

Resources for Conducting an “Almond Hazard Analysis”



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FDA FOOD SAFETY MODERNIZATION ACT

Current Good Manufacturing Practice, Hazard Analysis,
and Risk-Based Preventive Controls for Human Food

21 CFR 117 Subpart C Hazard Analysis Risk-Based
Preventive Controls **§ 117.130 Hazard analysis**

Hazard Analysis

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- Must be written
 - Prepared or preparation overseen by qualified individual

- Must identify and evaluate:
 - known or reasonably foreseeable hazards for each type of food
 - Based on experience, illness data, scientific reports, and other information

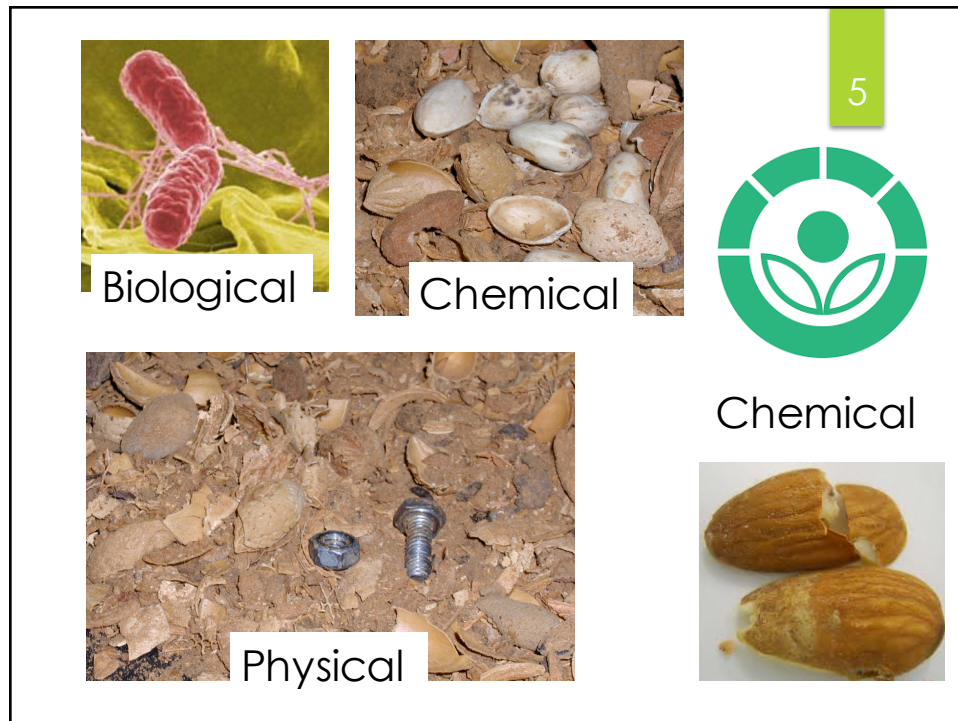
- Determine whether there are any hazards requiring a preventive control.

HACCP



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TEAM WORK!



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Biological

Chemical

Chemical

Physical

Process to Identify Hazards and Controls

1. List process steps and ingredients
2. Identify **known or reasonably foreseeable** (i.e., potential) **food safety hazards**
3. Determine if the hazard **requires a preventive control**
 - Severity and probability in the absence of control
4. Justify the decision
5. Identify preventive controls for significant hazards

Preventive Controls May Include:

- Process preventive controls (traditional CCPs)
- Food allergen preventive controls
- Sanitation preventive controls
- Supply-chain program
- Recall plan
- Other preventive controls

Potential Preventive Control Examples

Biological hazards

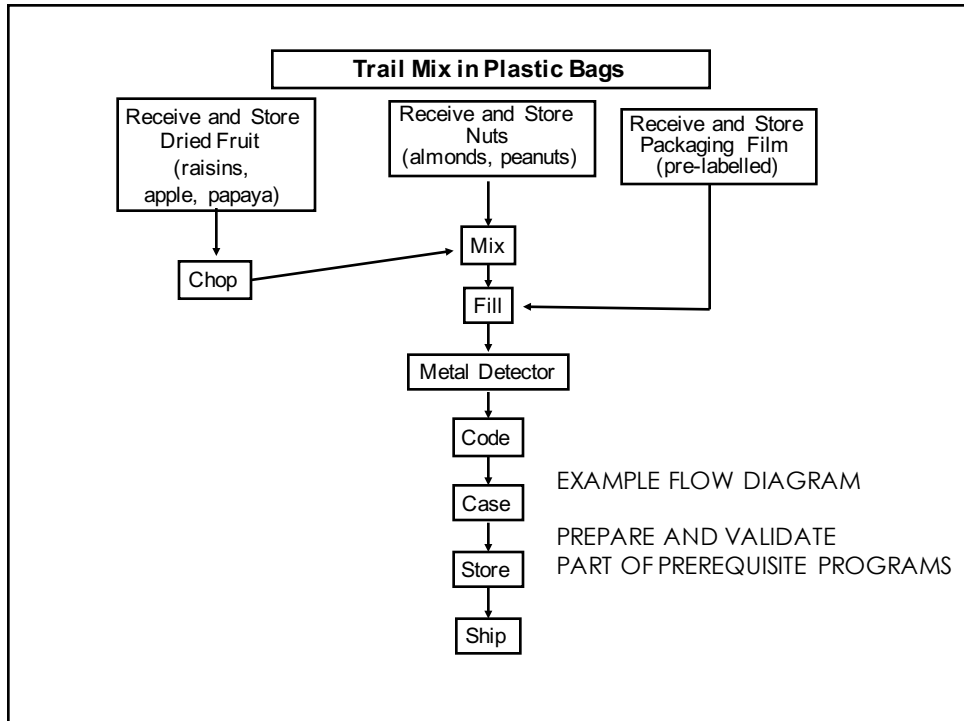
- Process controls that kill pathogens
 - E.g., thermal treatment
- Supply-chain programs for sensitive ingredients used without a kill step
 - E.g., spices
- Sanitation controls that prevent recontamination

Chemical hazards

- Supply-chain programs
- Allergen labeling
- Sanitation controls to prevent allergen cross-contact

Physical hazards

- Process controls such as
 - Filtering, metal detection, X-ray devices



Hazard Analysis		PRODUCT:			PAGE X of Y	
PLANT NAME					ISSUE DATE	mm/dd/yy
ADDRESS					SUPERSEDES	mm/dd/yy

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
B							
C							
P							

Hazard Analysis Form Example -
other formats may be used

FROM FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD CURRICULUM

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Examples of Other Hazard Analysis Formats

(1) Ingredient/ Processing Step	(2) <u>Reasonably foreseeable</u> food safety hazards introduced, controlled or enhanced at this step (B=biological; C=chemical, including radiological; P=physical)	(3) Hazard severity	(4) Is hazard a significant hazard?	(5) Justify your decision for column 4	(6) What <u>preventive</u> control(s) are applied to significantly minimize or prevent the food safety hazard?	(7) Is this step a CCP?
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(1) Ingredient/ Processing Step	Hazard description			Hazard evaluation			Preventive control(s)		
	(2) Identify <u>reasonably foreseeable</u> food safety hazards introduced, controlled or enhanced at this step	(3) Origin or source of the hazard	(4) Nature of the hazard [hazardous level in end product]	(5) Likelihood of occurrence	(6) Severity of health effect	(7) Is hazard significant requiring a preventive control?	(8) Justify decision for column (7)	(9) What control measure(s) are applied to significantly minimize or prevent the food safety hazard?	(10) Nature of control measure CCP Other

FROM FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD CURRICULUM



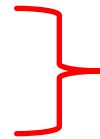
Biological Hazard

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Evaluating Likelihood of Occurrence

- Requires consideration of factors including:
 - Data from past foodborne illness outbreaks
 - Recall data from similar products
 - Information in the scientific literature
 - Historical information in the establishment
 - Regulatory guidance*
 - Warning letters, 483s
 - Trade association information
 - University extension documents



Resources

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A screenshot of the regulations.gov website. The header includes the logo 'regulations.gov' with the tagline 'Your Voice in Federal Decision-Making'. Navigation links for 'Home', 'Help', 'Resources', and 'Contact Us' are visible. A search bar is present. The main content area shows 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, it says 'Docket Browser' and 'Return to Docket Folder Summary'. At the bottom, it provides the 'Docket ID: FDA-2013-N-0747', the 'Agency: Food and Drug Administration (FDA)', and the 'Parent Agency: Department of Health and Human Services (HHS)'. A URL is also displayed: 'https://www.regulations.gov/#!docketBrowser;rpp=25;po=0;D=FDA-2013-N-0747;dct=PS'.

Resources

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December 15, 2013

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

REF: Docket # FDA-2013-N-0747
Assessment of the Risk of Human Salmonellosis Associated With the Consumption of
Tree Nuts; Request for Comments, Scientific Data and Information

Resources

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www.ucfoodsafety.ucdavis.edu/Nuts_and_Nut_Pastes/

Nuts and Nut Pastes

Food safety information for nuts and nut products.

General Food Safety Information

- Bibliography: Containing a comprehensive list of references pertaining to microbial safety of nuts and sesame seed. [Publications on the Microbial Safety of Nuts and Sesame Seeds \(updated 5-4-16\) \(PDF 219 KB\)](#)
- [GMA Equipment Design Checklist for Low Moisture Foods \(will open as MS Excel spreadsheet.\)](#)
- [Inactivation of Microorganisms in Nuts and Nut Pastes: Table and References \(updated 12-08-15\) \(PDF 70 KB\)](#)
- [Outbreaks from Tree Nuts, Peanuts, and Sesame Seeds \(updated 5-4-16\) \(PDF 130 KB\)](#)
- [Recalls of Nuts \(U.S.\) \(updated 5-4-16\) \(PDF 206 KB\)](#)
- [Reportable Food Registry Annual Report \(FDA\)](#)
- [Surveys for Foodborne Pathogens on Nuts \(updated 12-8-15\) \(PDF 143 KB\)](#)
- [Survival of Foodborne Pathogens on Nuts \(updated 12-8-15\) \(PDF 102 KB\)](#)

Industry Handbook for Safe Processing of Nuts

- [Industry Handbook for Safe Processing of Nuts](#) (Grocery Manufacturer's Association) (PDF 1.56 MB)
 - [Addendum I: Industry Handbook for the Safe Shelling of Peanuts \(PDF 222 KB\)](#)
 - [Addendum II: Good Agricultural Practices for California Pistachio Growers \(PDF 141 KB\)](#)
 - [Addendum III : Good Agricultural Practices for Almond Growers \(PDF 1.5 KB\)](#)
 - [Executive Summary: Industry Handbook for Safe Processing of Nuts \(PDF 42 KB\)](#)
 - [Facility Design Checklist \(will open as MS Excel spreadsheet.\)](#)
 - [Technical Guidance and Tools](#)

New version available soon!!
July 2016?

Resources

www.ucfoodsafety.ucdavis.edu/Nuts_and_Nut_Pastes/

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University of California
UC Food Safety

Home Better Process Control Schools Consumers Food Safety Links Pre- & Post-harvest Produce
Food Service/Retail Food Processing Food Industry Contacts UC Publications Contact Us

Nuts and Nut Pastes

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Outbreak Table

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Outbreaks of foodborne illness associated with the consumption of tree nuts, peanuts, and sesame seeds

Type	Product (source)	<i>Salmonella enterica</i> serovar or other pathogen	Year	Number of cases	Isolated from product?	Outbreak location(s)	Source
Tree nuts							
Almond	raw whole (California)	S. Enteritidis PT 30	2000-01	168	yes	Canada, USA	CDPH, 2002; Chan et al., 2002; Isaacs et al., 2005
	raw whole (California)	S. Enteritidis PT 9c	2004	47	no	Canada, USA	CDC, 2004; CDPH, 2004
	raw whole (California?)	S. Enteritidis NST 3+ (aka PT 30)	2005-06	15	no	Sweden	Ledet Müller et al., 2007
	raw whole (Australia)	S. Typhimurium	2012	27	yes	Australia	FSANZ, 2012; Whitworth, 2012 (and personal communication)

Harris, L. J., M. Palumbo, L. R. Beuchat, and M. D. Danyluk. 2015. Outbreaks of foodborne illness associated with the consumption of tree nuts, peanuts, and sesame seeds [Table and references]. *In* Outbreaks from tree nuts, peanuts, and sesame seeds. Available at: http://ucfoodsafety.ucdavis.edu/Nuts_and_Nut_Pastes.

Recalls U.S.

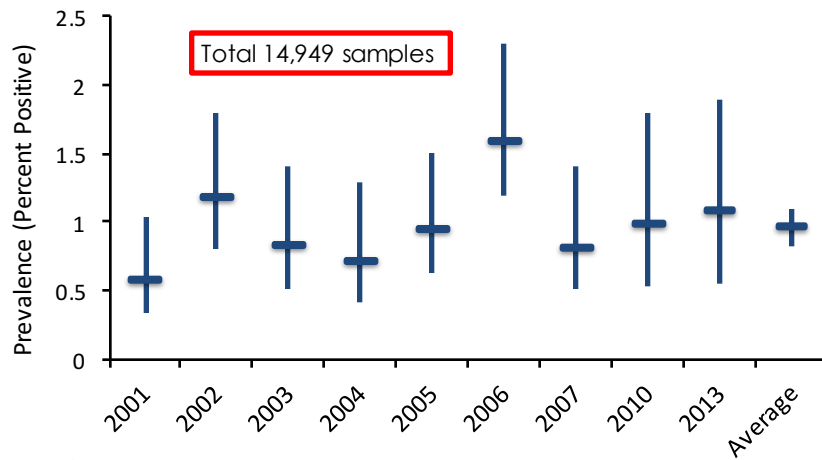
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- *Salmonella*
 - almonds (2001, 04)

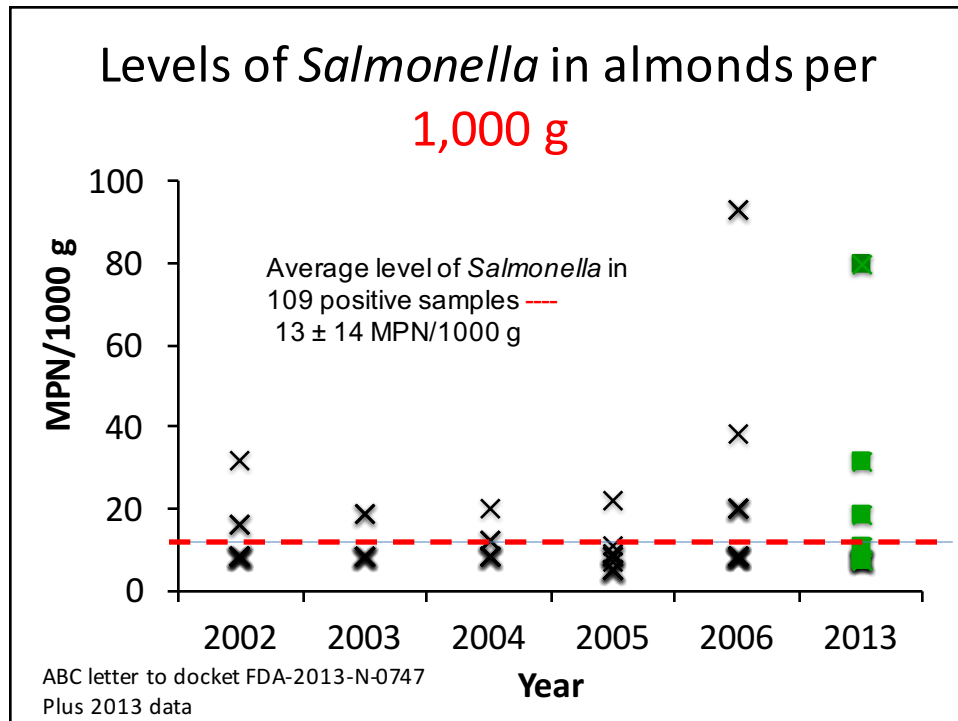
Palumbo, M., L. R. Beuchat, M. D. Danyluk, and L. J. Harris. 2015. Recalls of tree nuts and peanuts in the U.S., 2001 to present [Table and references]. In U.S. recalls of nuts. Available at: http://ucfoodsafety.ucdavis.edu/Nuts_and_Nut_Pastes.

Prevalence of *Salmonella* in 100-g Raw Almond Kernels With 95% Confidence Intervals (Wilson Score)



ABC letter to docket FDA-2013-N-0747
Plus 2013 data

~1% positive



Contamination Source

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- Evidence suggests under **normal** circumstances contamination is:

- *Environmental*
- Sporadic
- Random
- Low levels

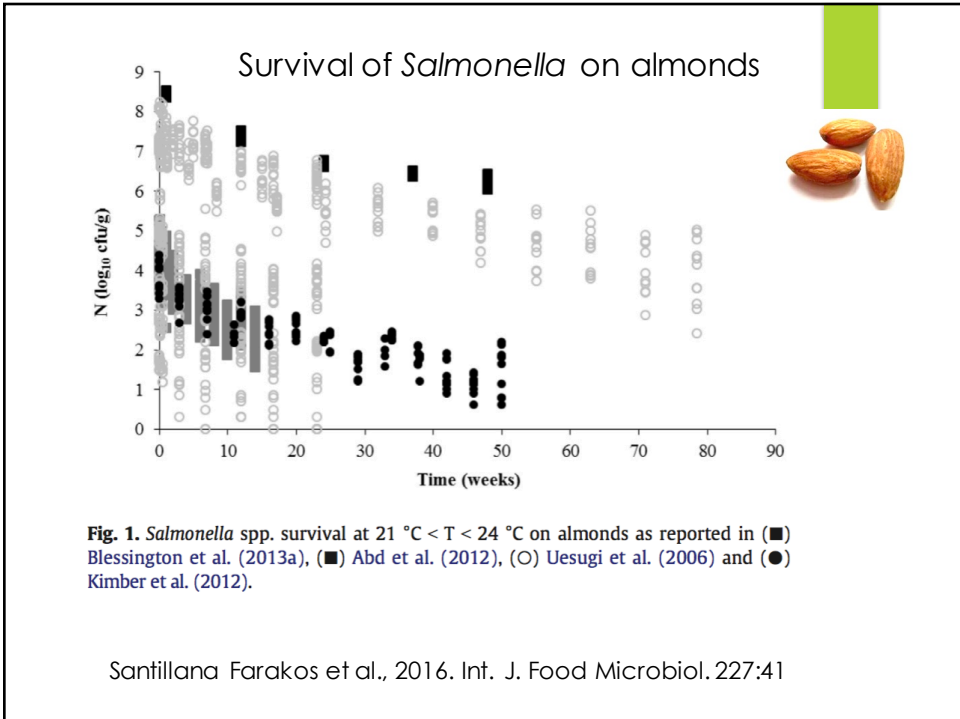


Preharvest/Harvest Control

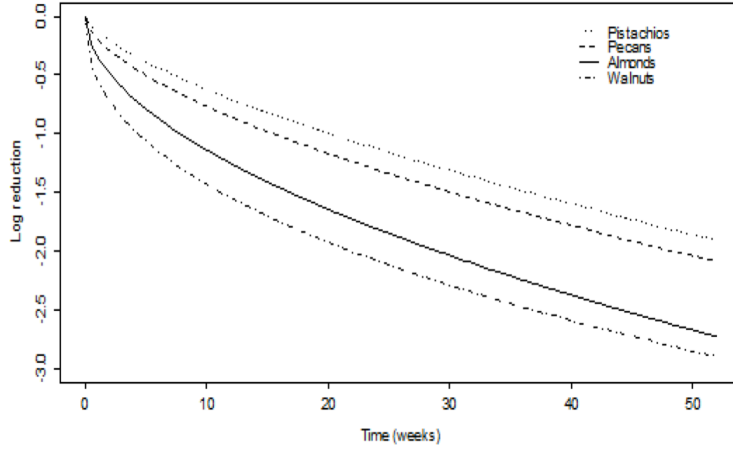
<http://www.almonds.com/growers/growing-safe-product/gaps>




DOCUMENTATION & TRACEABILITY ▶
EMPLOYEE TRAINING
FERTILIZER & SOIL PRACTICES
WATER QUALITY & SOURCE
ORCHARD FLOOR MANAGEMENT
FIELD SANITATION & EMPLOYEE HYGIENE
PESTS AND WILDLIFE
HARVEST & DELIVERY SANITATION
STOCKPILE MANAGEMENT



Survival of inoculated *Salmonella* on tree nuts stored at 21 to 24°C



Santillana Farakos et al., 2016. Int. J. Food Microbiol.

Severity and probability in the absence of preventive controls



		Severity		
		Low	Medium	High
Likelihood	High		PC	PC
	Medium	GMP		PC
	Low	GMP	GMP	

Salmonella in almonds

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- Known or reasonably foreseeable hazards
- Hazard requiring a preventive control

7 CFR Part 981.442

(1) *Treatment process.* Treatment processes shall utilize technologies that have been determined to achieve in total a minimum **4-log reduction of *Salmonella* bacteria** in almonds, pursuant to a letter of determination issued by the Food and Drug Administration (FDA), or acceptance by a scientific review panel as identified by the Board (**Technical Expert Review Panel or "TERP"**).

Lambertini, E., M. D. Danyluk, D. W. Schaffner, C. K. Winter, and L. J. Harris. 2012. Risk of salmonellosis from consumption of almonds in the North American market. *Food Res. Int.* 45:1166–1174.



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



GMPS

STOCKPILING

PEM

HACCP & CCP

PASTEURIZATION ▶

AFLATOXIN

ALLERGEN CONTROL

PESTICIDE MRLS

Process Preventive Controls

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Plus Many Other Equipment-Specific Technologies

ABC Guidance documents for process validation
TERP review of validation

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Outbreaks – tree nuts

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Salmonellosis

o Almonds – raw (U.S. source)

- 2000-01, Canada/U.S.
- 2003-04, U.S./Canada
- 2006, Sweden



o Almonds - raw (Australia source)

- 2012, Australia

o Cashews – raw (SE Asia)

- 2013, U.S.



o Pine nuts - raw (Turkey)

- 2011, U.S.

o Pistachios - raw and roasted? (U.S.)

- 2009 (1 case), 2013, 2016

E. coli O157:H7 gastroenteritis

o Inshell hazelnuts (U.S.)

- 2011, US/Canada

o Walnuts –raw (U.S.)

- 2011, Canada (linked)



Recalls U.S. nuts and (some) seeds

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- *Salmonella*
 - almonds (2001, 04), cashew (2014, 15), hazelnuts (2009, 13), macadamia (2009, 10, 12, 14, 15), pecans (2009, 10, 14, 15), pine nut (2011, 15), inshell pistachios (2009,13), walnut (2014, 15)
- *E. coli* O157:H7
 - hazelnuts (2011), walnuts (2011)
- *Listeria monocytogenes*
 - Peanut butter (2014), walnuts (2009, 13), sunflower (2016)



U.S. Food and Drug Administration
Protecting and Promoting *Your Health*

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<http://www.fda.gov/Safety/Recalls/>

Recalls, Market Withdrawals, & Safety Alerts

[f SHARE](#)
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[PIN IT](#)
[EMAIL](#)
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The list below provides information gathered from press releases and other public notices about certain recalls of FDA-regulated products. Not all recalls have press releases or are posted on this page. See [Additional information about recalls](#) for a more complete listing.

For recall notices older than 60 days, see the [Recall and Safety Alerts Archive](#).


[Sign up to receive Recalls, Market Withdrawals and Safety Alerts.](#)



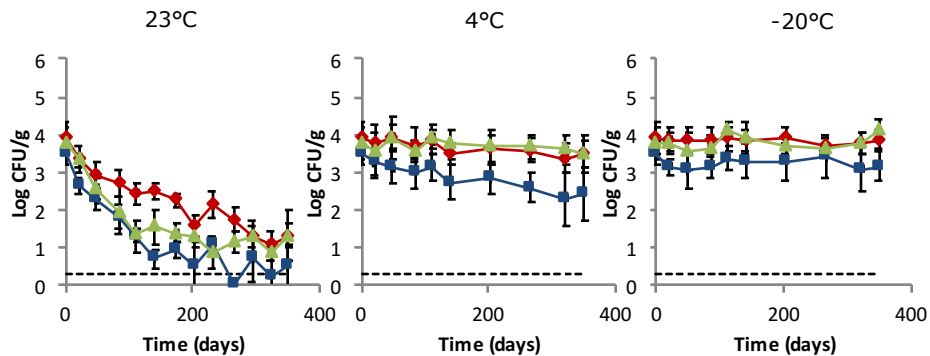
E. coli O157:H7 – survey *L. monocytogenes* (no survey data)

- California Almonds 2013
 - 977 samples of 375 g
 - NONE POSITIVE

- California Walnuts 2011, 2012, 2013
 - 3,839 samples of 375 g
 - NONE POSITIVE

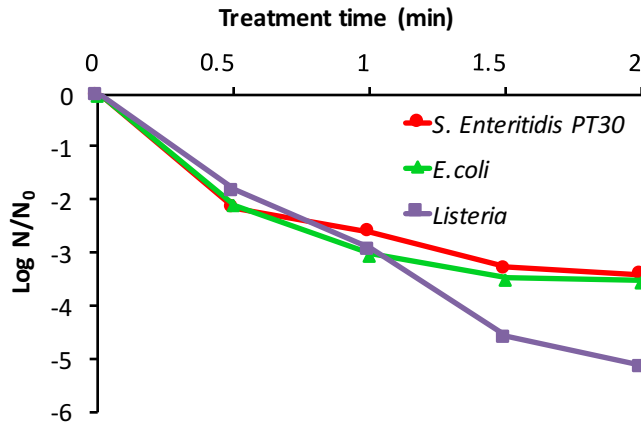


Survival of *Salmonella*, *E. coli* O157:H7, and *L. monocytogenes* on stored almonds

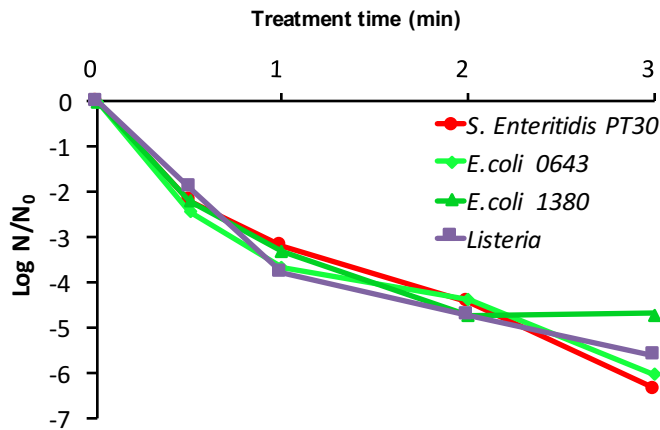


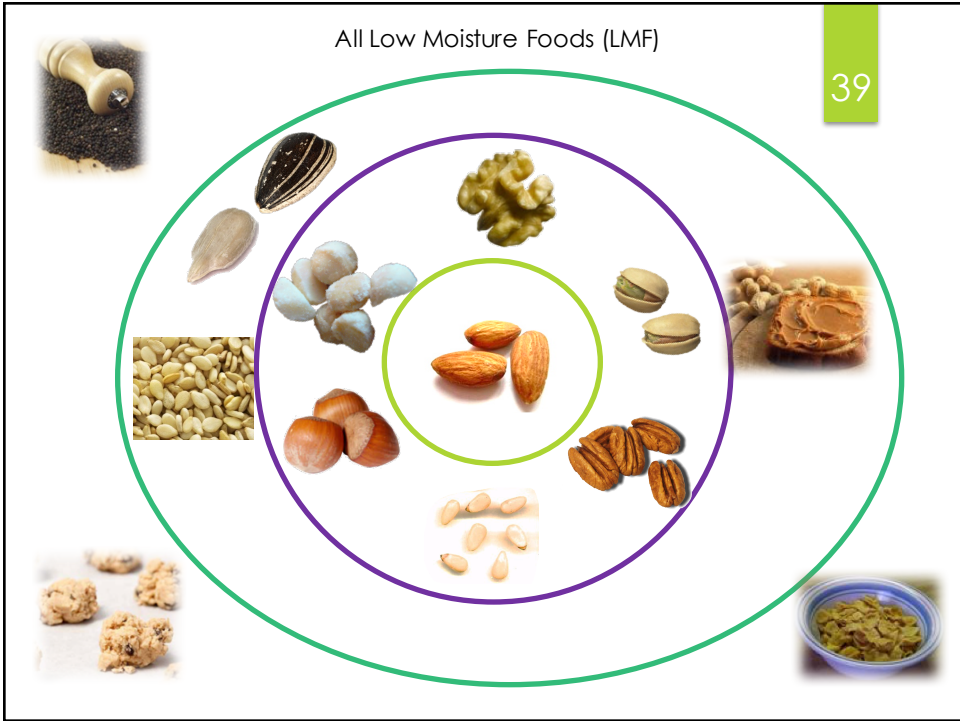
Kimber, M. A., H. Kaur, L. Wang, M. D. Danyluk, and L. J. Harris. 2012. Survival of *Salmonella*, *Escherichia coli* O157:H7, and *Listeria monocytogenes* on inoculated almonds and pistachios stored at -19, 4, and 24°C. *J. Food Prot.* 75:1394–1403.

Reduction of *E. coli* O157:H7
Listeria monocytognes (single strains, more resistant) and *Salmonella* Enteritidis PT30
 on almonds: oil at 250°F



Reduction of *E. coli* O157:H7
Listeria monocytognes (single strains, more resistant) and *Salmonella* Enteritidis PT30
 on almonds: water at 176°F






LMF Outbreaks – Reoccurring Themes

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- DUST
 - Poor traffic flow
 - Air quality
 - Construction
- PRODUCT
 - Raw and processed
- ENDPRODUCT TESTING
 - Inappropriate use of end-product testing
 - INSUFFICIENT FOLLOW UP TO POSITIVE RESULTS

LMF Outbreaks – Reoccurring Themes

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- WATER
 - Inadvertent introduction
 - Poor traffic flow
 - Wet sanitation procedures
 - Inadequate follow up



Surface that remain wet = harborage
Organic matter = growth potential



Hazard Evaluation Considerations

- Formulation of the food
- Condition, function and design of facility and equipment
- Raw materials and ingredients
- Transportation practices
- Processing procedures, including rework
- Packaging and labeling activities
- Storage and distribution
- Intended or reasonably foreseeable use
- Sanitation including employee hygiene
- Others relevant factors

The Salmonella Control Equation



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

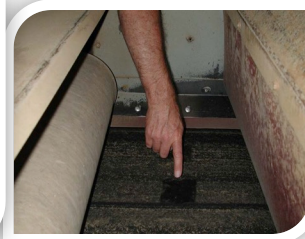
**SALMONELLA
CONTROL**



Outbreaks – what does it take?

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- ENVIRONMENTAL MONITORING
- Lack of or inappropriate environmental monitoring program
 - INSUFFICIENT FOLLOW UP TO +'VES



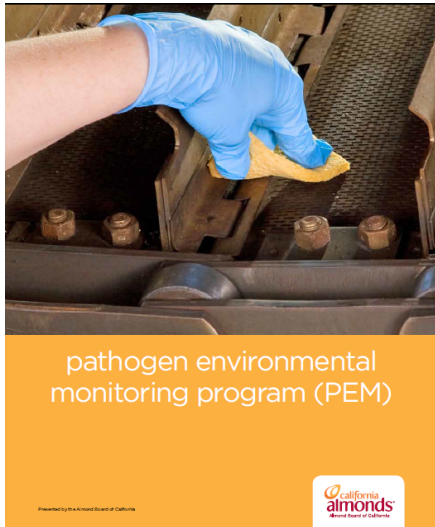
Hazard evaluation

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- must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging
 - If a post-packaging treatment is not applied



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

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Other important resources

- Employees
- Colleagues
- Supply companies
- Scientific/food safety meetings
- Barfblog
- Foodsafetynews

