

# 2017 FDA Almond Risk Assessment – What did they find, and what does it mean?

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JUNE 22, 2017

**UCDAVIS**  
**FOOD SCIENCE AND  
TECHNOLOGY**



## Outline

- Background
- Almond risk assessment
  - Almond Board of California 2006 and 2012
  - FDA May 2017
- Other risk assessments
  - Pecans
  - Pistachios

## Background: Risk Analysis

- (Quantitative) Risk Assessment
  - How big is the risk, what factors control the risk?
  - Scientific process
- Risk Communication
  - How can we talk about the risk with affected individuals?
  - Social and psychological process
- Risk Management
  - What can we do about the risk?
  - Political/management process

Journal of Food Protection, Vol. 69, No. 7, 2006, Pages 1594-1599  
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**Danyluk et al., 2006**

### **Monte Carlo Simulations Assessing the Risk of Salmonellosis from Consumption of Almonds**

MICHELLE D. DANYLUK,<sup>1</sup> LINDA J. HARRIS,<sup>1\*</sup> AND DONALD W. SCHAFFNER<sup>2</sup>

Available from [jfoodprotection.org](http://jfoodprotection.org) at no cost – see available issues

#### First Risk Assessment

Helped Almond Board Management Decision  
to set

**4-log** reduction of *Salmonella* in almonds  
7 CFR 981.442(b)

Note: log = logarithm



*Journal of Food Protection*, Vol. 69, No. 7, 2006, Pages 1594–1599  
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Danyluk et al., 2006


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Lambertini et al., 2012 Food Research International 45 (2012) 1166–1174

Contents lists available at ScienceDirect



**Food Research International**

journal homepage: [www.elsevier.com/locate/foodres](http://www.elsevier.com/locate/foodres)



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Risk of salmonellosis from consumption of almonds in the North American market  
Elisabetta Lambertini <sup>a</sup>, Michelle D. Danyluk <sup>b</sup>, Donald W. Schaffner <sup>c</sup>, Carl K. Winter <sup>a</sup>, Linda J. Harris <sup>a,\*</sup>

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Available from Harris (request via e-mail)

Second Almond Risk Assessment

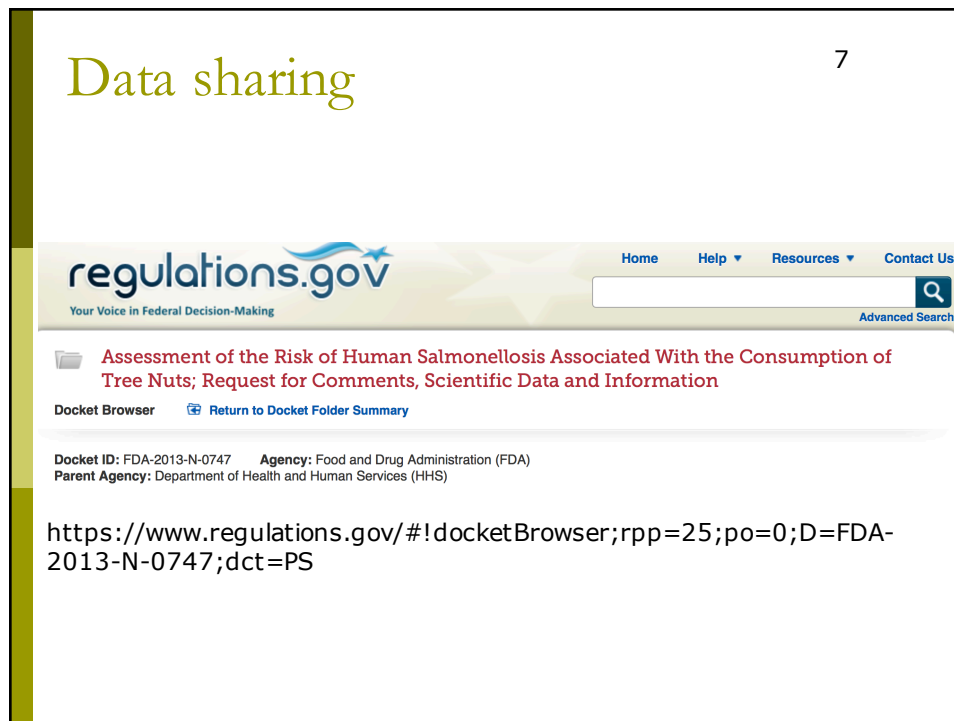
- Used updated data (reduced uncertainty)
- Evaluated "state of the industry"
- Evaluated ABC "pasteurization" program
- Evaluated "limits" where program might fail
- Evaluated 2000/2001 outbreak data



**FDA to Assess Risk of  
Salmonellosis Associated with  
Eating Tree Nuts July 17, 2013**

## Data sharing

7



The screenshot shows the regulations.gov website interface. At the top, there is a navigation bar with links for Home, Help, Resources, and Contact Us. Below this is the site logo and a search bar. The main content area displays a docket entry titled "Assessment of the Risk of Human Salmonellosis Associated With the Consumption of Tree Nuts; Request for Comments, Scientific Data and Information". Below the title, there are links for "Docket Browser" and "Return to Docket Folder Summary". Further down, the docket ID (FDA-2013-N-0747) and the parent agency (Department of Health and Human Services) are listed. At the bottom of the screenshot, a URL is provided: <https://www.regulations.gov/#!docketBrowser;rpp=25;po=0;D=FDA-2013-N-0747;dct=PS>

## FDA Tree Nut Risk Assessment

“The purpose of the risk assessment will be to quantify the public health risk associated with the consumption of potentially *Salmonella* contaminated tree nuts and to evaluate the impact of risk-based preventive controls on the risk of human salmonellosis arising from consumption of tree nuts.”

## FDA to Assess Risk of Salmonellosis Associated with Eating Tree Nuts July 17, 2013

*Journal of Food Protection, Vol. 80, No. 5, 2017, Pages 863–878*  
 doi:10.4315/0362-028X.JFP-16-403  
 Published 2017 by the International Association for Food Protection  
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Journal of Food Protection 80:863-878  
 Open Access Article (free)  
[jfoodprotection.org](http://jfoodprotection.org)

### Research Paper

## A Quantitative Assessment of the Risk of Human Salmonellosis Arising from the Consumption of Almonds in the United States: The Impact of Preventive Treatment Levels

SOFIA M. SANTILLANA FARAKOS,<sup>1\*†</sup> RÉGIS POUILLOT,<sup>1†</sup> RHOMA JOHNSON,<sup>1</sup> JUDITH SPUNGEN,<sup>1</sup> INSOOK SON,<sup>1</sup> NATHAN ANDERSON,<sup>2</sup> AND JANE M. VAN DOREN<sup>1</sup>  
Santillana Farakos et al., [May 2017](#)

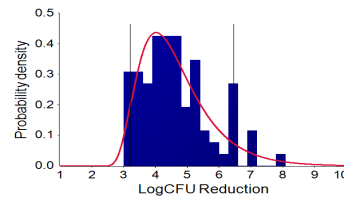
### Third almond risk assessment

- Updated data and reevaluated data
- Evaluated “variability” and “uncertainty”
- Evaluated theoretical reductions
- Evaluated “exceptional events”
- Evaluated 2000/2001 outbreak data



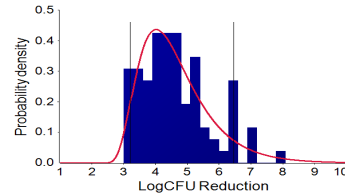
## Variability and Uncertainty

- Variability
  - Heterogeneity of the data
  - Not changed by additional data collection

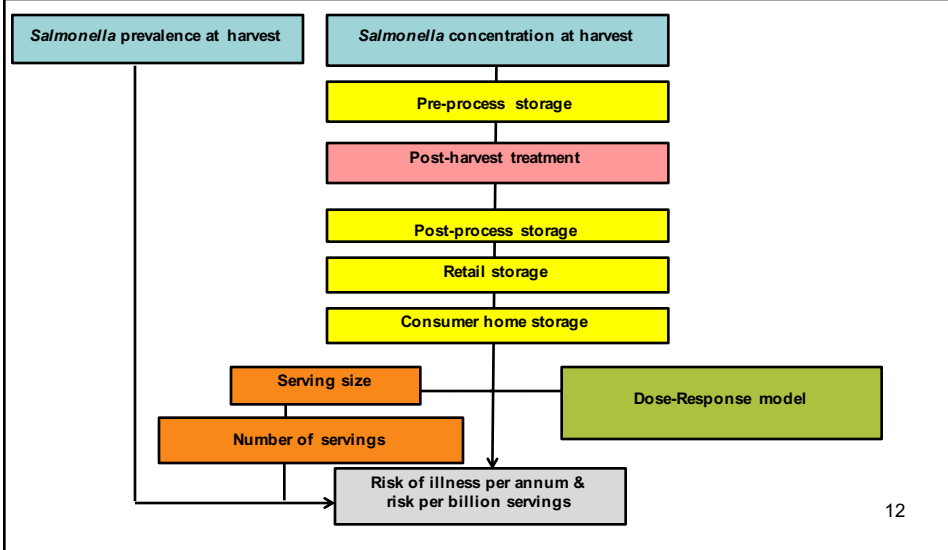


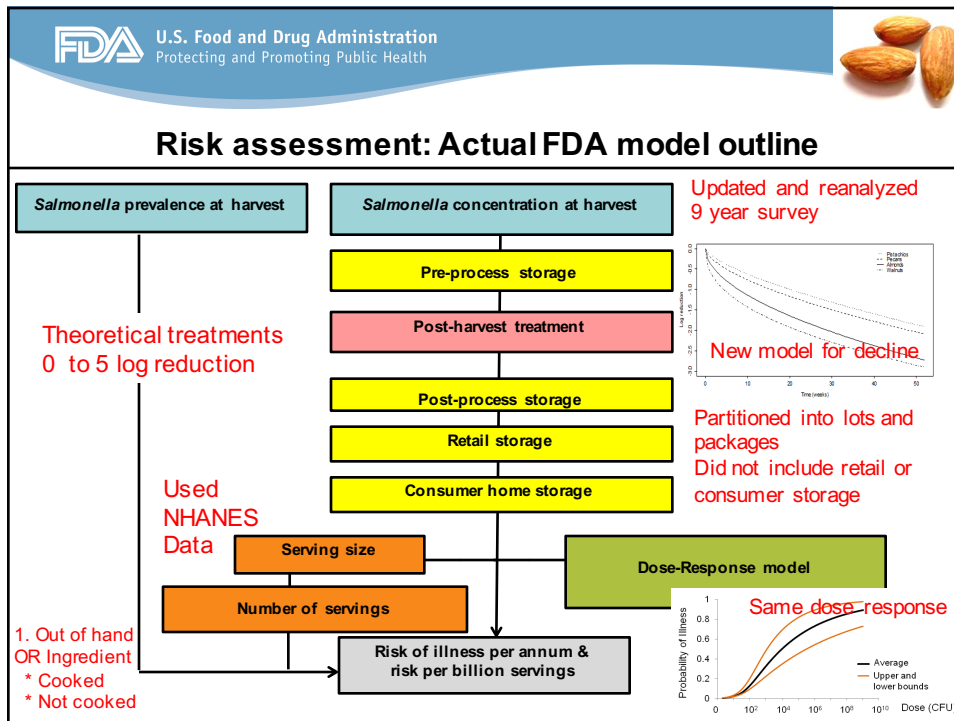
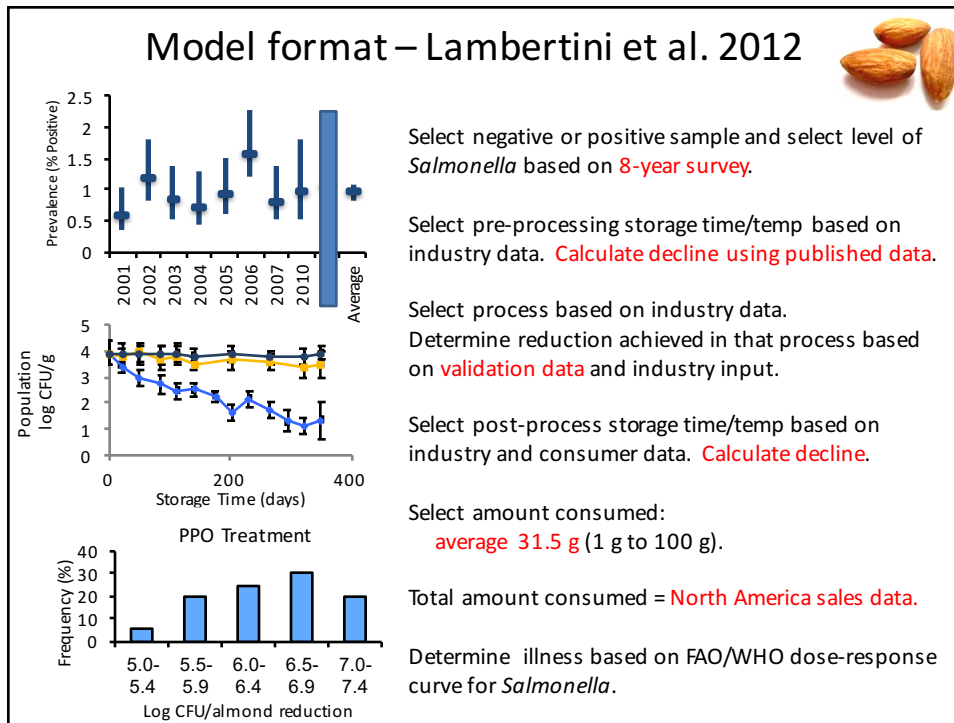
## Variability and Uncertainty

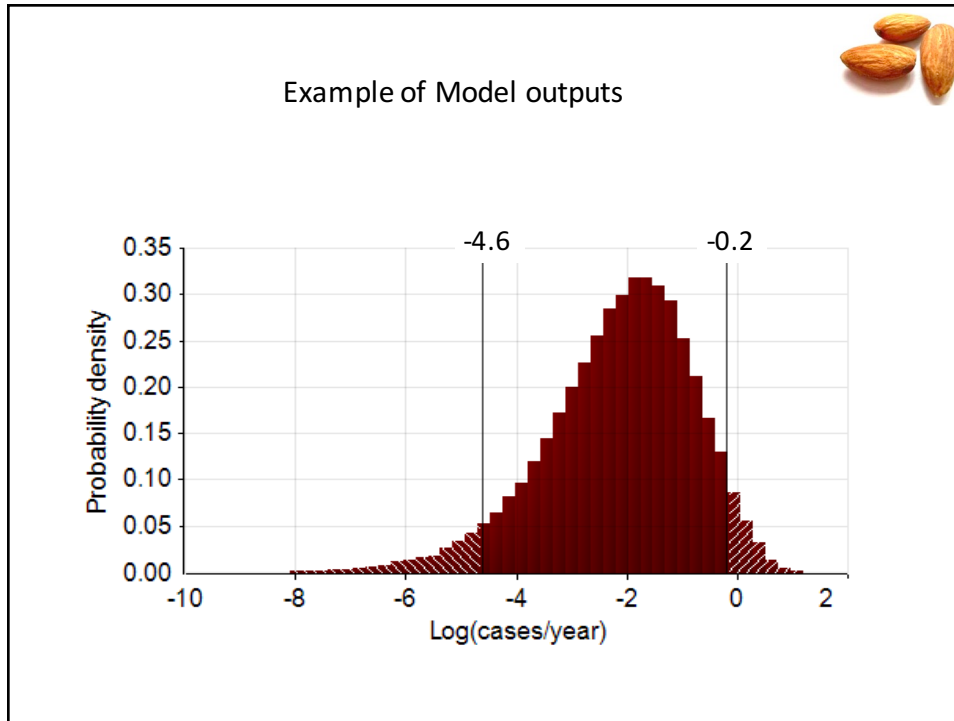
- Variability
  - Heterogeneity of the data
  - Not changed by additional data collection
  
- Uncertainty
  - Lack of knowledge
  - Reduced by additional data



### Risk assessment: Proposed model outline based on Lambertini et al., 2012







Example of Model outputs

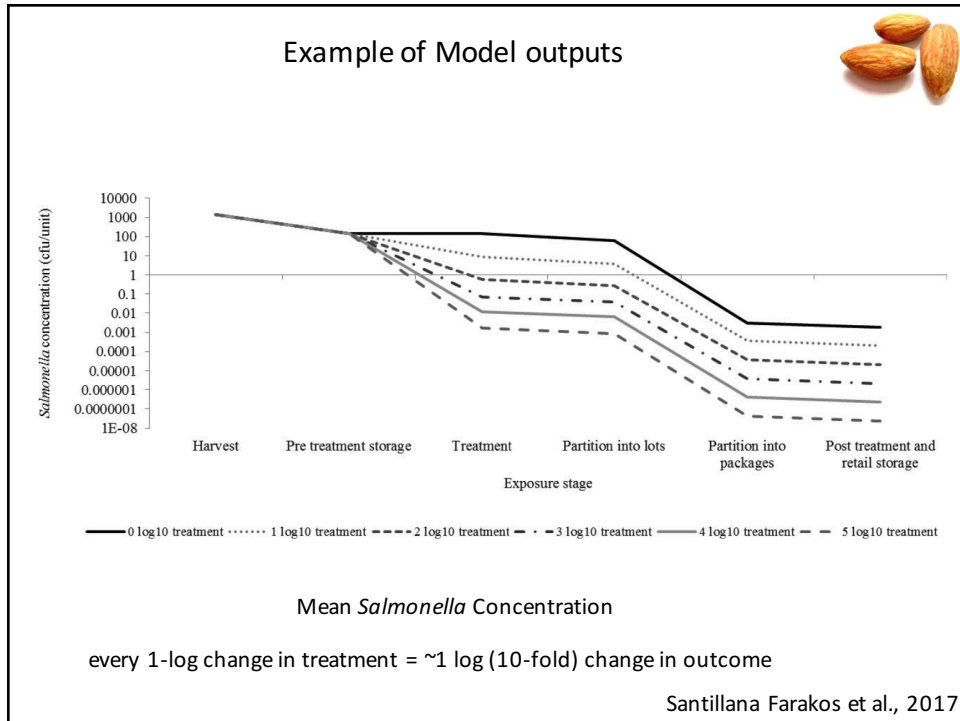
TABLE 4. *Salmonellosis risk per serving for consumption of almonds in the U.S. population<sup>a</sup>*

Only show data for out of hand almonds not cooked by consumer

Treatment (log)		Almonds consumed as core product not cooked at home			
		Mean	SD	Quantiles of variability	
				50%	97.5%
0	Estimate	9.3E-07	1.3E-05	1.2E-08	4.9E-06
	95% CI <sup>b</sup>	6.4E-07	5.4E-06	3.8E-09	3.3E-06
		1.9E-06	8.0E-05	2.4E-08	6.7E-06
1	Estimate	9.3E-08	1.2E-06	1.1E-09	5.0E-07
	95% CI	6.5E-08	5.5E-07	3.7E-10	3.4E-07
		1.9E-07	9.2E-06	2.3E-09	6.6E-07
2	Estimate	9.5E-09	1.3E-07	1.2E-10	4.8E-08
	95% CI	6.4E-09	5.7E-08	3.9E-11	3.1E-08
		2.0E-08	9.8E-07	2.4E-10	6.5E-08
3	Estimate	9.4E-10	1.3E-08	1.2E-11	4.6E-09
	95% CI	6.4E-10	5.9E-09	4.0E-12	3.0E-09
		2.0E-09	1.1E-07	2.5E-11	6.2E-09
4	Estimate	9.5E-11	1.5E-09	1.2E-12	4.9E-10
	95% CI	6.2E-11	5.7E-10	4.0E-13	3.3E-10
		2.1E-10	1.1E-08	2.5E-12	6.5E-10
5	Estimate	9.5E-12	1.3E-10	1.2E-13	4.9E-11
	95% CI	6.4E-12	5.4E-11	4.0E-14	3.3E-11
		2.1E-11	1.1E-09	2.5E-13	6.7E-11

Santillana Farakos et al., 2017





### Comparing Almond Risk Assessments

Almond Treatment	Mean No. cases per billion servings (95% CI - variability)	Mean No. cases per year (95% CI - variability)
Lambertini et al., 2012 Baseline all commercially processed	0.0084 (Not done)	0.037 (Not done)

<sup>a</sup> The number of servings consumed per year: Lambertini et al., 2015 - 6.6 billion in North America; FDA 8.3 billion servings in U.S. – different serving sizes

Lambertini et al., 2012 and Santillana Farakos et al., 2017 (FDA)

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FDA Baseline 0 log (all raw)	930 (12 to 13,000)	1,697 (1,162 to 3,501)

<sup>a</sup> The number of servings consumed per year: ABC - 6.6 billion in North America; FDA 8.3 billion servings in U.S. – different serving sizes

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FDA 3 log	0.94 (0.012 to 13)	2 (1 to 4)
FDA 4 log	0.095 (0.0012 to 1.5)	<1 (<1 to <1)

every 1-log change in treatment = ~1 log (10-fold) change in outcome

<sup>a</sup> The number of servings consumed per year: ABC - 6.6 billion in North America; FDA 8.3 billion servings in U.S. – different serving sizes

Lambertini et al., 2012 and Santillana Farakos et al., 2017 (FDA)

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FDA 4 log	0.095 (0.0012 to 1.5)	<1 (<1 to <1)
Uncertainty	FDA 4 log 2.5th	N/A
	FDA 4 log 97.5th	N/A



<sup>a</sup> The number of servings consumed per year: ABC - 6.6 billion in North America; FDA 8.3 billion servings in U.S. – different serving sizes

Lambertini et al., 2012 and Santillana Farakos et al., 2017 (FDA)

## FDA Almond Risk Assessment



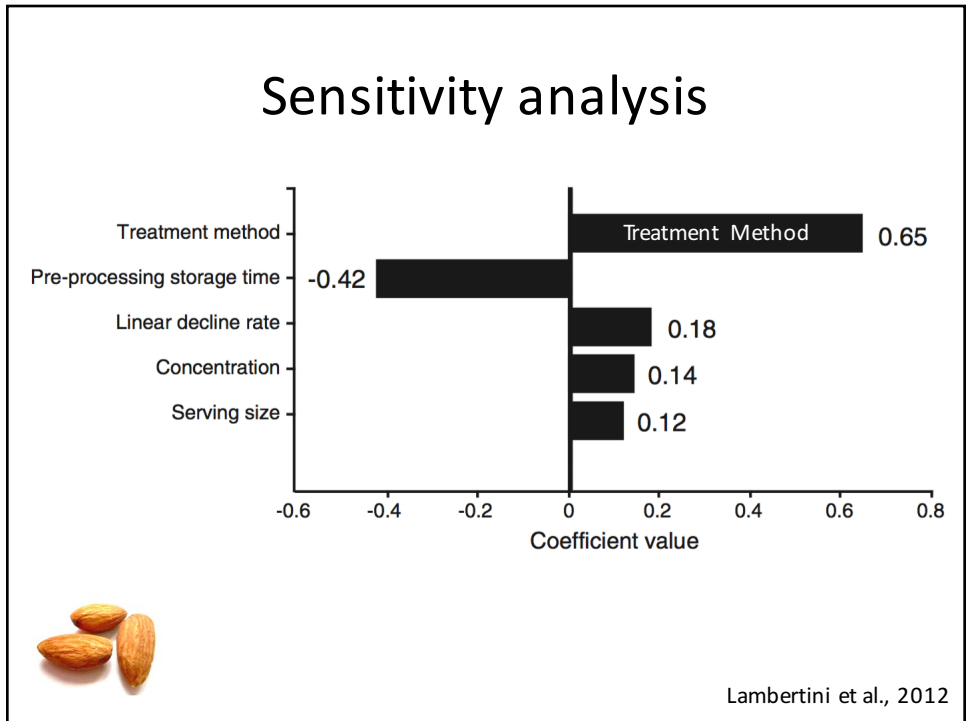
- Good News!!!
  - 3-log reduction treatment
    - Est. 2 cases per year for almonds out of hand
  - 4-log reduction treatment
    - < 1 case per year for almonds out of hand
      - Including variability and uncertainty!
    - Would have prevented 2001 outbreak
      - BUT uncertainty high

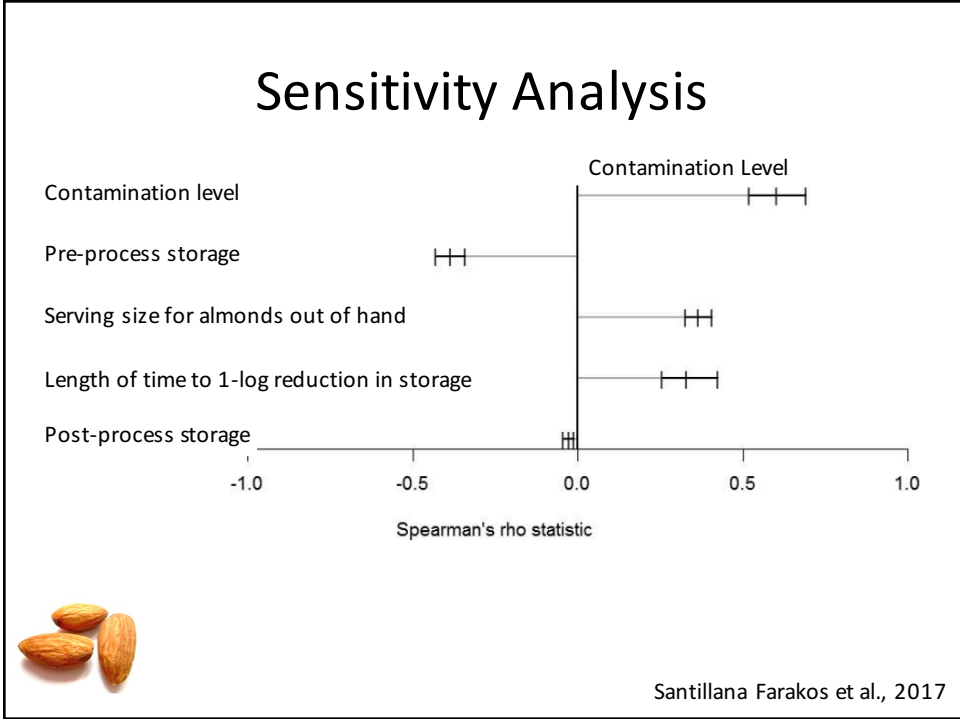


Quantitative Microbial Risk Assessment  $\neq$  Target Process Control

Scientific Process Political/Management Process

FDA risk assessment is an affirmation of 7 CFR 981.442(b) (4-log *Salmonella* treatment). (Harris opinion)





What about the exceptional situations?



## Lambertini et al., 2012

- What does it take to move estimated cases to more than one per year?
  - Increases in whole crop prevalence of *Salmonella* from 1% to 25%
  - Increases in levels of *Salmonella* from 1 cell per 100 g to 25 cells per 100 g
  - Not treating 0.05% of the product consumed



## FDA Modeling Exceptional Situations

- #1 Rain event
- One inshell almond
  - Modeled
    - Growth over several days
    - Reduction on drying
    - Transfer to kernel through hull/shell
    - Cross contamination from “wetted” almond to others
      - 100 g to 10 kg
    - “Wet” almond subsequently discarded

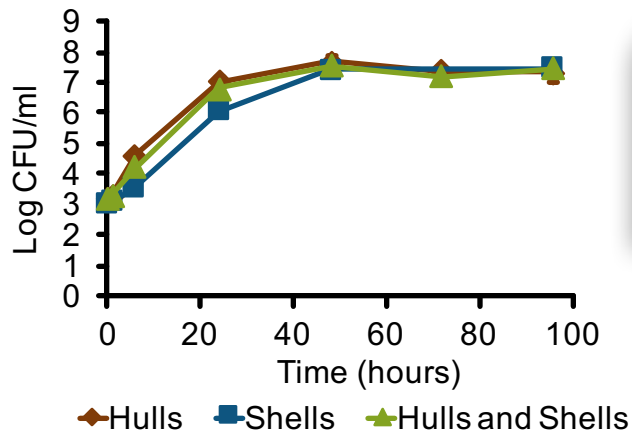


Santillana Farakos et al., 2017

## Why did FDA choose this exceptional event?

- Research had shown
  - Growth of *Salmonella* in wet hulls
  - Transfer from hull to shell to kernel

Can *Salmonella* Enteritidis PT30 multiply in wet hulls and shells at 25°C (75°F)?



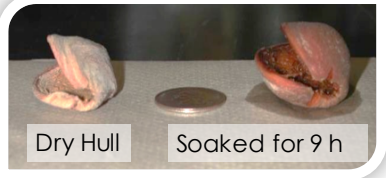
Wet weather potentially amplified *Salmonella* in the orchard

Uesugi and Harris, 2006

What happens when dry hulls or shells get wet?

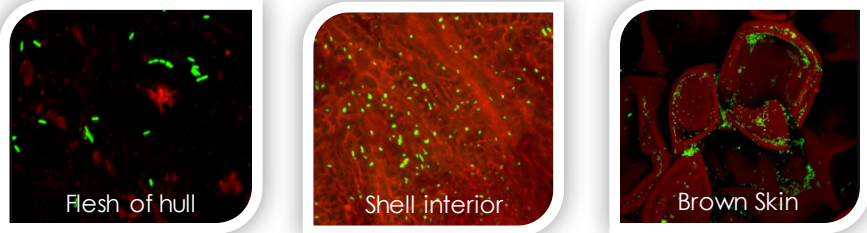


hull      shell      kernel



Dry Hull      Soaked for 9 h

Water uptake to 300% of initial weight



Flesh of hull      Shell interior      Brown Skin


Salmonella migration through almond hull and shell

Uesugi and Harris, 2006; Danyluk, Brandl, and Harris, 2008

## FDA Modeling Exceptional Situations

### #2 Environmental Contamination

- Roof leak
  - Bird droppings:  
3 to 100 CFU of *Salmonella*  
per "lot" of almonds  
(100 g to 100 kg lots).

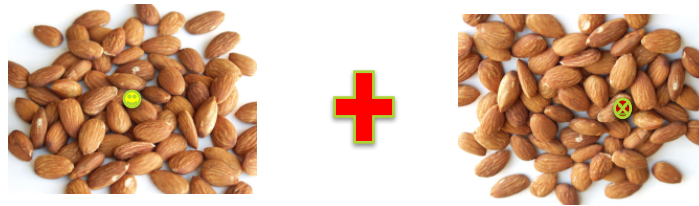


Santillana Farakos et al., 2017



## FDA Modeling Exceptional Situations

- #3 Mixing raw and processed product
  - One untreated lot mixed with one treated lot



Santillana Farakos et al., 2017

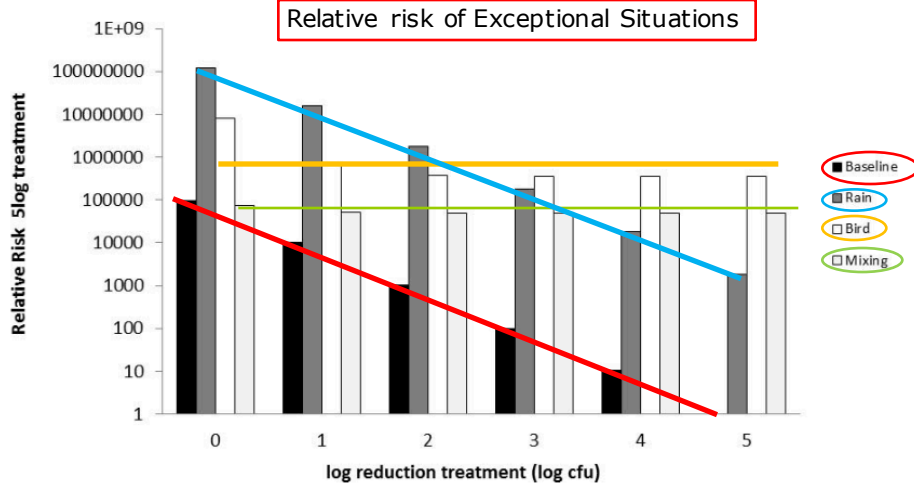


Figure 3 from Santillana Farakos et al., 2017

Acknowledge HIGH LEVEL OF UNCERTAINTY



## FDA Almond Risk Assessment

- **Cautions (Harris summary)!!**
  - Initial *Salmonella* concentration important
    - Good Agricultural Practices are important
      - Growers SHOULD understand contamination risks and work to reduce them
    - Good Hulling/Shelling Practices are important
  - Post-processing contamination very important
    - Need effective *Salmonella* control program



## The *Salmonella* Control Equation



TRAFFIC CONTROL  
(PERSONNEL &  
EQUIPMENT)  
+  
DUST CONTROL  
+  
WATER CONTROL  
+  
SEPARATION OF  
RAW & PASTEURIZED  
PRODUCT  
+  
EFFECTIVE  
CLEANING &  
SANITATION  
-----  
SALMONELLA  
CONTROL





pathogen environmental  
monitoring program (PEM)

<http://www.almonds.com/processors/processing-safe-product#pem>

## Summary

- FDA Almond risk assessment
  - Agreement with adequacy of a 4-log target process control
  - **Caution - Important**
    - initial contamination levels and
    - post-process contamination


## So what's next?

- ABC petition FDA for recognition of 4-log treatment as “pasteurized”
- An FDA risk management decision

## So what's next?

- Pecan risk assessment
  - FDA accepted for publication and in press (anticipated very soon – August?)
- Pistachio risk assessment
  - Harris published (currently available)
  - FDA in preparation
- Presentations at International Association for Food Protection Annual Meeting July 2017 Tampa, FL
  - FDA pistachio “exceptional situations”
  - Harris pistachio harvest model






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Food Microbiology

journal homepage: [www.elsevier.com/locate/fm](http://www.elsevier.com/locate/fm)



**Modeling the risk of salmonellosis from consumption of pistachios produced and consumed in the United States**



Elisabetta Lambertini <sup>a,1</sup>, Javad Barouei <sup>a</sup>, Donald W. Schaffner <sup>b</sup>, Michelle D. Danyluk <sup>c</sup>, Linda J. Harris <sup>a,d,\*</sup>

<sup>a</sup> Department of Food Science and Technology, University of California, Davis, One Shields Avenue, Davis, CA 95616, USA  
<sup>b</sup> Department of Food Science, Rutgers University, 65 Dudley Road, New Brunswick, NJ 08901-8520, USA  
<sup>c</sup> Department of Food Science and Human Nutrition, Citrus Research and Education Center, University of Florida, 700 Experiment Station Road, Lake Alfred, Florida 33850, USA  
<sup>d</sup> Western Center for Food Safety, University of California, Davis, 279 Cousteau Place, Suite 100, Davis, CA 95616, USA

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Questions?