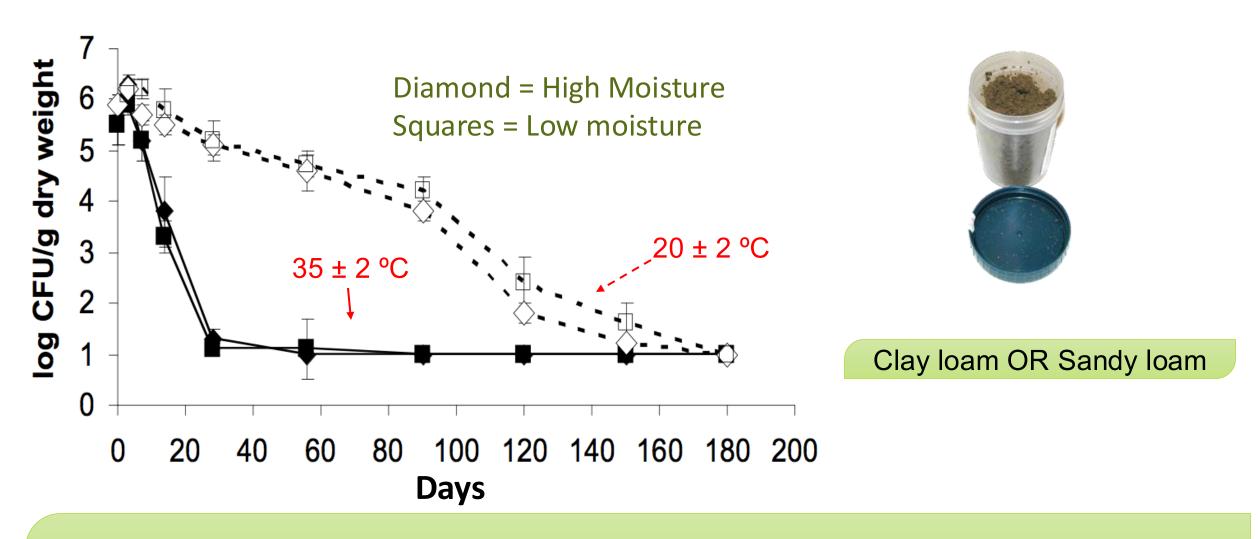




Significant rain 10/9 - 10/10, 2000

Clay-like soil, difficult to harvest, high level of soil carry-over

### Does Salmonella Enteritidis PT 30 survive in soil?

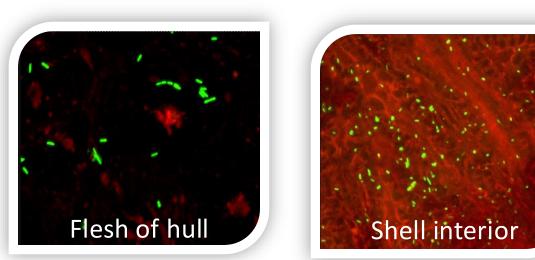


Temperature influenced survival of Salmonella in soil more than moisture or soil type

### What happens when dry hulls or shells get wet?



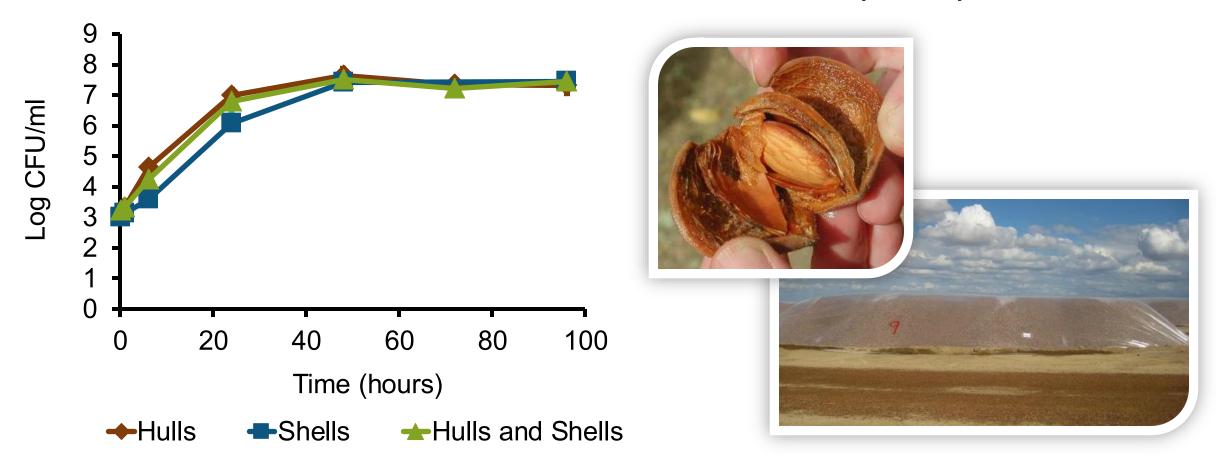
Water uptake to 300% of initial weight





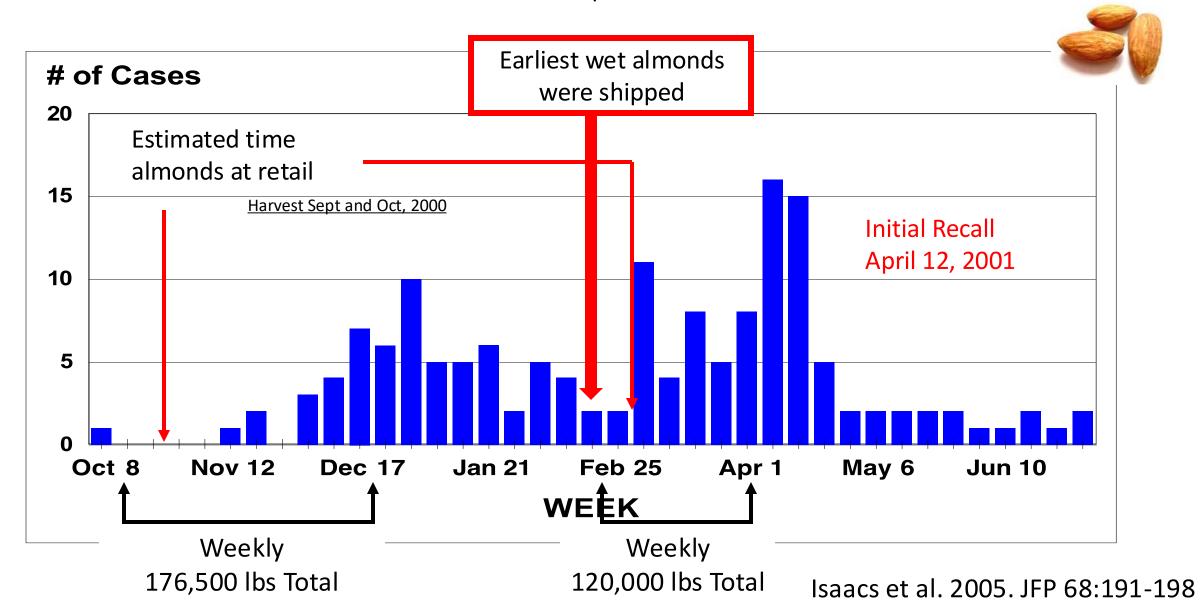
Salmonella migration through almond hull and shell

## Can Salmonella Enteritidis PT 30 multiply in wet almond hulls and shells at 25°C (75°F)?



Wet weather potentially amplified Salmonella in the orchard

## 2001 almond outbreak: Onset Dates of *Salmonella* Enteritidis PT30 Cases Canada/Raw Almond Shipments from California



## Huller and Sheller: Almonds

Receiving Pit



**Pre-Cleaning** 



Remove hulls/shells



Sort kernels from debris



Transport to handler



Storage





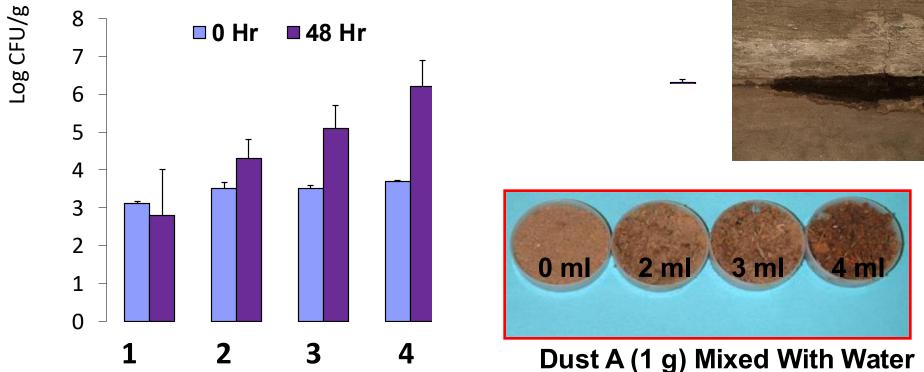




### Water matters after harvest

• Salmonella CAN multiply in the presence of even small amounts of water in "almond dust" at 30°C/86°F

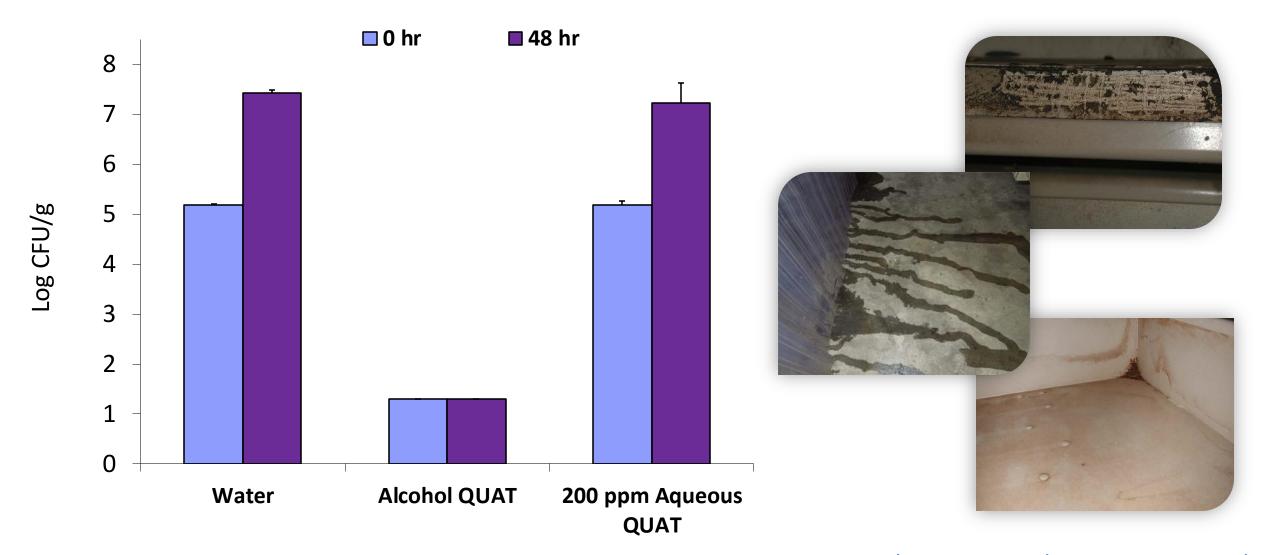




Milliliters of water per gram of almond dust

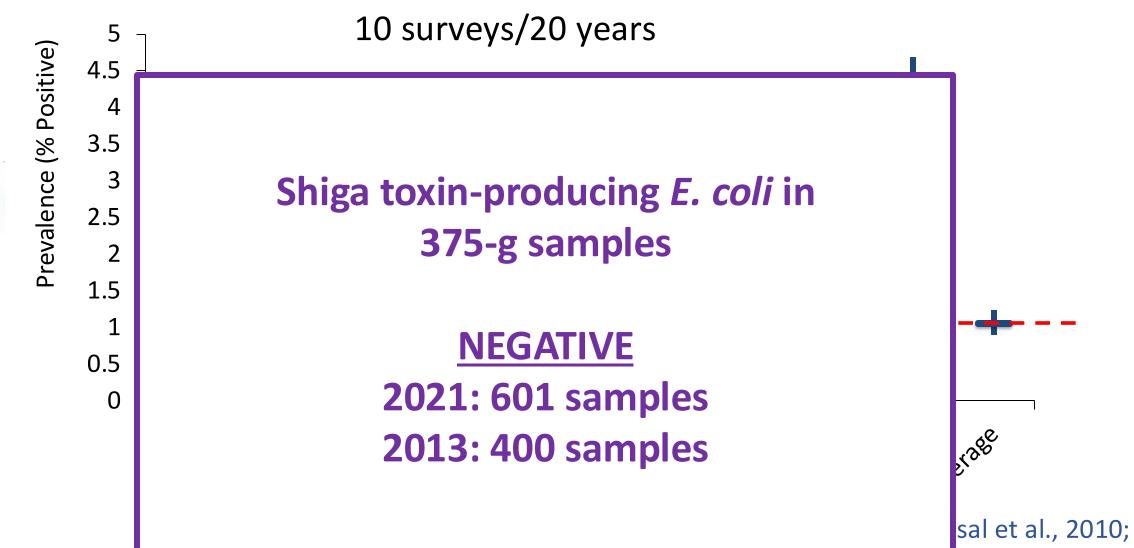
Du et al., 2010. J. Food Sci.

## Aqueous QUAT is not effective in reducing *Salmonella* and preventing growth in almond dust (86°F/30°C)



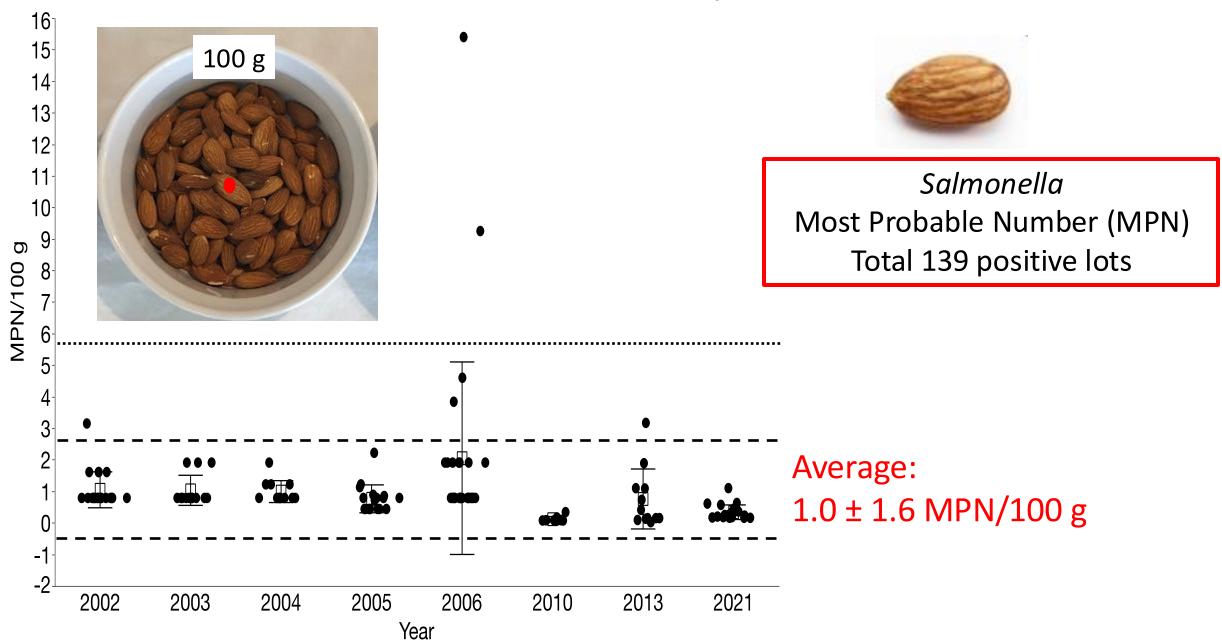
Du et al., 2007. Food Protection Trends

Prevalence of *Salmonella* in 100-g Raw Almond Kernels at Harvest With 95% Confidence Intervals



arris et al., 2025

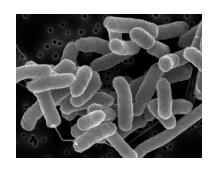
### Levels of Salmonella in positive almonds





## Hypothesis: Contamination Source

- Evidence suggests under <u>normal</u> circumstances contamination on the farm and during harvest/hulling/shelling is:
  - Environmental
  - Sporadic
  - Random
  - Low levels







### Almond Harvesting, Processing, and Microbial Flora

A. DOUGLAS KING, JR., MARY JO MILLER, AND LINDA C. ELDRIDGE

Western Regional Research Laboratory and Biometrical Services Staff, Agricultural Research Service, Albany, California 94710

Received for publication 23 March 1970

Research at the request of the almond industry to determine microbial quality of almonds. 1967 harvest

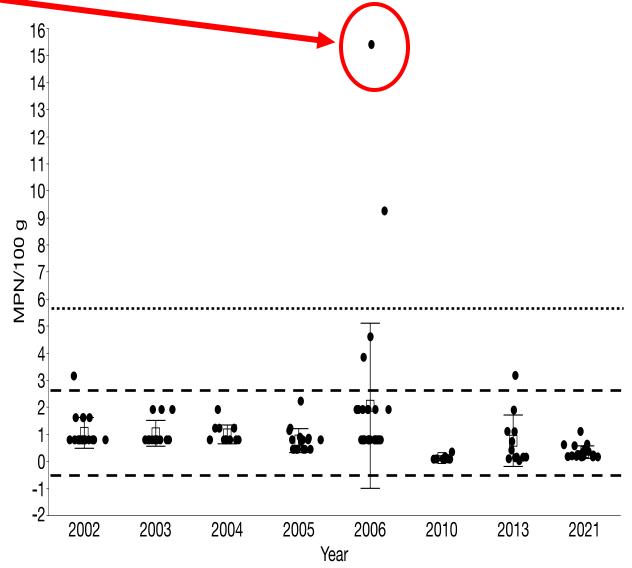
The data reported in this paper reflect the microbial population on the surface of almond meats. A portion of the bacterial contamination stems from soil and dust contact with nutmeats. This is shown by the lower counts for hard-shelled varieties which have a more complete shell and less chance for soil contamination. The effect of soil contact is also reflected in the lower counts for nuts harvested on cloths as opposed to those collected from the ground.



# Why/When? How often?



## Levels of *Salmonella* in almonds per 100 g



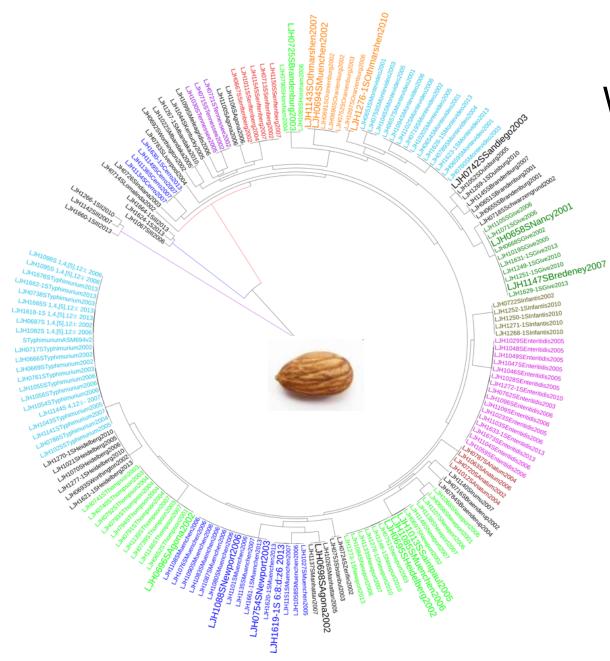
• Salmonella, not drawn to scale

# 2001 Outbreak Est. up to 120 cells/100 g Recalled almonds

## Why? How often?



• Salmonella, not drawn to scale

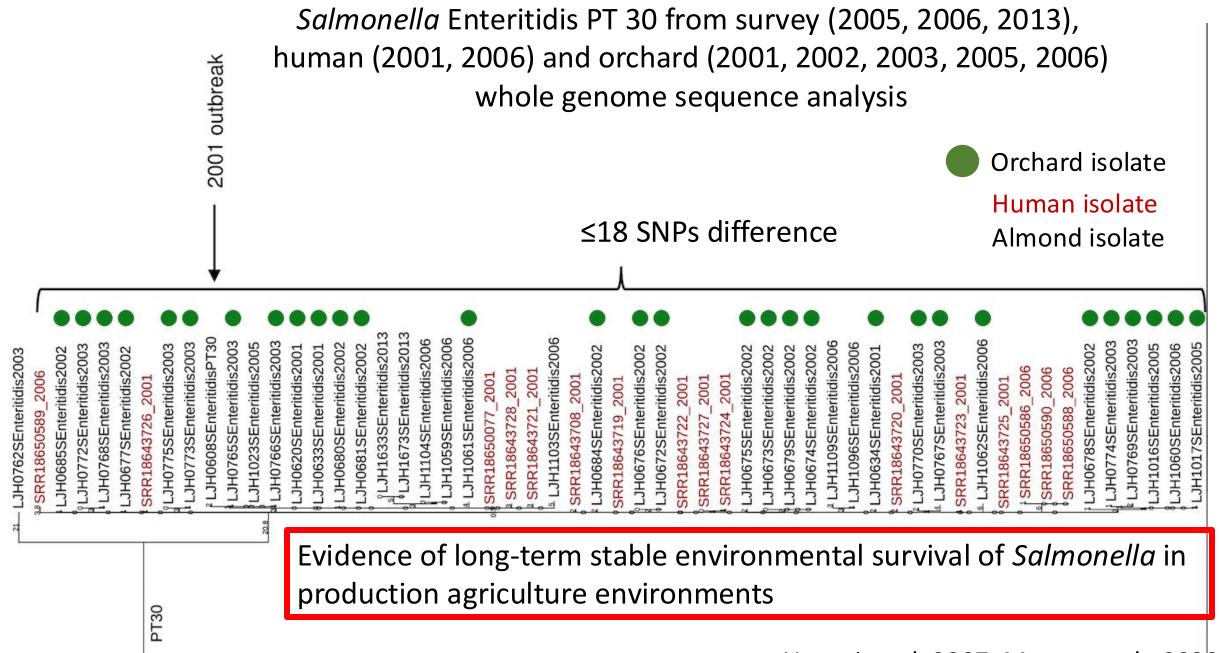


### Whole Genome Sequence Analysis

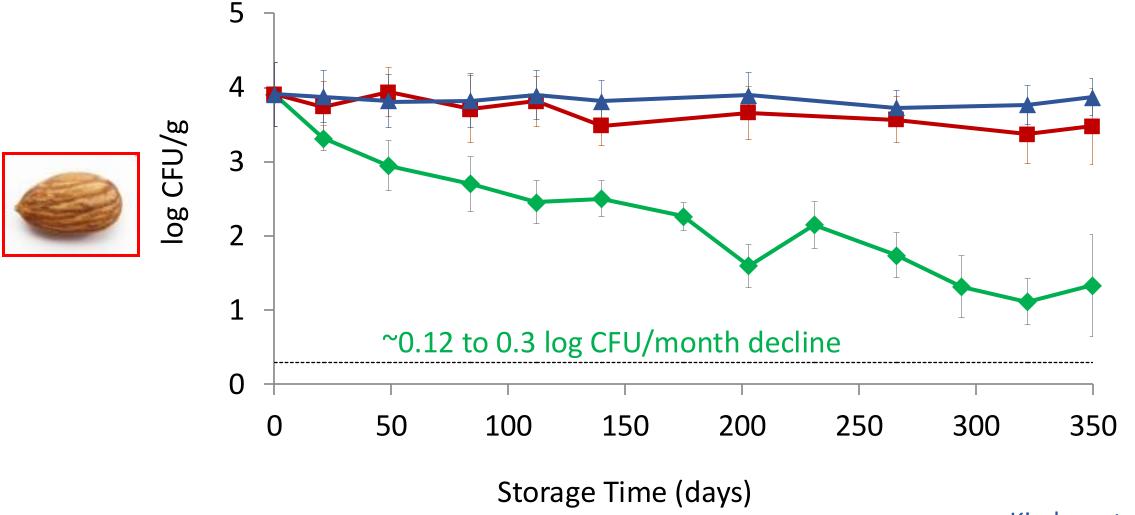
208 isolates from almond kernels 10 different years, 15,530 samples 20-year timespan 2001-2021

Wide range of Salmonella types

35 unique serovars 11 serovars isolated single times



## Survival of *Salmonella* (6-strain cocktail) during storage of almonds at 23°C (73°F), 4°C (39°F), and -20°C (-4°C).





#### 70°C/158°F hot water immersion



5-log (100,000-fold) reduction of *Salmonella* 10 seconds in uncured beef patty: 360 seconds on almonds

### Postharvest Treatment Options

Wet Heat

**Dry Heat** 

Nonthermal

Gas

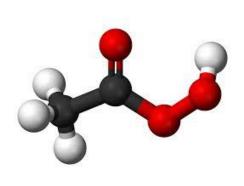
Other Chemical











Steam
Water
Humidity
Re-wetting
Vacuum

Convection
Baking,
Roasting,
Infrared, radio
frequency

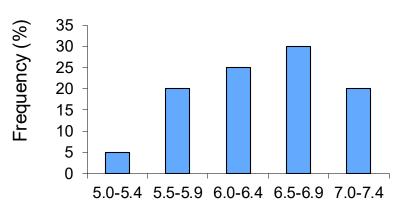
Radiation,
Plasma,
High pressure,
??

Propylene or Ethylene Oxide, Ozone

Acids,
Mixtures
??

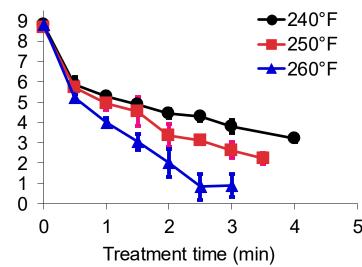
## Process Validation – Safe Harbors – no surrogate Letters of Determination from FDA 5-log reduction





Log CFU/almond reduction

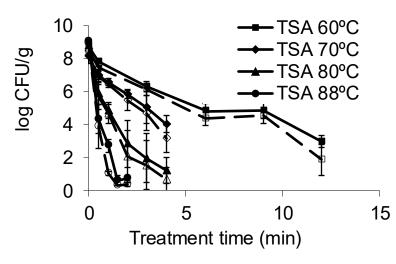




og CFU/g

Du, et al., 2010. J. Food Prot. 73:1238–46





Harris, et al., 2012. Food Res. Int. 45:1093–98

## 7 CFR Part 981.442b Effective Sept. 1, 2007

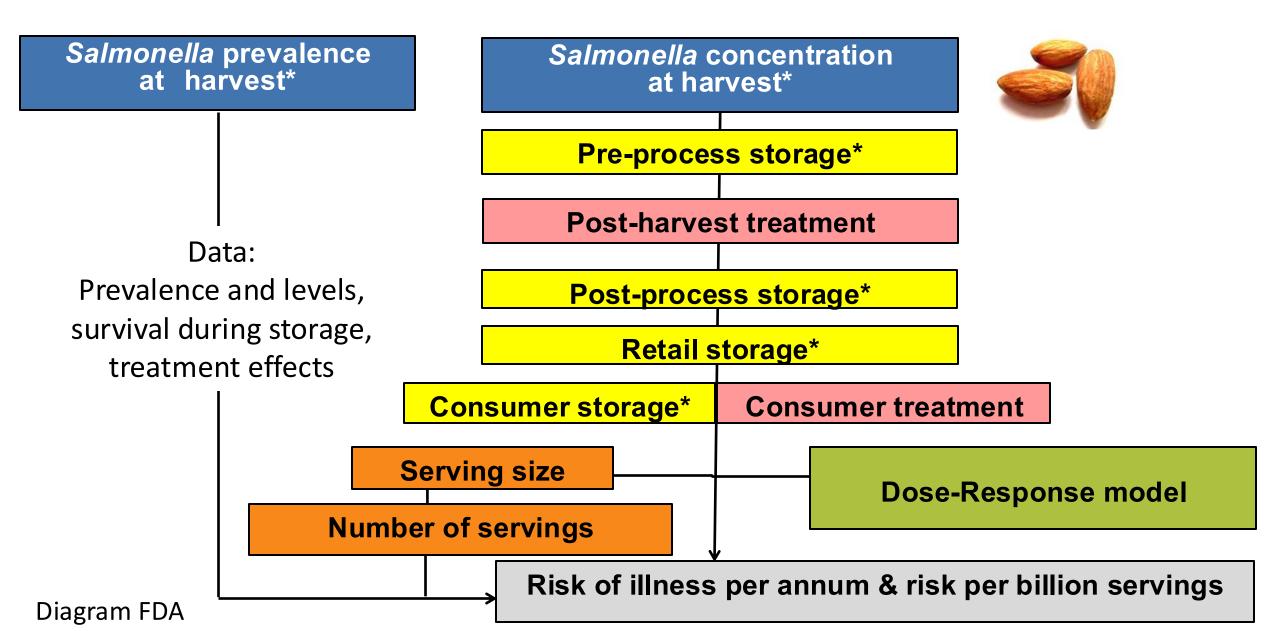
Regulation (USDA-AMS) under the Federal Marketing Order:

## Why

4 log (100,000-fold) reduction?

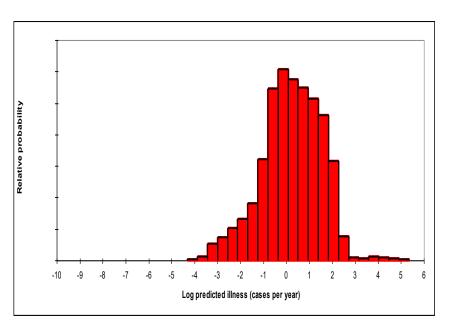
- Data must be reviewed and accepted by:
  - ABC Technical Expert Review Panel (TERP)
    - Independent group of scientists
  - Annual audits by approved auditors

### Quantitative Microbial Risk Assessment Model Outline/Overview



#### 4-log Reduction of Salmonella as a Process Criterion for Almonds

#### 2005 UC Davis Risk Assessment

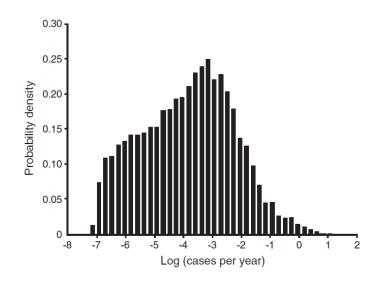


- 5±1 log reduction
  - reduced to <1% chance of >1 case

<u>Subsequent analysis</u> same true for:

• 4±1 log reduction

#### 2012 UC Davis Risk Assessment



**Fig. 4.** Number of salmonellosis episodes per year, as decimal logarithm, under the current production and treatment scenario.

- Confirmed effectiveness of ≥ 4-log treatment performance standard
- 4-log reduced predicted cases to
   <1/year even at assumed worst case</li>
   scenarios and modeled 2001 outbreak

#### 2017 FDA Risk Assessment

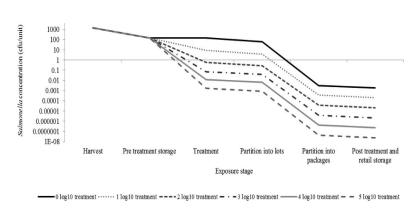


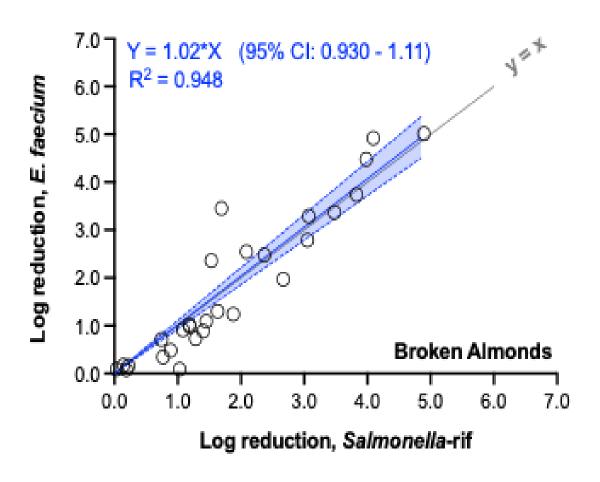
FIGURE 2. Mean Salmonella concentration levels in each of the exposure assessment stages for a simulated no treatment and for 1-, 2-, 3-, 4-, and 5-log reduction treatments (where the log reduction treatment levels in Salmonella cells are defined in CFU per unit of product being treated).

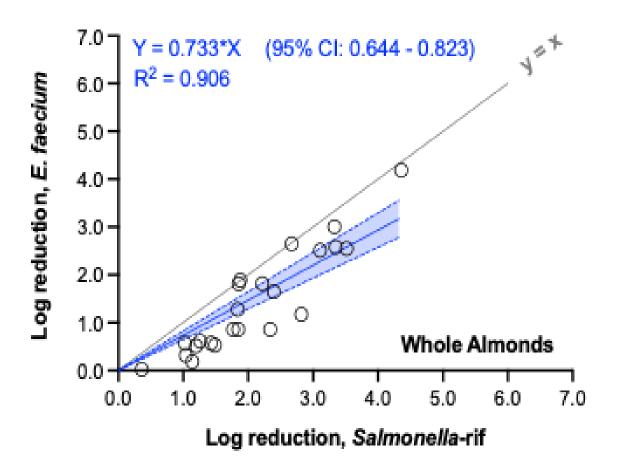
- ≥ 4-log reduction treatment: estimated illness <1 case/year</li>
- ≥ 4-log reduction treatment sufficient to prevent the 2001 outbreak in 2001 (exceptional circumstances)

Lambertini et al. 2012 Food Res. Int.

Santillana Farakos et al. 2017. JFP

## Reduction of Enterococcus faecium NRRL B-2354 and Salmonella on whole and broken almonds at 335°F (168°C) dry heat

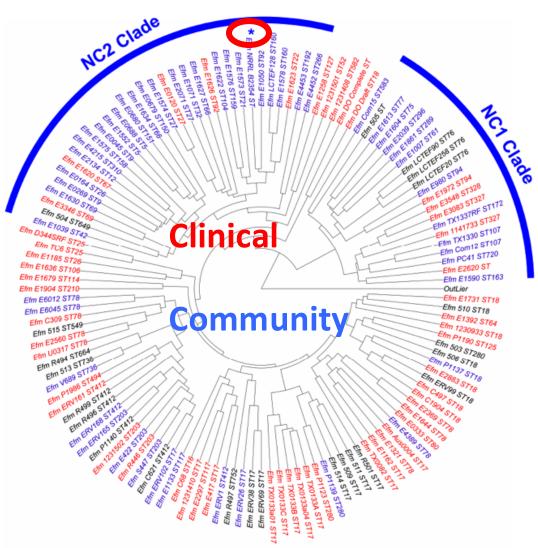




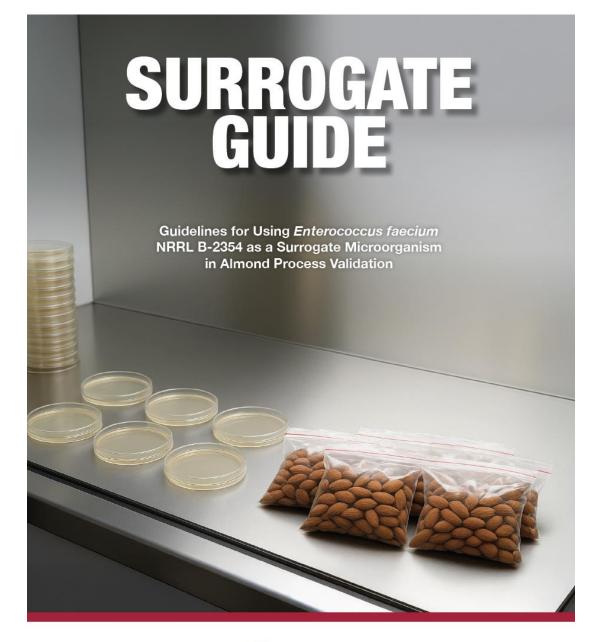
## Enterococcus faecium NRRL B-2354 and ATCC 8459 ATCC successfully petitioned to change classification to BSL1

- Genome sequenced using Illumina and PacBio technologies
  - Chromosome (2.6 Mbp)
  - One plasmid (214 kbp)
- Lacks virulence factors
- Compared to 128 E. faecium genomes
  - Most similar to community strains
- Phenotypic:
  - Sensitive to antibiotics





*,* 2014*,* 2026





### Scientific Publications: Microbiology of Almonds



10 publications over 62 years (1 every 6 years)

>165 publications over 25 years ~7 per year

most recent in 1986

first (non-outbreak pub) in 2005

Journal of Food Protection, Vol. 68, No. 8, 2005, Pages 1613–1622 Copyright ©, International Association for Food Protection



## Survival of *Salmonella* Enteritidis PT 30 on Inoculated Almonds after Commercial Fumigation with Propylene Oxide

MICHELLE D. DANYLUK, AARON R. UESUGI, AND LINDA J. HARRIS\*



## The next *Salmonella* outbreak from California almonds – Harris Prediction



- 1) Unusually high contamination of a lot during production or harvest
  - Contamination exceeds the capacity of a 4-log treatment
  - Should be addressed in grower food safety plan
  - Should be addressed in huller/sheller GMP program
- 2) Recontamination of adequately treated product
  - Handler cross contamination
  - Should be addressed in handler food safety plan
- 3) Consumption of raw product (sold outside of North America)
  - Should be addressed in handler food safety plan
  - Treatment at final destination













### **EVERYONE PLAYS A ROLE IN FOOD SAFETY**







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## Remain vigilant

Continually assessing trends across the supply chain and potential food safety risks

