

Regulation of Fresh Produce with a Case Study

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Caveats

- The data only represent those outbreaks and illnesses associated with FDA-regulated foods.
- The data do not contain information on outbreaks/illnesses where the point of contamination is the retail food setting or home.
- The data do not include illnesses transmitted from person-to-person.
- Illness data represent only the number of illnesses reported to CDC, FDA, and state/local health departments in association with an outbreak. The data do not include illnesses that may have occurred but were not reported.
- Information on outbreaks/illnesses reported prior to 2004 has been compiled from paper records; information on outbreaks/illnesses since 2004 has been entered into the CFSAN Outbreak Surveillance Database.
- The data do not include sporadic *Vibrio* infections.
- The outbreaks tracked by FDA are a subset of all the outbreaks tracked by CDC. Due to lags in reporting of illnesses, some differences in numerical tallies may exist between FDA and CDC data.

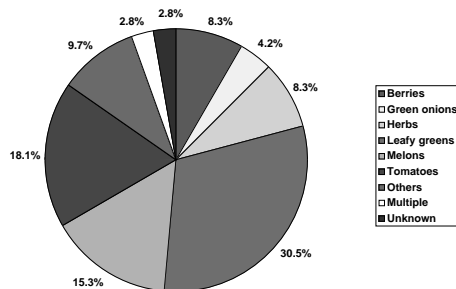
Outbreaks in FDA Regulated Foods 1996 - 2007

Year	Outbreaks	Illnesses
1996	69	3,379
1997	49	3,609
1998	41	2,096
1999	56	1,939
2000	45	1,806
2001	44	1,830
2002	34	1,653
2003	40	2,305
2004	34	1,691
2005	24	1,503
2006	18	1,617
2007	24	335
Total	478	23,763

Vehicle Categories 1996 - 2007

CATEGORY	OUTBREAKS	ILLNESSES
Eggs	207	6,609
Processed Foods	57	3,947
Produce	72	8,791
Sprouts	27	1,633
Seafood	115	2,783

Types Of Produce Associated With Outbreaks, 1996-2007 (N=72)



1998-2007 Produce Outbreaks

5 commodity groups make up >75 percent of produce related outbreaks

<u>Commodity</u>	<u>% produce outbreaks</u>
Lettuce/leafy greens	31%
Tomatoes	18%
Cantaloupe	13%
Herbs (basil, parsley)	8%
Berries	8%
Total % of 5 top commodities	78%

1998-2007 Fresh Cut Produce Outbreaks

- Romaine lettuce 2
- Lettuce 6
- Mixed lettuce 1
- Spinach 2
- Roma Tomatoes 2
- Tomatoes 3
- Mixed melons 2

Total = 18 outbreaks

History of Leafy Greens Outbreaks

- 1995 3 - *E. coli* O157:H7 105 cases
- 1996 2 - *E. coli* O157:H7 68 cases
- 1997 1 - *Cyclospora* 12 cases
- 1998 2 - *E. coli* O157:H7 6 cases
- 1999 6 - *E. coli* O157:H7 127 cases
- 2002 2 - *E. coli* O157:H7 53 cases
- 2003 3 - *E. coli* O157:H7 48 cases
- 2004 2 - *Cyclospora* 95 cases
1 - *Salmonella* 79 cases
1 - *E. coli* O157:H7 6 cases
- 2005 1 - *E. coli* O157:H7 32 cases
- 2006 3 - *E. coli* O157:H7 356 cases
- 2007 0 outbreaks 0 cases

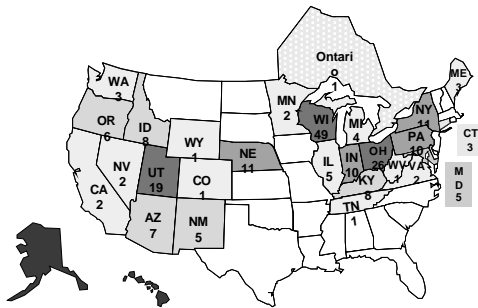
History of Tomato Outbreaks

- 1998 *S. Baildon* 86 cases
- 2000 *S. Thompson* 29 cases
- 2002 *S. Newport* 512 cases
S. Newport 12 cases
S. Javiana 90 cases
- 2004 *S. Javiana* 471 cases
S. Braenderup 123 cases
- 2005 *S. Newport* 71 cases
S. Braenderup 76 cases
S. Enteritidis 77 cases
- 2006 *S. Typhimurium* 186 cases
***S. Newport* 107 cases**
- 2007 *S. Newport* 57 cases

Produce Outbreak Reservoirs 1996 - 2007

<u>Zoonotic</u>	<u>Human</u>
21 <i>E. coli</i> O157:H7	16 <i>Cyclospora</i>
29 <i>Salmonella</i> sp.	3 Hepatitis A
	2 <i>Shigella</i>
<u>Source</u>	
27 Domestic	1 Domestic
7 Foreign	12 Foreign
15 Unknown	8 Unknown
<u>49 Total</u>	<u>21 Total</u>

206 Cases of *E. Coli* O157:H7 Infection Were Detected in 26 U.S. States and Canada



Outbreak 2: Nov – Dec 2006 Cases in 5 states + Canada Suspect cases in 3 additional states

Outbreak setting: Restaurant (Taco Bell)
First illness onset date: Nov. 20, 2006
Last illness onset date: Dec. 8, 2006

No. ill*: 71
No. hospitalized*: 53
No. HUS*: 7
No. deaths*: 0
Vehicle: Shredded Lettuce
Agent: *E. coli* O157:H7

* All data are preliminary.

Outbreak 3: Nov – Dec 2006
Cases in 3 states – MN, IA, WI

Outbreak setting: Restaurant (Taco John)
First illness onset date: Nov. 27, 2006
Last illness onset date: Dec. 10, 2006

No. ill*: 81
No. hospitalized*: 26
No. HUS*: 3
No. deaths*: 0
Vehicle: Shredded Lettuce
Agent: *E. coli* O157:H7

* All data are preliminary.

Findings for Spinach and TJ

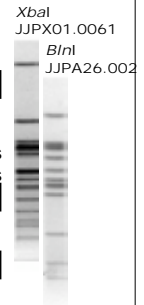
- Not just Salinas Valley
- The implicated ranch and several suspect ranches were not following GAPs
- Pollution sources were found on ranches or adjacent to ranches
 - Animals, Water
- TJ – positives on one ranch
- Post-harvest processing doesn't remove contamination

E. Coli O157:H7 and Leafy Greens

- 22 leafy green associated *E. coli* O157:H7 outbreaks in the last 12 years.
 - Of the 12 that have been traced, all 12 indicate a California source of the leafy greens.
 - Most, but not all, have traced to fields in the Salinas Valley.

History of Tomato Outbreaks

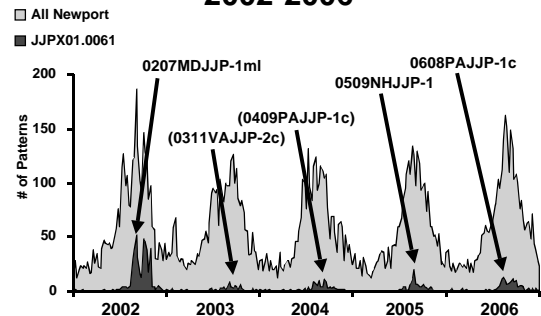
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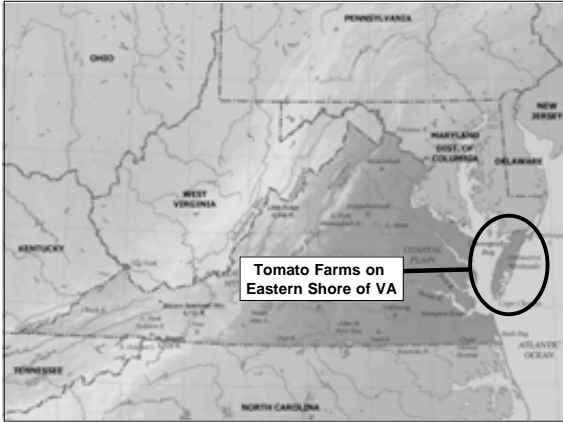


Lab Results Summary

- Packinghouse
 - All negative for *Salmonella*
- Tomatoes
 - All negative for *Salmonella*
- Matching PFGEs *Salmonella* Newport
 - 2002 Cantaloupe Sample
 - 2002 Patients / Cases
 - 2002 Salad from PA
 - 2003 Pond Sediment Farm A
 - 2005 Patients / Cases
 - 2005 Pond Sediment Farm B
 - 2006 Patients / Cases
 - 2007 Patients/Cases

S. Newport and Pattern JJPX01.0061 2002-2006





Characteristics of Produce Outbreak Investigations

- Widely dispersed, individual patient-cases in many states
- Low attack rates
- Epidemiology is tedious
- Intermittent, low level contamination
- Tracebacks are difficult due to complexity of the supply chain
- Implicated produce is rarely still available
- S. Newport outbreaks extend over several months

Farm Investigations

Farm Investigations



Baby Spinach Harvesting



Animals

E. Coli O157:H7 and Spinach

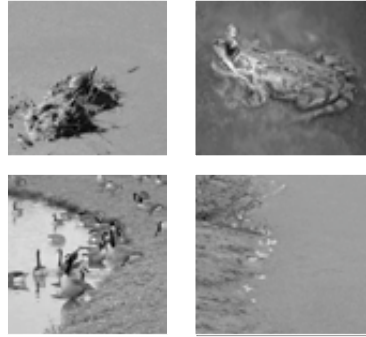


E. Coli O157:H7 and Spinach



FARM INVESTIGATIONS

Potential Sources of Contamination



Birds





Water

FARM INVESTIGATIONS



Where Does Water Contact The Fruit?
What Is The Quality Of The Water?



Source Water For Sprayers

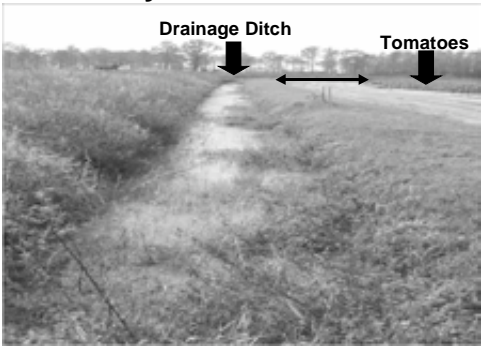


Surface Water - Ponds

Pump From Pond To Fill Sprayer

Well Water And Hose To Fill Sprayer

Proximity to the Environment



Drainage Ditch

Tomatoes



Historical Use Of the Land



Workers

Harvesting

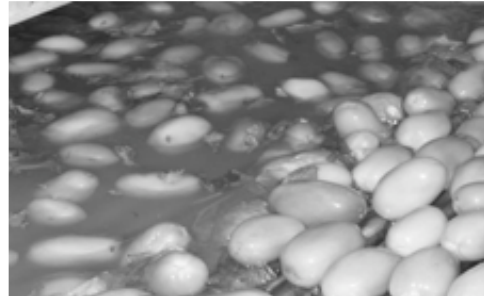


Packing House

Fluming into the Dump Tank



Heavy Organic Load in the Dump Tank



Outbreak Investigation Findings

- Animals/Environment
- Water
- Workers
- Processing
- Equipment

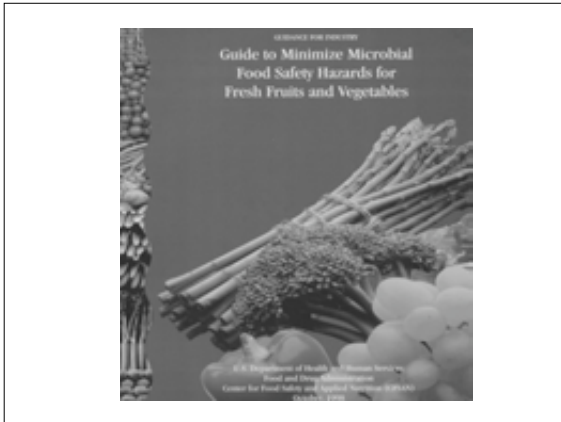
Good Agricultural Practices – Good Manufacturing Practices (GAPs/GMPs)

History

- 1970s -1990s - CDC reports increased FBIO associated with fresh produce
- 1998 Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (GAPs/GMPs Guide)
- 2004 Produce Safety Action Plan (PSAP)
- 2004 Implementing PSAP
- 2007 Produce Safety Hearings
- 2007 Food Protection Plan

Fresh Produce - Concerns

- Grown in a non-sterile environment
- Opportunities for contamination
- Likely to be consumed raw
- Presence of Pathogens is NOT the natural state of fresh produce – practices can minimize risk



The GAPs/GMPs Guide

Broadscope - practices common to the growing and packing of most fresh produce consumed in the U.S.

Risk – may result from interaction of several factors

Risk Reduction - not elimination

Guidance - not a regulation

GAPs/GMPs Guide

Table of Contents

- Water
- Manure and Municipal Biosolids
- Worker Health and Hygiene
- Sanitary Facilities
- Field/Packing Facility Sanitation
- Transportation
- Traceback

Produce Safety Actions

- Communicating Concerns
- Working Collaboratively
- Produce Safety Action Plan
- Commodity Specific Supply Chain Guidance
- Leafy Greens Safety Initiative
- Tomato Safety Initiative
- Farm Investigations
- Produce Surveys
- Consumer Education
- Research

Summary

- Produce outbreaks are a major food safety issue
- Fresh cut produce is a significant component
- Animals/Environment and Water play an important role
- Research is needed to explain the mechanisms of contamination

