



Produce Safety: Regulations, Outbreaks & Lessons Learned

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Roles & Responsibilities

Food Industry is responsible for producing safe food.

Government Agencies are responsible for:

- setting food safety standards (FSMA, FD&C Act),
- conducting inspections,
- ensuring that standards are met, and
- maintaining a strong enforcement program to deal with those who do not comply with standards.

From: FoodSafety.Gov



Legal Liability...

First Lawsuit Filed in Salmonella Cantaloupe Outbreak Today

POSTED BY [BILL MARLER](#) ON AUGUST 22, 2012
CHAMBERLAIN Farms

“...the five named firms could create a pool of about \$20 million... "we are going to sit down with the retailers and see how they can help.”

Produce News on May 30, 2012
Jensen Farms

- Suing is good business
 - ✓ Getting better
- Up till now focus on producer
- Moving to:
 - ✓ Shippers, handlers
 - ✓ Auditors, retailers, foodservice...
- Brand protection – new driver!
- Liability vs Negligence



U.S. Food & Drug Administration



The Preeminent Produce Safety Regulatory Agency

Authority Derived from:

- ❖ Federal Food Drug & Cosmetic Act (FD&C)
- ❖ Food Safety Modernization Act (updates FD&C)
- ❖ Bioterrorism Act of 2002
- ❖ Public Health Service Act

Specific Regulatory Requirements Articulated in:

- ❖ Implementing Regulations
- ❖ Code of Federal Regulations

Compliance Policy Guides & Industry Guidance



Specifically Prohibited Acts FD&C Act

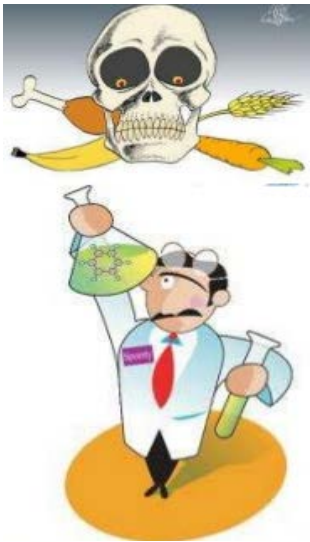
- ❖ Introduction into interstate commerce any food that is adulterated / misbranded;
- ❖ The adulteration / misbranding of any food while in interstate commerce;
- ❖ The receipt in interstate commerce of any food that is adulterated/misbranded, and delivery;
- ❖ The alteration, mutilation, destruction, obliteration, removal or other act concerning the labeling of a food which results in the food being adulterated/misbranded;
- ❖ Giving a false food guaranty regarding compliance with laws, unless based on another guaranty and reasonably assumed to be factual.



Adulteration

Section 402. 21 U.S.Code. 342 – Adulteration Provisions

- ❖ (a)(1) Food contains any added poisonous or deleterious substance which may render the food injurious;
- ❖ (a)(4) Food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or may have been rendered injurious;



Adulteration

Food contains any added poisonous or deleterious substance which may render the food injurious;

FDA No Tolerance Policy for Human Pathogens in Food

- ❖ Pathogenic *E. coli* (e.g. *E. coli* O157:H7)
- ❖ *Salmonella spp*
- ❖ *Listeria monocytogenes*

FDA Does Typically Consider (especially for Lm)

- ❖ the food & how it is consumed
 - is it ready-to-eat?
 - Nobody eats the peel, right?
- ❖ human pathogen levels & prevalence in the product,
- ❖ importantly whether or not the food will support the growth of Lm.



Adulteration

Food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or may have been rendered injurious;

- ❖ “Insanitary conditions” adulteration provision is now increasingly important in regulating produce.
- ❖ Focuses on place where food is prepared/packed/held. Food can be deemed to be adulterated even if not shown to be unsafe.
- ❖ Challenged in 1950’s on constitutional grounds (“void for vagueness”) under 6th Amendment. Upheld in 9th Circuit (reasonable possibility of food becoming contaminated) and other circuits.



What is an FDA Recall?

- ❖ A firm's removal or correction of a marketed product that FDA considers to be in violation of the laws which it administers and against which the Agency would initiate legal action.

Possible Recall Triggers:

- ❖ Consumer complaints or reported injury
- ❖ Customer communications (supplier recall),
- ❖ Internal food safety data (product or environmental testing),
- ❖ Regulatory agency product sampling or illness reports (i.e. foodborne illness outbreak)



When Does FDA Request A Recall?

- ❖ A distributed food product presents risk of illness, injury or death or gross consumer deception.
- ❖ A firm has not initiated a recall.
- ❖ FDA concludes action is necessary to protect public health or welfare.
- ❖ FDA can make mistakes?



FDA Administrative Tools

- ❖ Request a Recall,
- ❖ Require a Recall,
- ❖ Press Release: Public Health Advisory
- ❖ Withdrawal of Food Facility Registration,
- ❖ Product Seizure or Administrative Detention,
- ❖ Court Ordered Injunction.



FDA & Recalls

Most food recalls are voluntary.

- ❖ **Class I recall** -- reasonable probability that exposure to product will cause serious adverse health consequences or death
- ❖ **Class II recall** -- may cause temporary or medically reversible adverse health consequences, or probability of serious health effects is remote
- ❖ **Class III** – exposure not likely to cause adverse health consequences
- ❖ **FDA policy on recalls** -- health hazard evaluation, classification, strategy, communications, status reports, termination of a recall.

www.fda.gov/Safety/Recalls/IndustryGuidance/



Why Does FDA Request A Recall?

- ❖ Prevent consumption of potentially contaminated product.
- ❖ Inform consumers that they may have eaten a potentially contaminated food product.
- ❖ Inform food prepares (consumers, restaurants, retailers) that they may have handled contaminated product.
- ❖ Inform consumers and food manufacturers that they may have used and incorporated contaminated food ingredient in foods they have prepared.



Are You Recall Ready?

- ❖ Product Traceability (forward and back),
- ❖ “Lot” designations
- ❖ Communications (buyers, consumers, media, internally),
- ❖ Technical Expertise,
- ❖ Legal Expertise (regulatory & liability)
- ❖ Recall Plans Serve as Firewalls to Protect Consumer Health and Enterprise Viability.



**When I say hazards, risks
and regulation most...**



But, we are all risk managers...



Lightning:

- Chance of getting lightning struck
- Manage risks:
 - Identify Hazard (i.e. lightning)
 - Factors Affecting Getting Struck
 - Risk of Getting Struck (probability & severity)
 - Actions to Prevent Getting Struck

Food Safety:

- Chance of contamination
- Manage risks:
 - Identify Hazards
 - Factors (Routes) Affecting Contamination
 - Assessment of Risks
 - Food Safety Plan (Preventive Controls)

Routes of Produce Contamination

- ❖ Soil amendments (compost, manure, etc.)
- ❖ Agricultural water
- ❖ Domesticated and wild animals
- ❖ **Equipment, tools, buildings and sanitation**
- ❖ Worker health and hygiene
- ❖ Growing, **harvesting, packing and holding activities**
- ❖ Others?



Hazard

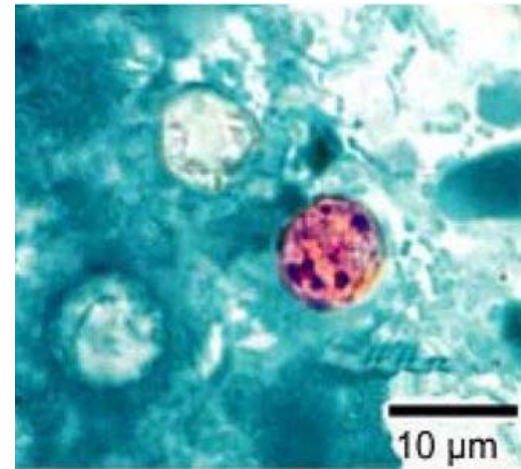
any biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury.

Produce Microbial Hazards

- ❖ Pathogenic *E. coli* (STEC's, EHEC's e.g. *E. coli* O157:H7)
- ❖ *Salmonella spp.*
- ❖ ***Listeria monocytogenes***
- ❖ Protozoa- parasites (e.g. *Cyclospora cayetanensis*)
- ❖ Viruses (e.g. Hepatitis A, Norovirus)
- ❖ Others? *Yersinia pseudotuberculosis*?

Resource: FDA Bad Bug Book 2nd Edition (2012)

www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/



Listeria monocytogenes:

- ❖ **Prevalence:** Lm is commonly found in the environment especially in moist environments, soil, and decaying vegetation.
- ❖ **Persistent:** **Can establish niches/harborage in food handling/manufacturing environments.***
- ❖ **Susceptibility:** Pregnant women, fetus, those with weak immune systems.
- ❖ **Illness Severity:**
 - Among leading cause of foodborne illness deaths
 - 15-30% morbidity rate
- ❖ **Can Grow at Low Temperatures*:** (cold storage temps albeit slowly)

Resources:

FDA Bad Bug Book 2nd Edition (2012)

www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/

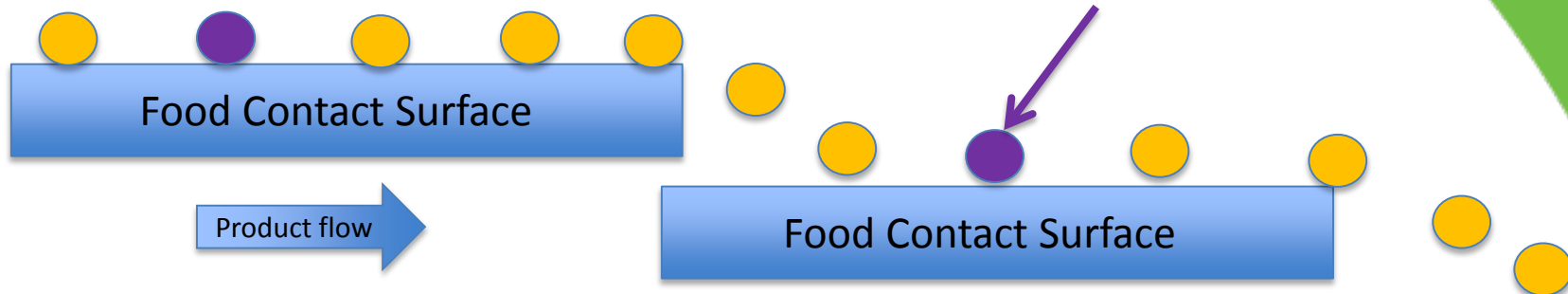
FDA Lm Guidance DRAFT (2008)

www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm

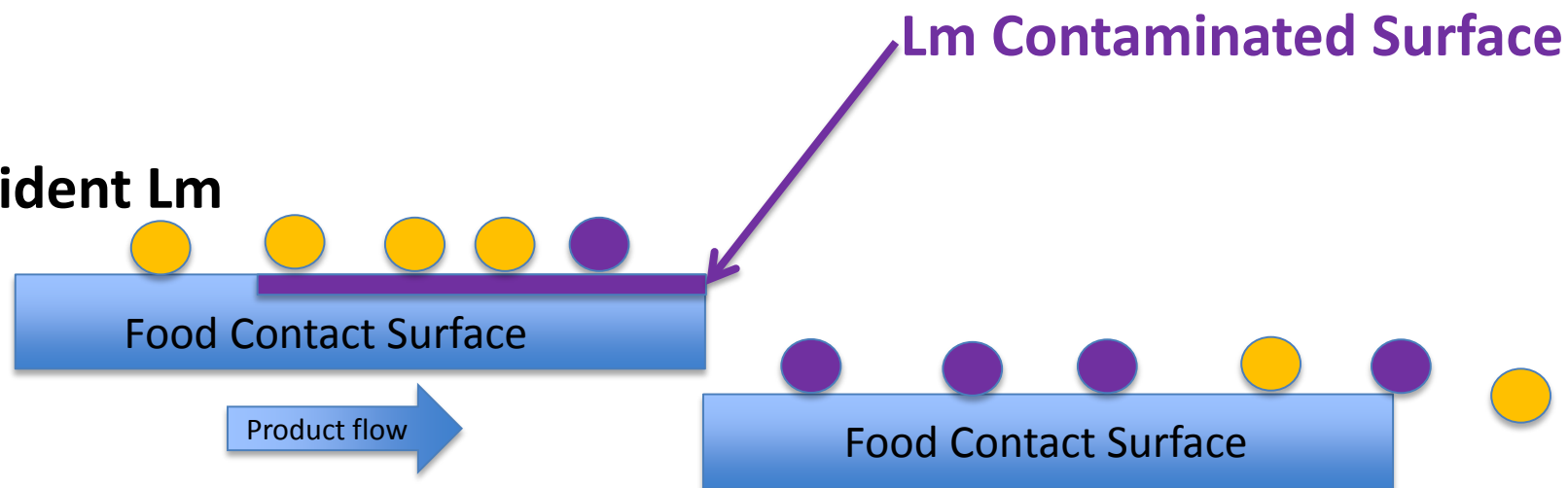


Transient vs Resident Lm

Transient Lm



Resident Lm



“Risk” Defined:

❖ Probability of Illness (adverse health consequences)

- Agent Prevalence (frequency of presence)
- Agent Dose (how much is present)
- Possible Changes in Dose (increase, decrease, no change)
- Consumption (serving size and frequency)

❖ Severity of Illness

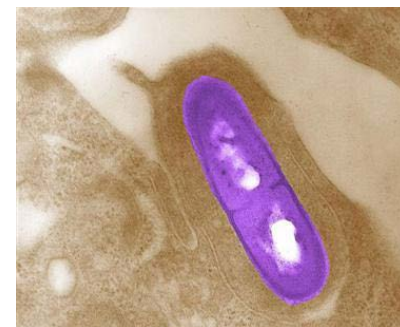
STEC's, **Lm** > HepA > *Salmonella* > Protozoa > Norovirus

Like lightning strikes, produce hazards are rare but when encountered, they can have severe consequences.

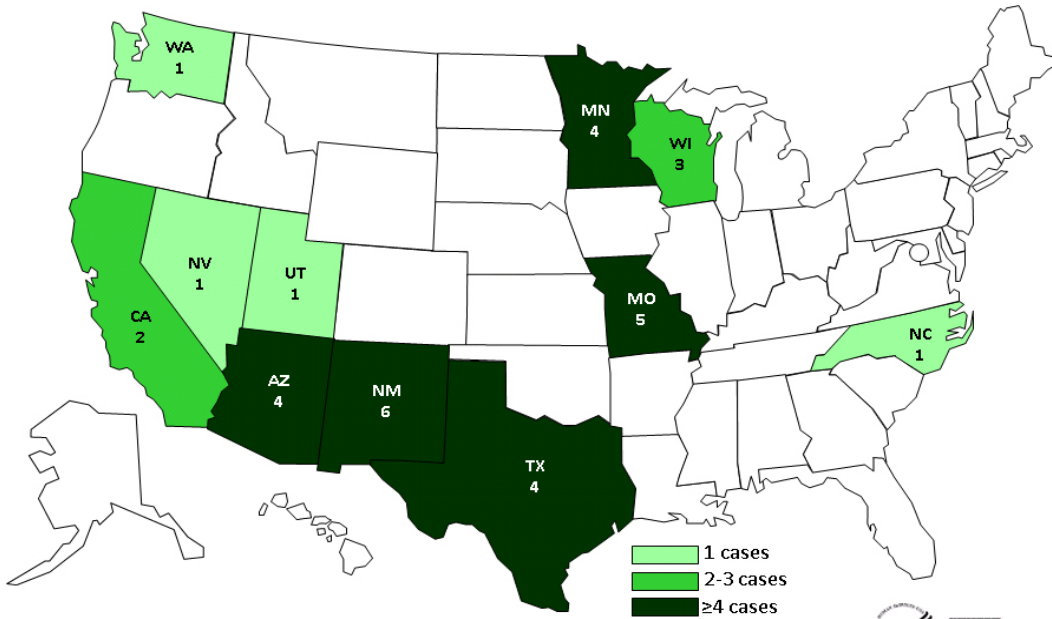


Core Lessons Learned from Outbreaks

Multi-State Outbreak of Listeriosis Associated with Caramel Apples, 2014



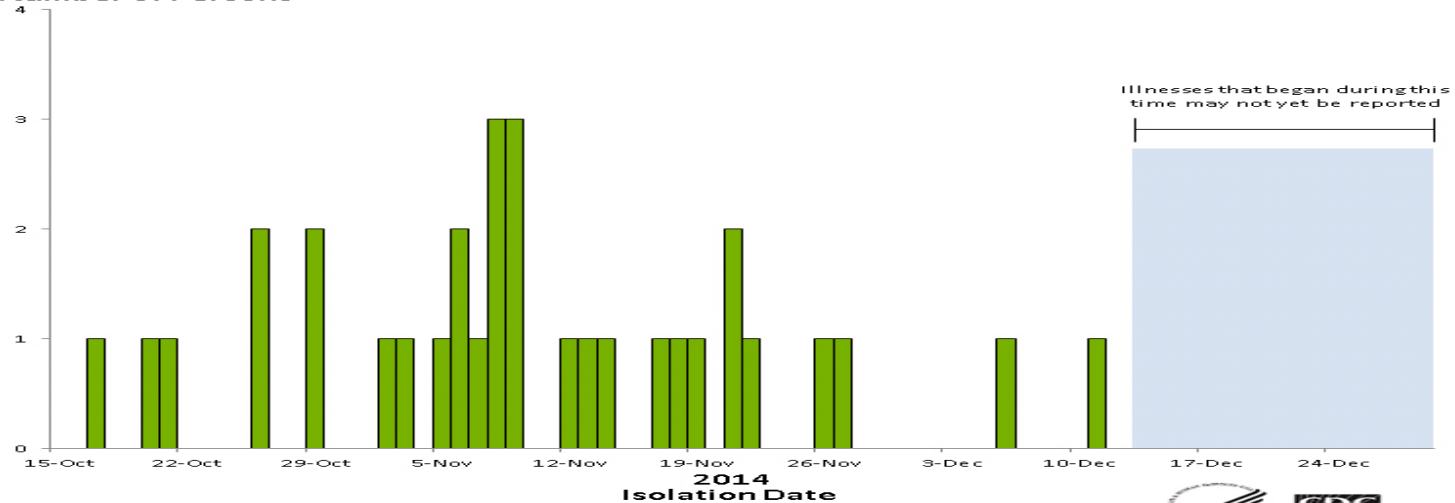
Profile of the Outbreak - Bidart



- ❖ 32 persons in 11 states infected
- ❖ ? Lm outbreak strains
- ❖ 7 deaths and one miscarriage
- ❖ 89% of ill persons ate caramel apples
- ❖ 1st Lm outbreak associated with whole fresh apples



Number of Persons



3 Legs of Foodborne Illness Outbreak Investigation

1) Epidemiology

- ❖ Surveillance Detects the Outbreak
- ❖ Interview ill persons (cases)
- ❖ Compare ill persons to non-ill persons
- ❖ Determine the most likely food vehicle



2) Traceback / Trace Forward

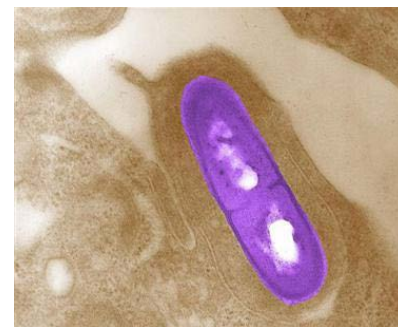
- ❖ Helps rule-in / rule-out likely food vehicle (plausibility)

3) Sample Positives

- ❖ Product or environmental samples
 - 6 zone I Lm+ PFGE match (polishing brushes, drying brushes, auto line singulator, pack line floor)
 - 1 zone III Lm+ PFGE match (wooden bin)
- ❖ Matching + samples rarely occur in perishable foods
 - 5 subsample Lm+ PFGE match from Bidart whole fresh apples in commerce

Core Lessons Learned from Outbreaks

Multi-State Outbreak of Listeriosis Associated with Consumption of Fresh Whole Cantaloupe, 2011



3 Legs of Foodborne Illness Outbreak Investigation

1) Epidemiology

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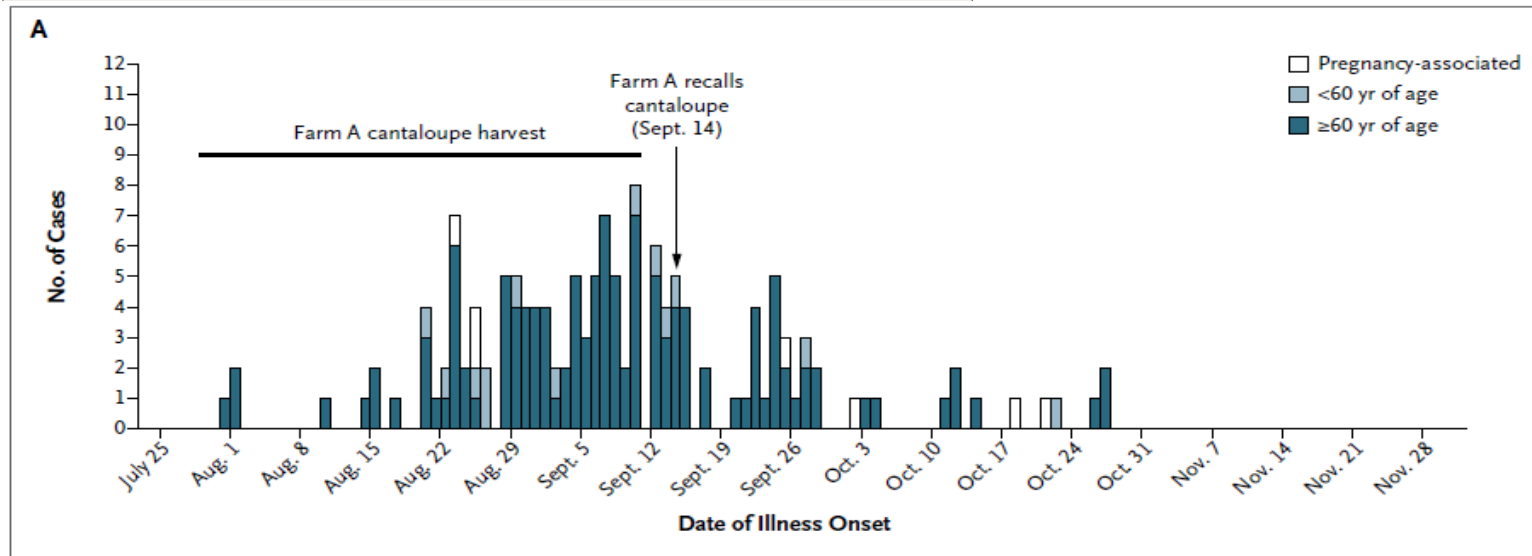
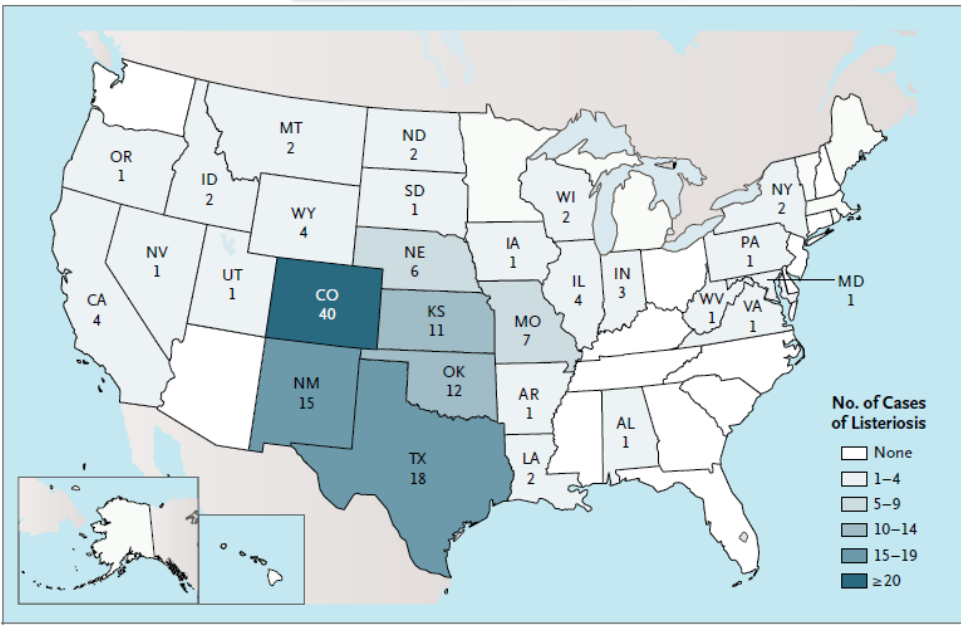
3) Sample Positives

- Product or environmental samples
- Matching + samples rarely occur in perishable foods

Profile of the Outbreak

- ❖ 146 persons in 28 states infected
- ❖ 5 Lm outbreak strains
- ❖ 33 deaths and one miscarriage
- ❖ Deadliest foodborne disease outbreak in the United States in nearly 90 years.
- ❖ 1st Lm outbreak associated with fresh whole cantaloupe
- ❖ Lm previously considered a fresh-cut issue

From: McCollum et al, 2013



Sample Findings

Packing Facility & Cold Storage (Samples Collected during September 10, 2011 FDA inspection)

1. Product Samples

- ❖ Fresh whole cantaloupe from Jensen Farms Lm+ with PFGE patterns indistinguishable from outbreak strains

2. Environmental Samples

- ❖ 39 swabs – 13 confirmed positive
- ❖ PFGE patterns indistinguishable from outbreak strains collected from affected patients
- ❖ Of 13 positive environmental swabs:
 - 12 collected at packing line equipment/food contact surfaces
 - 1 collected in packing area.

Environmental Assessment Findings



The following factors may have contributed to the introduction, growth, or spread of Lm contamination:

1. Facility Design
2. Equipment Design
3. Postharvest Practices
4. Recommendations

Environmental Assessment Findings

1. Facility Design

- ❖ Refrigeration unit drain line, allowed for water to pool on the packing facility floor in areas adjacent to packing facility equipment, may have extended and spread the pathogen to food contact surfaces.
- ❖ Samples collected from areas where pooled water had gathered tested positive for an outbreak strain of Lm. And may have contributed to the introduction, growth, or spread of Lm.
- ❖ Packing facility floor where water pooled was directly under the packing facility equipment from which FDA collected environmental samples that tested positive for Lm with PFGE pattern combinations that were indistinguishable from outbreak strains.
- ❖ Packing facility floor was constructed in a manner that was not easily cleanable. Specifically, the trench drain was not accessible for adequate cleaning and may have served as a harborage site for Lm or contributed to the growth, or spread of the pathogen.

Environmental Assessment Findings

2. Equipment Design

- ❖ Environmental samples collected from the packing facility equipment tested positive for Lm with PFGE pattern combinations that were indistinguishable from three of the four outbreak strains.
- ❖ July 2011, the firm purchased and installed equipment for its packing facility that had been previously used at a firm producing a different RAC. Lm could have been introduced as a result of past use of the equipment.
- ❖ Packing equipment, including equipment used to wash and dry the cantaloupe, did not lend itself to be easily or routinely cleaned and sanitized.
- ❖ Several areas on both the washing and drying equipment appeared to be uncleanable, and dirt and product buildup was visible on some areas of the equipment, even after it had been disassembled, cleaned, and sanitized. Corrosion was also visible on parts of the equipment.
- ❖ Cantaloupe that is washed, dried, and packed on unsanitary food contact surfaces could be contaminated with Lm or could collect nutrients for Lm.



Environmental Assessment Findings

3. Postharvest Practices

- ❖ Free moisture or increased water activity of the cantaloupe rind from postharvest washing procedures may have facilitated Lm survival and growth.
- ❖ Cantaloupes were not pre-cooled to remove field heat before cold storage.
- ❖ The availability of nutrients on the cantaloupe rind, increased rind water activity, and lack of pre-cooling before cold storage may have provided ideal conditions for Lm to grow and outcompete background microflora during cold storage.
- ❖ Samples of cantaloupe collected from refrigerated cold storage tested positive for Lm with PFGE pattern combinations that were indistinguishable from two of the four outbreak strains.

Environmental Assessment Findings

4. Recommendations for Prevention of Lm Contamination

- ❖ Employ GAPs and GHPs
- ❖ Assess produce facility and equipment design to ensure adequately cleanable surfaces and eliminate opportunities for introduction, growth, and spread of Lm and other pathogens.
- ❖ Assess and minimize opportunities for introduction of Lm and other pathogens in packing facilities.
- ❖ Implement cleaning and sanitizing procedures.
- ❖ Verify the efficacy of cleaning and sanitizing procedures.
- ❖ Periodically evaluate the processes and equipment used in packing facilities to assure they do not contribute to fresh produce contamination.



From: FDA Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis (October 19, 2011)
<http://www.fda.gov/Food/FoodSafety/Foodbornellness/ucm276247.htm>
Photo Source USA Today

Food Safety Modernization Act (FSMA)

- ❖ FSMA marks the biggest change to our nation's food laws in more than 70 years.
- ❖ Prevention is the focus.
- ❖ Confirms industry's primary role on food safety.
- ❖ Science & Risk-based.



Illustration: Don Smith



Food Safety Modernization Act (FSMA)

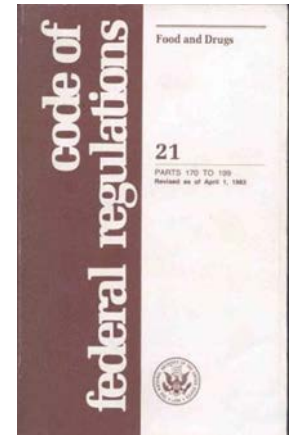


New FDA Authorities / Tools

- ❖ Mandatory Recall
- ❖ Administrative Detention
- ❖ Withdrawal of Facility Registration

Proposed Rules

- ❖ Produce Rule
- ❖ Preventive Controls for Human Food
- ❖ Foreign Supplier Verification Programs (FSVP – Imports)
- ❖ Preventive Controls for Animal Feed
- ❖ Traceability (Pending)



FSMA Compliance Dates by Business Size (anticipated)

Rule	2014 Dec 15	2015		2016	2017	2018	2019	2020	2021
		Aug 30	Oct 31						
Produce Safety	Suppl. Prop.	Final		Large	Large	Water	Water		
				Small	Small	Small	Water	Water	
				V. Small	V. Small	V. Small	Water	Water	
Preventive Controls Human	Suppl. Prop.	Final	Large						
			Small		Small				
			V. Small		V. Small				
Preventive Controls Animal	Suppl. Prop.	Final	Large						
			Small		Small				
			V. Small		V. Small				
FSVP	Suppl. Prop.	Final		Large					
				Small		Small			
				V. Small		V. Small	Water		



Summary: so, where to from here?



- ❖ Get started!
- ❖ “Own” your produce safety program
- ❖ Be grounded in risk/science-based requirements
- ❖ Start preparing to implement FSMA
 - Training
 - Capital Improvements
 - Recurring Costs Recordkeeping
 - Expertise (Technical / Legal)
- ❖ Don't let perfect be enemy of good

Remember...



You can do this!



CONNECTED SOLUTIONS
FOR A NEW ECONOMY

Thank You

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