



CFSAN/Office of Plant and Dairy Foods
November 4, 2005

Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce

This letter is intended to make you aware of the Food and Drug Administration's (FDA's) serious concern with the continuing outbreaks of foodborne illness associated with the consumption of fresh and fresh-cut lettuce and other leafy greens. We also outline below what we plan to do and the actions that we expect your industry will take to enhance the safety of these products.

FDA is aware of 18 outbreaks of foodborne illness since 1995 caused by *Escherichia coli* O157:H7 for which fresh or fresh-cut lettuce was implicated as the outbreak vehicle. In one additional case, fresh-cut spinach was implicated. These 19 outbreaks account for approximately 409 reported cases of illness and two deaths. Although tracebacks to growers were not completed in all 19 outbreak investigations, completed traceback investigations of eight of the outbreaks associated with lettuce and spinach, including the most recent lettuce outbreak in Minnesota, were traced back to Salinas, California.

Because these products are commonly consumed in their raw state without processing to reduce or eliminate pathogens, the manner in which they are grown, harvested, packed, processed, and distributed is crucial to ensuring that microbial contamination is minimized, thereby reducing the risk of illness to consumers. In 1998, the FDA issued guidance to industry entitled "[Guide to Minimize Microbial Food Safety Hazards for Fruits and Vegetables](#)." This Guide recommends good agricultural practices (GAPs) and good manufacturing practices (GMPs) that growers, packers, and shippers may undertake to address common risk factors in their operations, and thereby minimize food safety hazards potentially associated with fresh produce.



CFSAN/Office of Plant and Dairy Foods
November 4, 2005

Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce

- 18 lettuce-associated *E. coli* O157:H7 outbreaks since 1995
- “serious concern with continuing outbreaks”
- “We [FDA] believe that there are actions that can and should be undertaken immediately to address this issue.”
- “... it is clear that more needs to be done.”

recommends good agricultural practices (GAPs) and good manufacturing practices (GMPs) that growers, packers, and shippers may undertake to address common risk factors in their operations, and thereby minimize food safety hazards potentially associated with fresh produce.

Outbreak of *Escherichia coli* O157:H7 Infections Associated with Lettuce at a Fast-Food Chain Restaurant – Minnesota, 2006

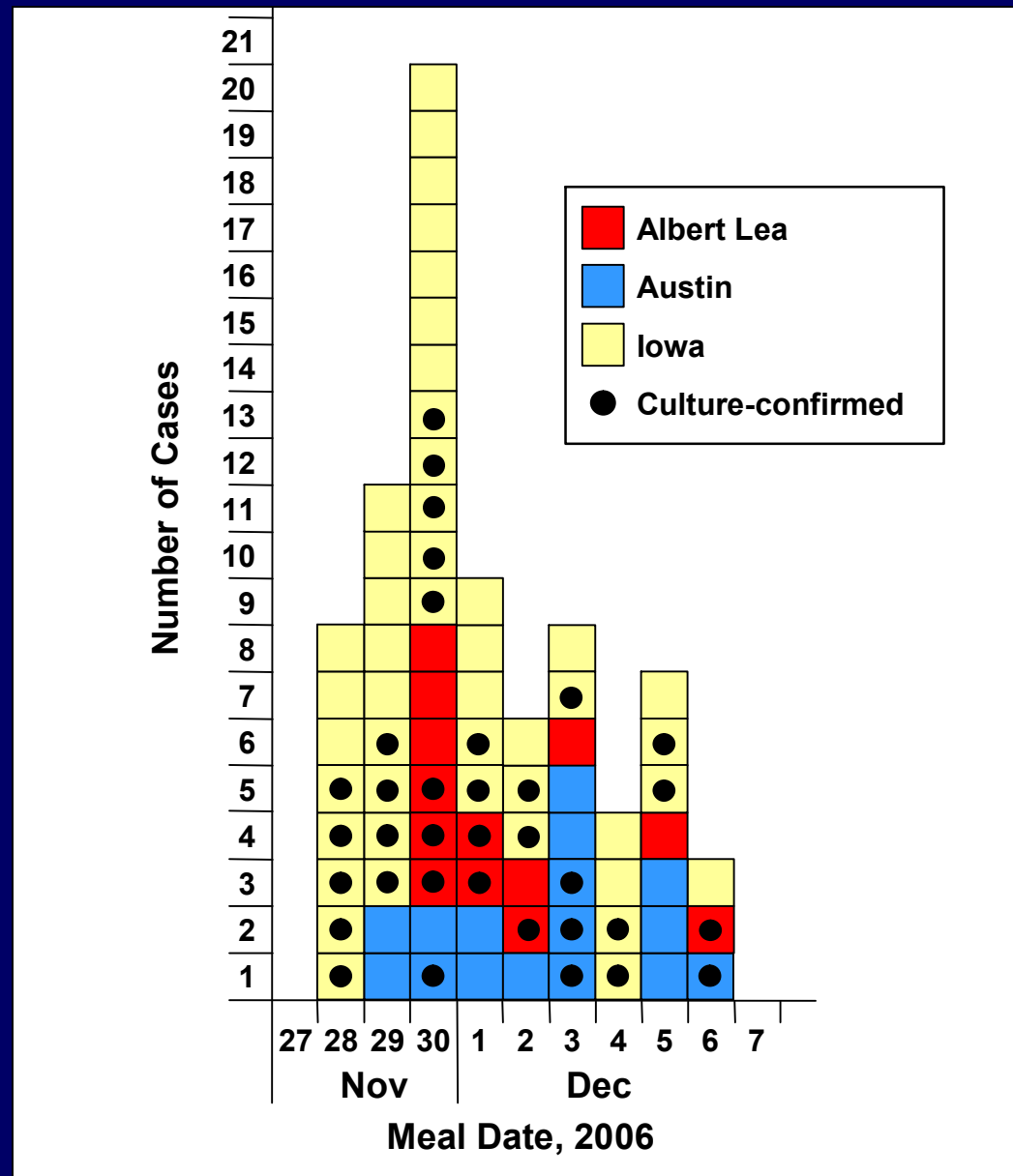


Outbreak Investigation

December 11, 2006

- Five *E. coli* O157:H7 cases interviewed
 - All had eaten at a Taco John's restaurant in Albert Lea
- *E. coli* O157:H7 outbreak in Iowa associated with Taco John's
- MDH issued a press release and health alert

E. coli O157:H7 Cases Associated with Taco John's in Minnesota and Iowa, by Meal Date

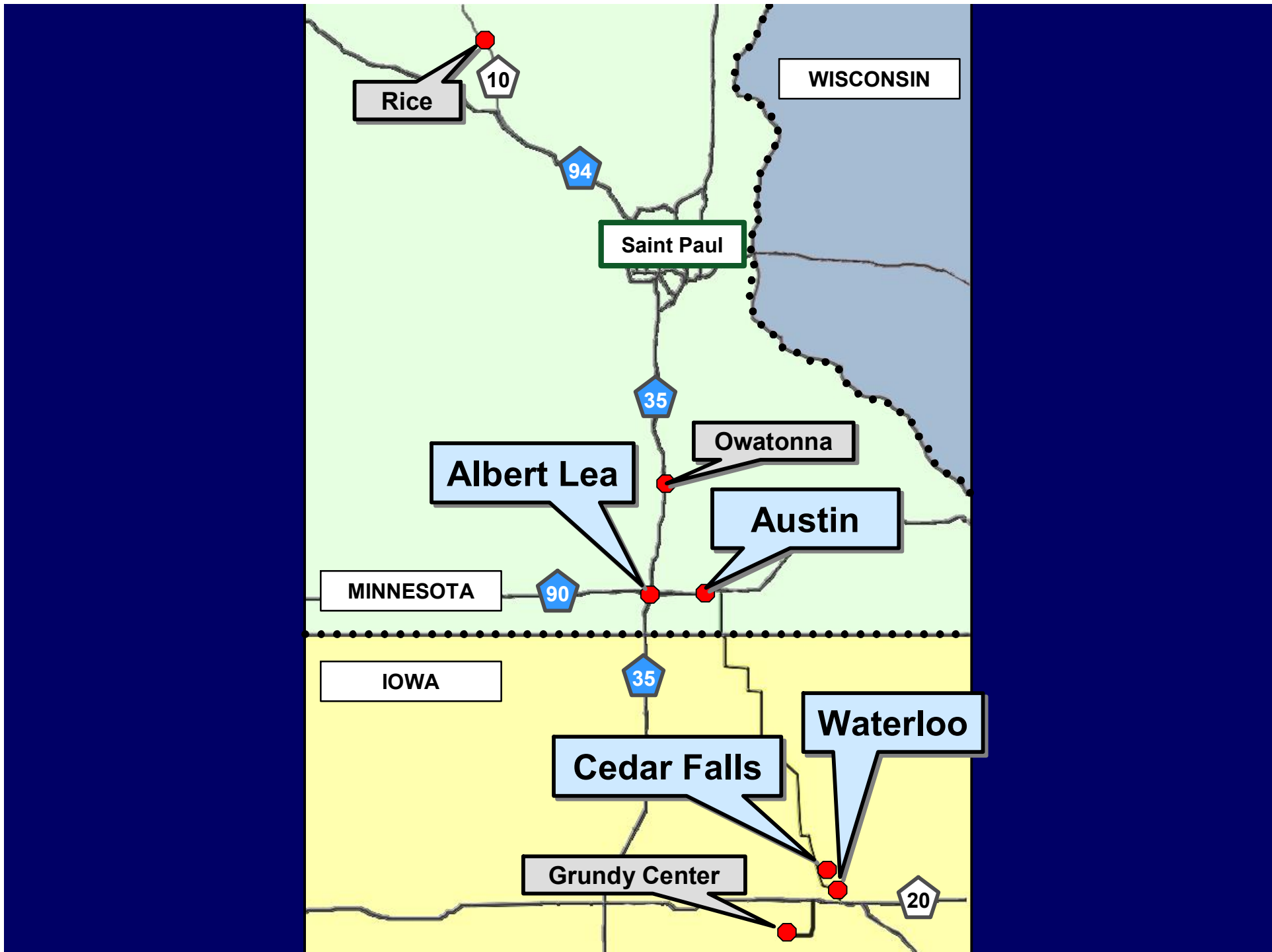


Case-Control Study Results Minnesota

	Case	Control	
Lettuce	31	9	40
No Lettuce	1	12	13
	32	21	53

Odds Ratio = 41.3

95% Confidence Interval: 4.7 – 362.3



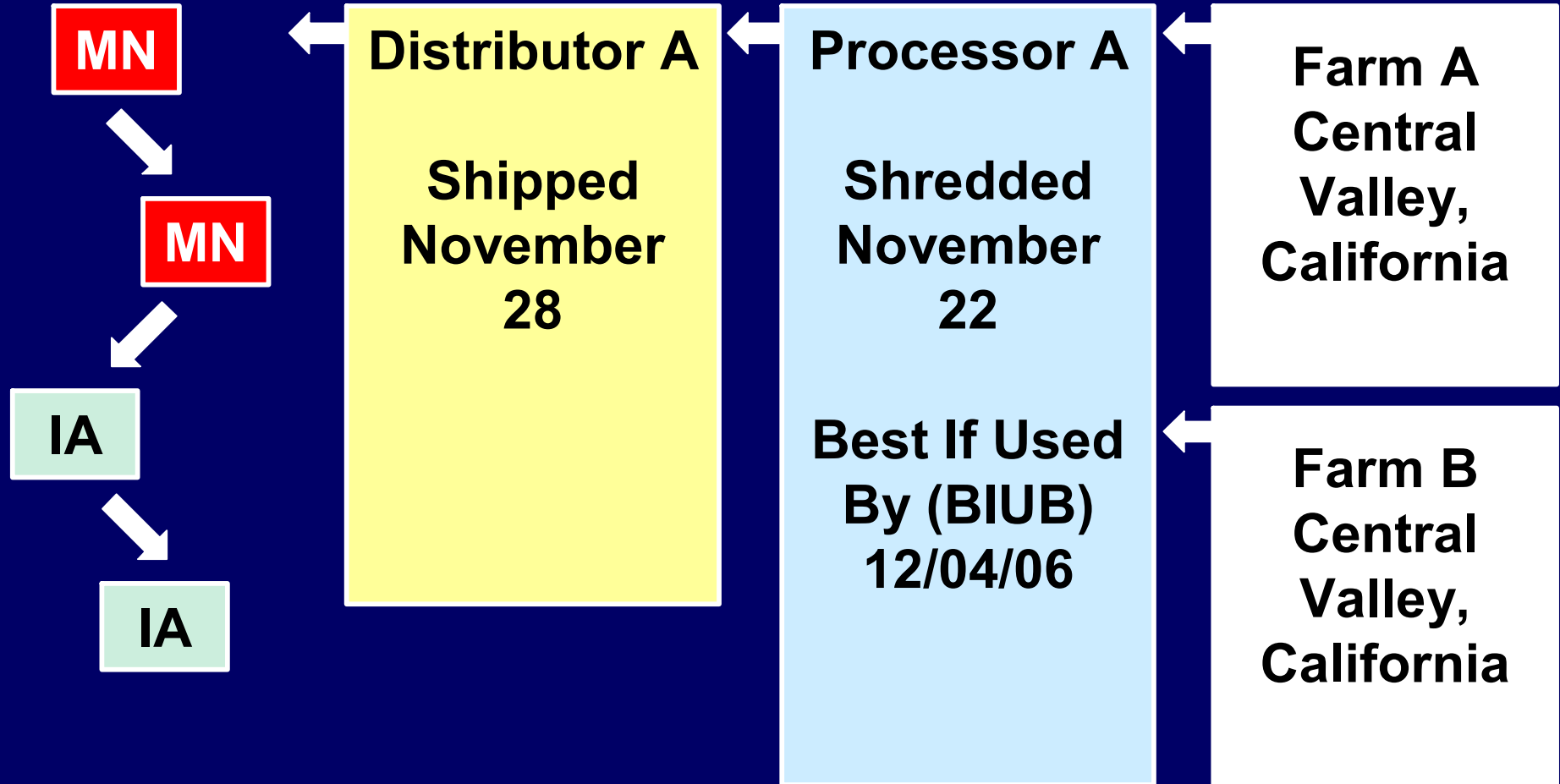
Lettuce Flow

Restaurant

Distributor

Processor

Farm





FDA News

FOR IMMEDIATE RELEASE

P07-05

January 12, 2007

Media Inquiries:

Michael Herndon, 301-827-6242

Consumer Inquiries:

888-INFO-FDA

FDA and States Closer to Identifying Source of *E. coli* Contamination Associated with Illnesses at Restaurants

The Food and Drug Administration (FDA) today announced that it has moved closer to identifying the source of illness for the *E. coli* outbreak. FDA and the state of California, working in conjunction with state health officials in Minnesota, Iowa, and Wisconsin, have DNA-matched the strain of *E. coli* O157:H7 bacteria associated with the outbreak with two environmental samples gathered from

“....have DNA-matched the strain of *E. coli* O157:H7 bacteria....with two environmental samples gathered from dairy farms near a lettuce growing area in California’s Central Valley.”

Flow of *E. coli* O157:H7 Contamination

UC Vegetable Research & Information Center



Farm

**Farm A
Central
Valley,
California**

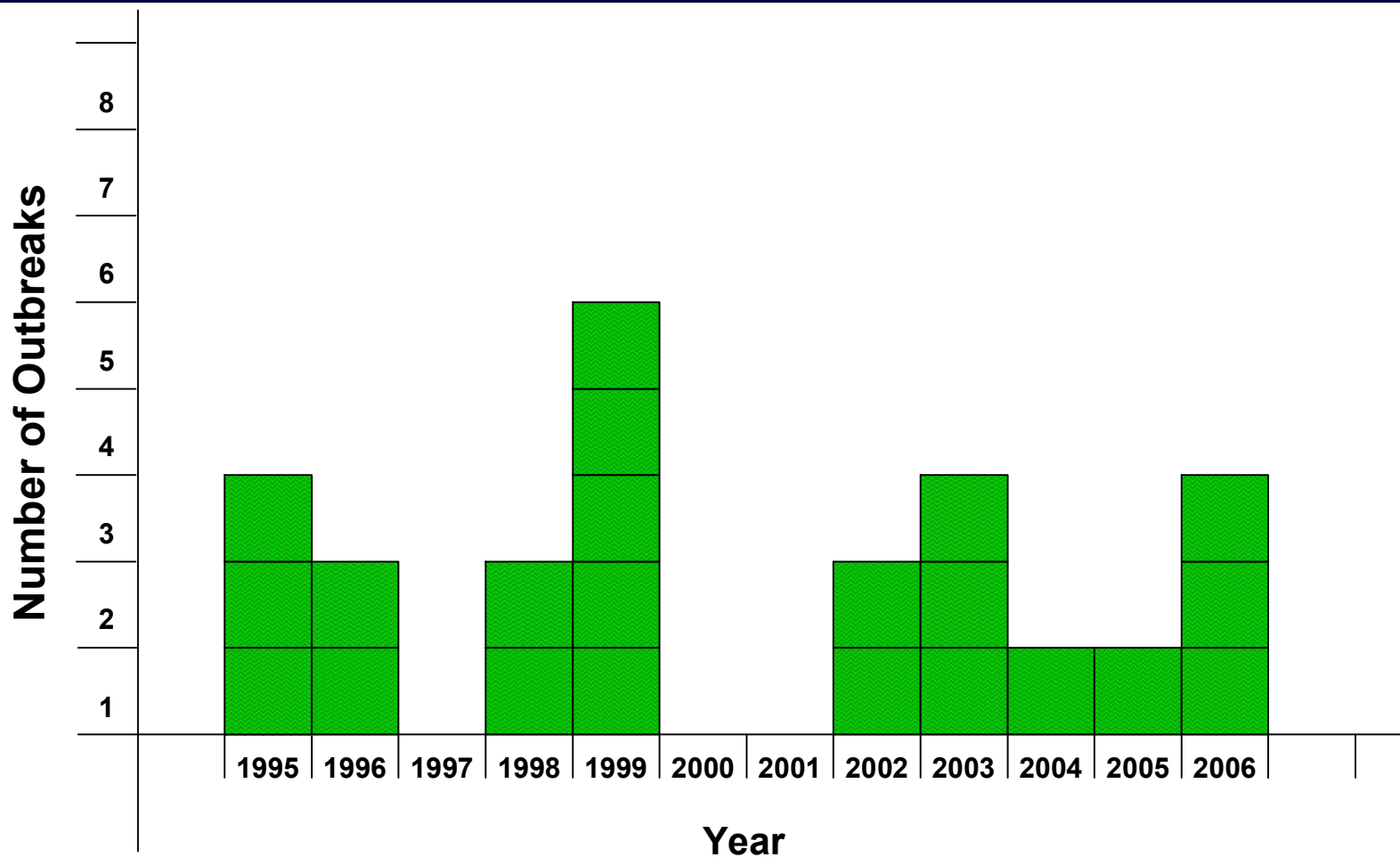
**Manure
from Dairy
Farm**



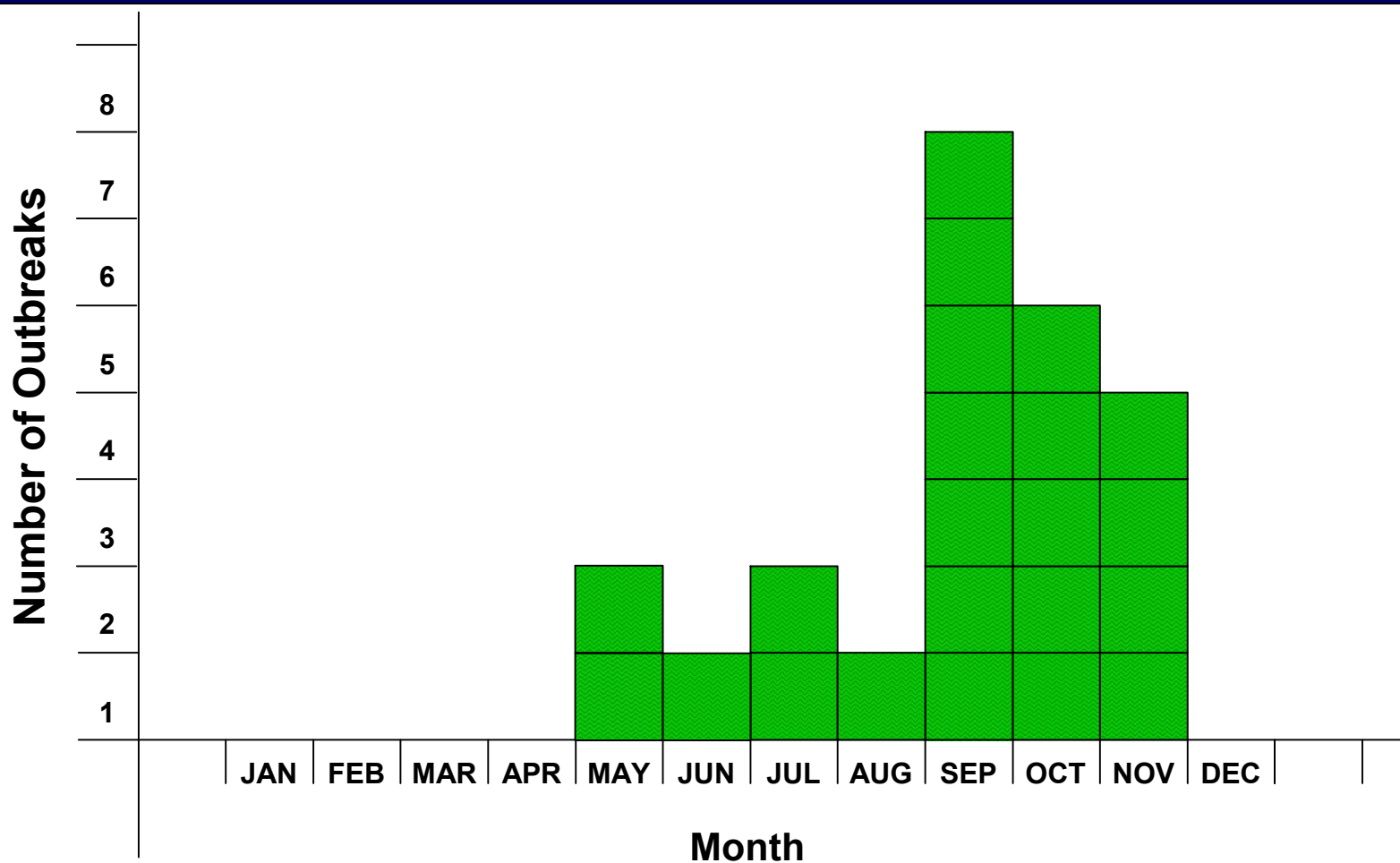
***E. coli* O157:H7 Outbreaks Associated with Leafy Greens**

<u>Onset Month</u>	<u>Year</u>	<u>Ill</u>	<u>Known or Suspected Vehicle</u>	<u>General Geographic Location</u>
July	1995	74	Lettuce (leafy green, red, romaine)	
September	1995	20	Romaine lettuce	
October	1995	11	Lettuce	
May	1996	61	Mesclun mix lettuce	Salinas Valley, CA
June	1996	7	Mesclun lettuce (suspected)	
May	1998	2	Salad	
September	1998	4	Lettuce	
September	1999	8	Romaine lettuce	Salinas Valley, CA
September	1999	6	Romaine lettuce	Salinas Valley, CA
October	1999	47	Lettuce	
October	1999	3	Romaine hearts	Salinas Valley, CA
October	1999	41	Romaine lettuce	Salinas Valley, CA
July	2002	29	Romaine lettuce	Salinas Valley, CA
November	2002	24	Lettuce	Lenmoore, CA
September	2003	27	Lettuce	Salinas Valley, CA
September	2003	5	Lettuce mix w/ romaine	CA?
October	2003	16	Spinach	Salinas Valley, CA
November	2004	6	Lettuce	CA?
September	2005	34	Romaine mix w/ other vegetables	Salinas Valley, CA
August	2006	204	Spinach	Salinas Valley, CA
November	2006	67	Iceberg lettuce	Pending
November	2006	18	Iceberg lettuce	Pending

E. coli O157 Outbreaks Associated with Leafy Greens, by Year, United States, 1995-2006



E. coli O157 Outbreaks Associated with Leafy Greens, by Month, United States, 1995-2006



All Lettuce, Acres Harvested for Sale: 2002

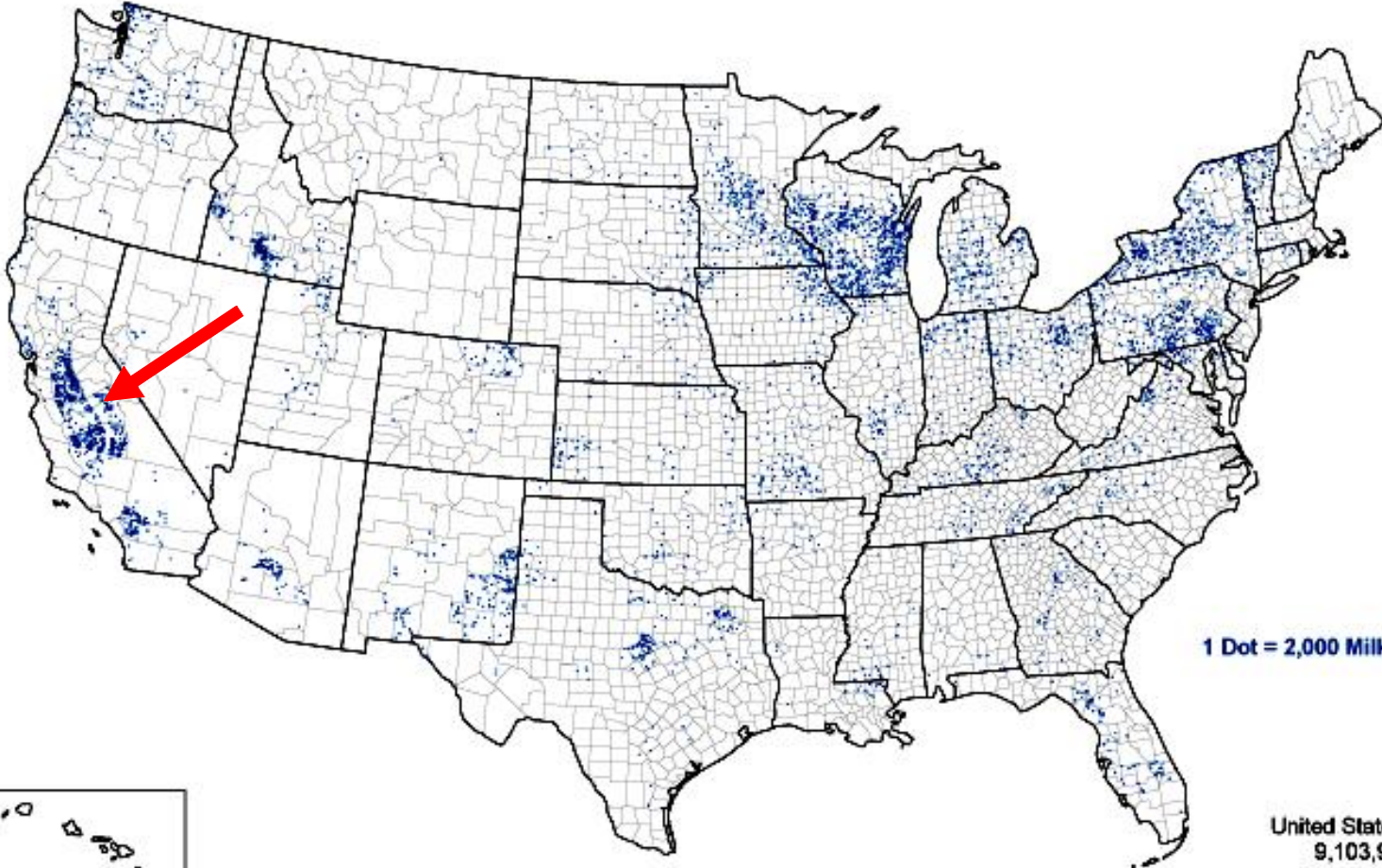


1 Dot = 300 Acres

United States Total
306,849



Milk Cows - Inventory: 2002



1 Dot = 2,000 Milk Cows

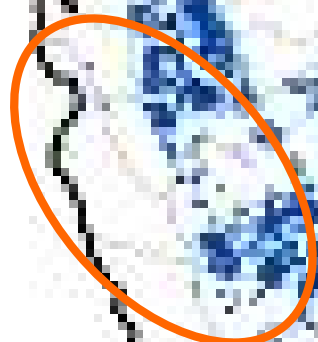
United States Total
9,103,959



Lettuce



Milk cows



|Guidance for Industry

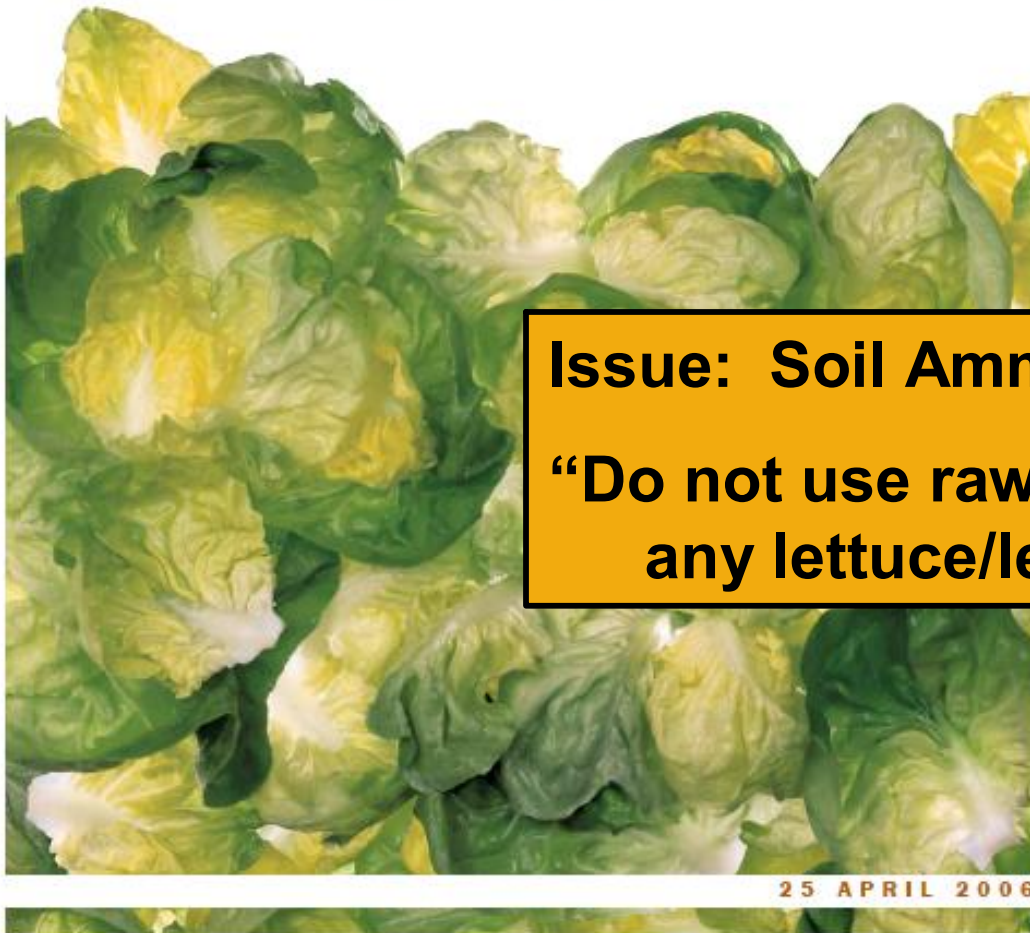
**Guide to Minimize Microbial
Food Safety Hazards for
Fresh Fruits and Vegetables**

III. Manure And Municipal Biosolids p. 23

“Applying raw manure, or leachate from raw manure, to produce fields during the growing season prior to harvest is not recommended.”

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
October, 1998

Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain



Issue: Soil Ammendments p. 5

“Do not use raw animal manure with any lettuce/leafy greens crop.”

25 APRIL 2006



U.S. Food and Drug Administration




CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

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March 2007

Guidance for Industry

Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables

**Draft Final Guidance
Contains Non-Binding Recommendations** 

*Additional copies are available from:
Office of Plant and Dairy Foods
Division of Plant Product Safety (HFS-305)
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 301-436-1400
<http://www.cfsan.fda.gov/guidance.html>*

For questions regarding this document, contact Amy Green at the Center for Food Safety and Applied Nutrition (CFSAN) at (301) 436-2025.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
March 2007**

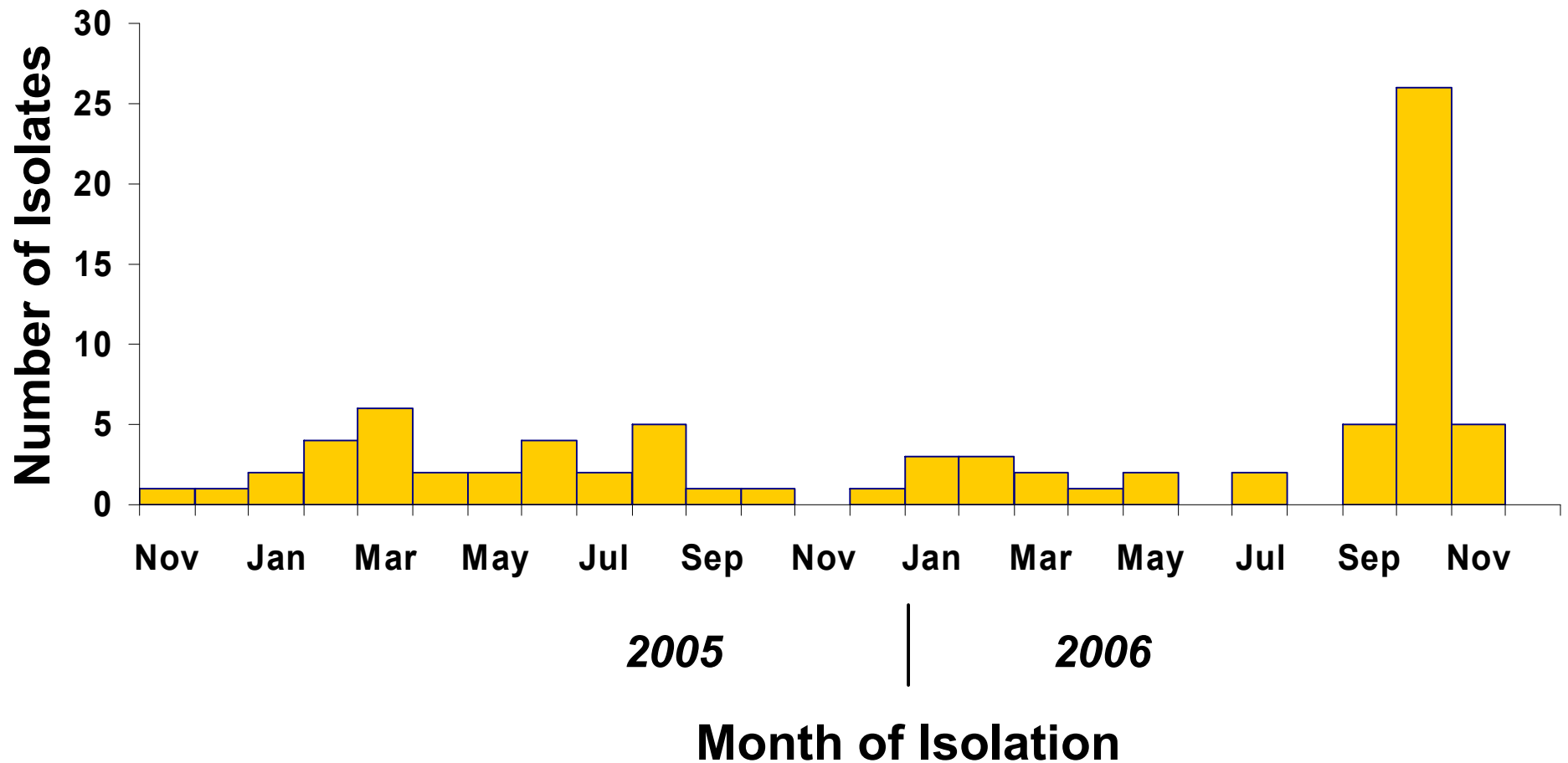
**Multistate Outbreak of
Salmonella serotype Tennessee Infections
Associated with Consumption of Peanut
Butter — United States, 2006-2007**

**Anandi Sheth, MD
Enteric Diseases Epidemiology Branch**

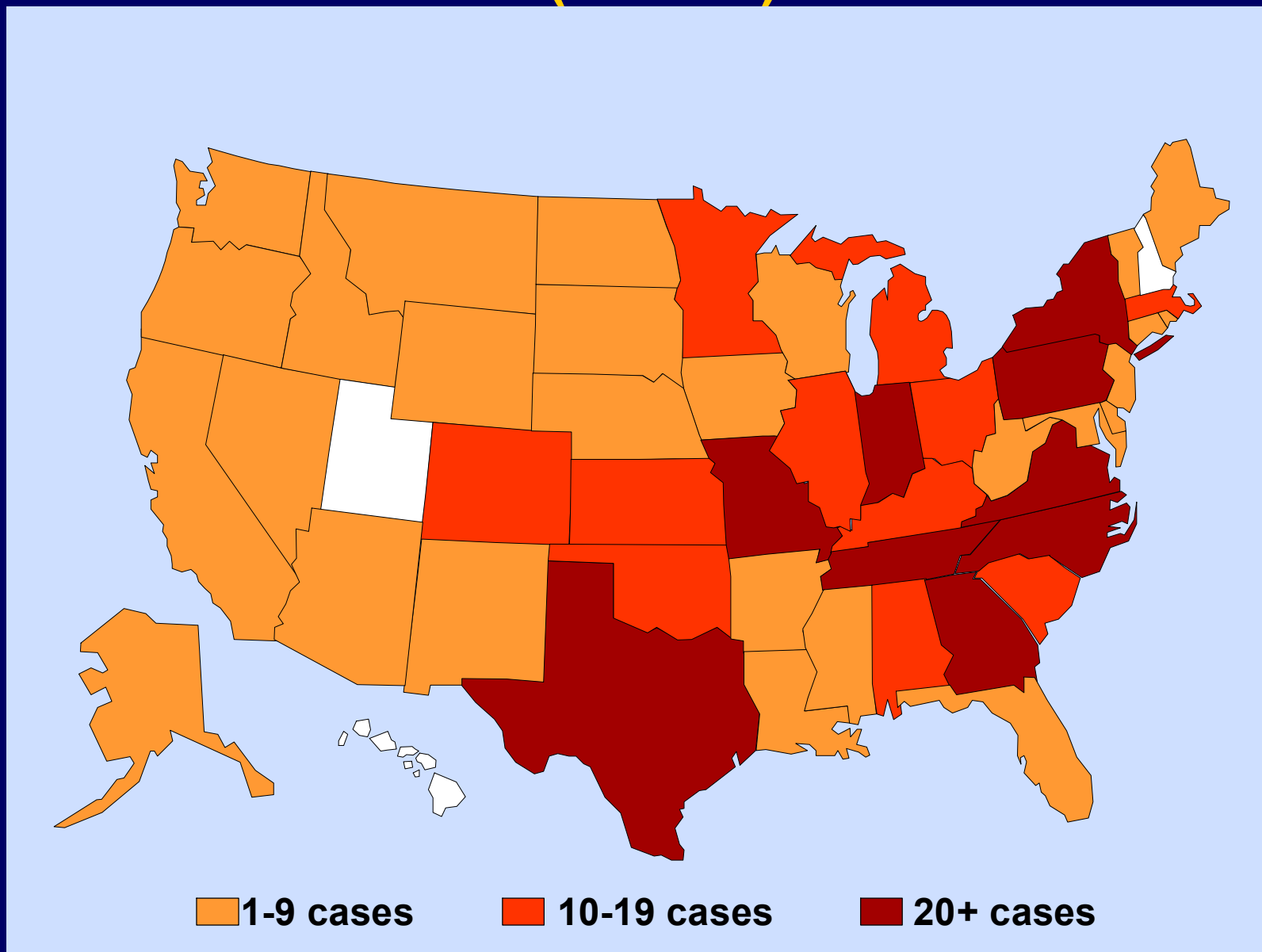


Outbreak Detection: Isolates of Outbreak Strain of *Salmonella* Tennessee, by Month, Nov 2004 – Dec 2006

Reported to CDC PulseNet as of January 1, 2007



Salmonella Tennessee Cases by State, (n=563)



Hypothesis Generation

Exposure	Percent of Cases (n=31)	Percent of Population (n=9093)	p-value
Peanut Butter	85	59	0.008
Potato	83	76	0.5
Banana	78	70	0.4
Milk	72	78	0.5
Eggs	71	75	0.5
Turkey	48	22	0.002

Could Peanut Butter be the Source?

- Never caused a U.S. outbreak
 - 1998 outbreak in Australia caused by peanut butter
- Peanut butter heated during processing
 - *Salmonella* can survive in peanut butter
- Popular among children
 - Eaten by members of all age groups
- Further interviews of 6 patients suggested common brand

Case-Control Study: Results

Exposure	Percent of Cases (n=65)	Percent of Controls (n=124)	mOR (95% CI)
Peanut butter	80	65	1.9 (0.8 – 5.2)
Peanut butter >once/wk	68	40	3.5 (1.4 – 9.9)
Peter Pan peanut butter	59	13	12.1 (3.6 – 63.3)
Great Value peanut butter	9	1	9.1 (1.0 – 433)

Action

- **Notified Food and Drug Administration (FDA) on February 13, 2007**
 - Peter Pan and Great Value brands produced at one plant
 - Distributed to all 50 states and >70 countries
- **Plant ceased all production on February 14**
- **Voluntary recall**
- **International notifications**



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DANGER ZONES KEEPING YOUR FAMILY SAFE SPECIAL REPORT

Salmonella found in peanut butter jars from Georgia plant
 POSTED: 11:55 a.m. EST, February 23, 2007



ConAgra Foods Inc. last week recalled all Peter Pan and Great Value peanut butter made at its Sylvester, Georgia, plant.

ADVERTISER LINKS

- [Pain Relievers](#)
- [Healthy Weight Loss](#)
- [Natural Weight Loss](#)
- [Rapid Weight Loss](#)

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www.starbarksonline.com

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Peanut Butter Stock
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www.pnuts.net

STORY HIGHLIGHTS

- **NEW:** Salmonella found in jars of peanut butter from Georgia plant
- At least 329 people from 41 states sickened by salmonella since August.
- No deaths confirmed; one alleged in Pennsylvania lawsuit

Adjust font size:

Omaha, Nebraska (AP) -- A week after ConAgra Foods Inc. recalled peanut butter from its Georgia plant after a salmonella outbreak, the Center for Disease Control confirmed the presence of the dangerous germ.

No deaths have been confirmed, although a Pennsylvania family filed a lawsuit Wednesday claiming a relative died from eating tainted peanut butter.

Opened jars from people who were sickened in New York, Oklahoma and Iowa tested positive for salmonella, said Dave Daigle, a spokesman for the CDC in Atlanta.

"Now the question becomes, how did the salmonella get in the jar," Daigle said.

ConAgra Foods Inc. last week recalled all Peter Pan and Great Value peanut butter made at its Sylvester, Georgia, plant after federal health officials linked the product to a salmonella outbreak that has sickened at least 329 people from 41 states since August.

Leslea Bennett-Webb, spokeswoman for the Oklahoma Department of Health, said the state recovered seven peanut butter jars from 11 cases confirmed by the state, and found the strain of salmonella in at least one.

In Iowa, Kevin Teale, spokesman for the state's Department of Health, said the positive match is from one of the state's six confirmed cases.

At least 51 people were hospitalized with symptoms of the disease between August 1 and February 2, with 60 percent of illnesses beginning after Dec. 1, according to the CDC.

Salmonella, which commonly originates from the feces of birds and animals, sickens

Plant Investigation Conducted by FDA

- Two environmental samples yielded outbreak strain
- Company reported leaky roof and faulty sprinkler may have caused moisture in the plant
- Can favor *Salmonella* growth



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