Why Big 6 Produce:

Science Behind Decisions

Craig Hedberg, PhD UMN School of Public Health

MINNESOTA INTEGRATED
FOOD SAFETY CENTER OF EXCELLENCE

UNIVERSITY OF MINNESOTA • MINNESOTA DEPARTMENT OF HEALTH

Big 6 Produce Items

- Leafy greens
- Sprouts
- Tomatoes
- Peppers
- Onions
- Melons

Big 6 Produce Items:

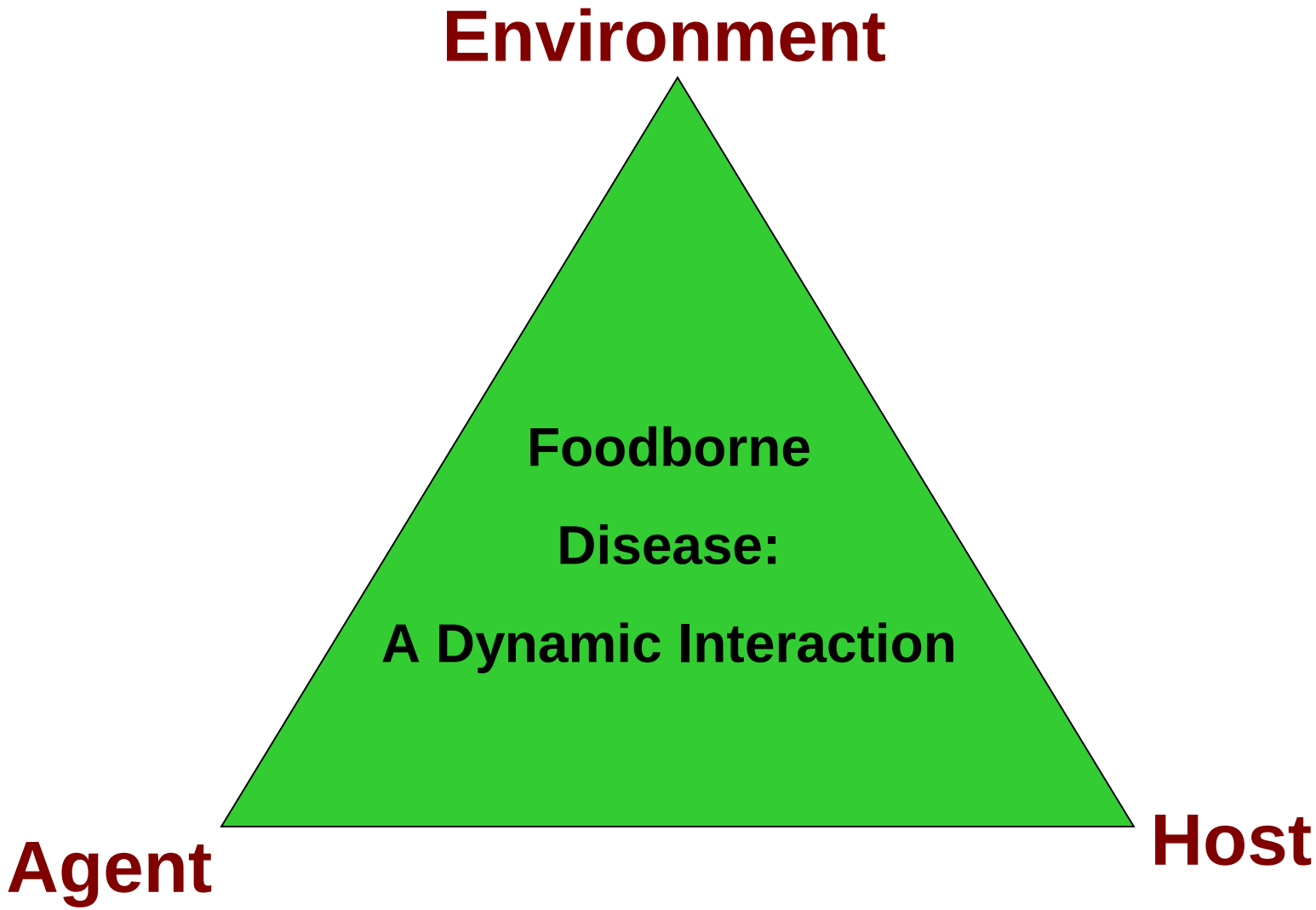
- Leafy greens
- Sprouts
- Tomatoes
- Peppers
- Onions
- Melons

Why?

- Characteristics of produce, source, propagation and distribution.
- Frequency of consumption, how and where consumed.
- Public health system awareness and ability to identify.

Lettuce

Open vs. closed heads


Environment
Foodborne
Disease:
A Dynamic Interaction
Agent
Host

Big 6 Pathogens

- Norovirus
- *Salmonella* Typhi
- Shiga-toxin producing *E. coli*
- *Shigella* spp.
- Hepatitis A Virus
- *Salmonella* (non-typhoidal)

Estimated Food-Related Cases of Big 6 Foodborne Pathogens

Agent	Food-Related Cases	(%)
Norovirus	5,500,000	(58.2)
Salmonella (non-typhoidal)	1,028,000	(10.9)
Shigella spp.	131,000	(1.4)
STEC, non-O157	113,000	(1.2)
E. coli O157:H7	63,000	(0.7)
Salmonella Typhi	1,800	(0.0)
Hepatitis A Virus	1,600	(0.0)

Emerg Infect Dis. 2011 Jan; 17(1): 7–15. doi: 10.3201/eid1701.P11101

Estimated Food-Related Cases of Big 6 Foodborne Pathogens

Agent	Food-Related Cases	(%)
Norovirus	5,500,000	(58.2)
Salmonella (non-typhoidal)	1,028,000	(10.9)
Shigella spp.	131,000	(1.4)
STEC, non-O157	113,000	(1.2)
E. coli O157:H7	63,000	(0.7)
Salmonella Typhi	1,800	(0.0)
Hepatitis A Virus	1,600	(0.0)

Emerg Infect Dis. 2011 Jan; 17(1): 7–15. doi: 10.3201/eid1701.P11101

IFSAC Food Categories: Fruits and Vegetables

Vegetables
- Fungi *portabellas, button mushrooms*
- Sprouts *alfalfa sprouts, mung bean sprouts*
- Root-underground
  - Roots *carrots, beets*
  - Tubers *potatoes, yams*
  - Bulbs *garlic, onions*
  - Other *ginger, taro*
- Seeded vegetables
  - Vine-grown *squashes, cucumbers*
  - Solanaceous *tomatoes, peppers*
  - Legumes *lima beans, snow peas*
  - Other *okras, sweet corns*
- Herbs *basil, cilantro*
- Vegetable row crops
  - Flowers *artichokes, broccoli*
  - Stems *asparagus, celeries*
  - Leafy *lettuce, spinach*

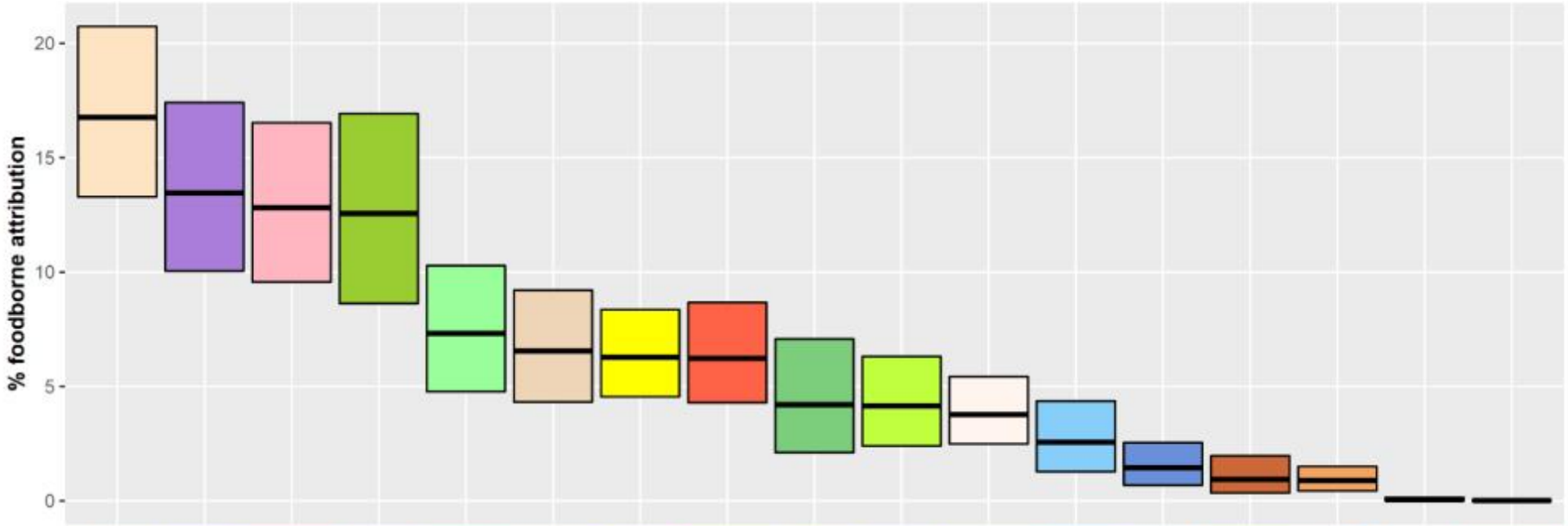
Fruits
- Melons *cantaloupes, watermelons*
- Pomes *apples, pears*
- Stones *apricots, cherries*
- Small *blueberries, strawberries*
- Tropical *bananas, mangoes*
- Sub-tropical *avocadoes, oranges*

https://www.cdc.gov/foodsafety/pdfs/IFSAC_Food_Categories_examples-H.pdf

Big 6 Produce Items: IFSAC Category

• Leafy greens	Vegetable Row Crop
• Sprouts	Sprouts
• Tomatoes	Seeded Vegetables
• Peppers	Seeded Vegetables
• Onions	Root-underground
• Melons	Fruits (Melons)

Salmonella Attribution to Food Categories, 2019

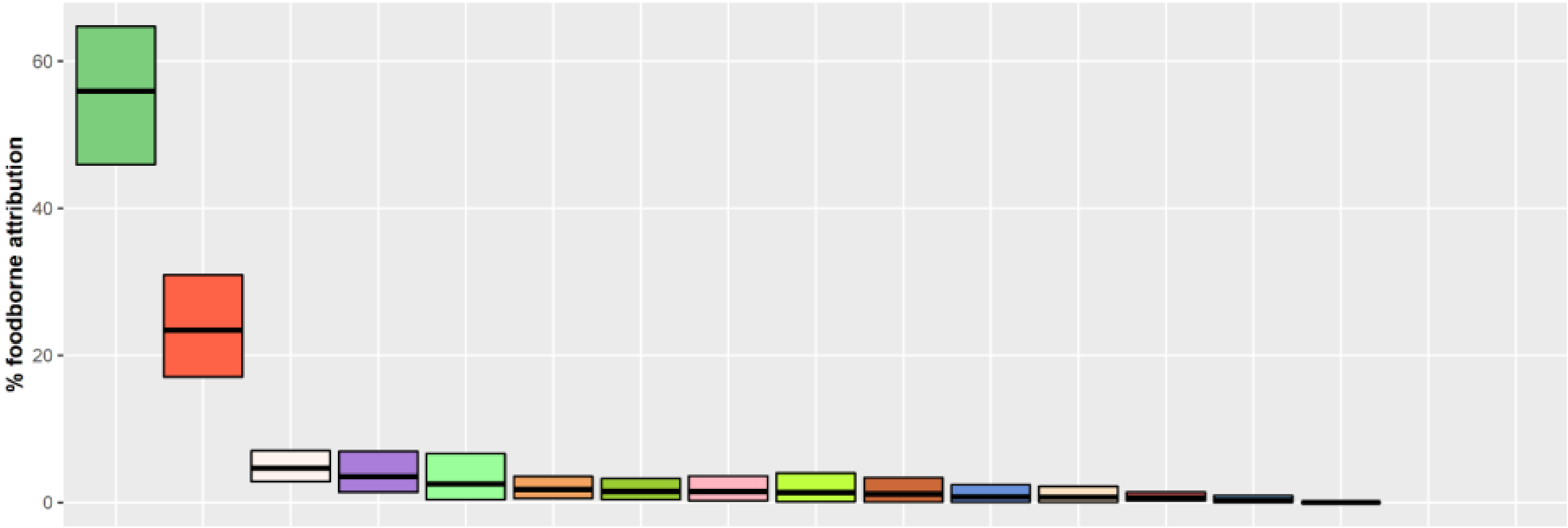


	Chicken	Fruits	Pork	Seeded Vegetables	Other Produce	Turkey	Eggs	Beef	Vegetable Row Crops	Sprouts	Dairy	Fish	Other Seafood	Grains-Beans	Other Meat/ Poultry	Oils-Sugars	Game
% attribution	16.8	13.5	12.8	12.6	7.3	6.6	6.3	6.2	4.2	4.2	3.8	2.6	1.4	0.9	0.9	< 0.1	< 0.1
cumulative attribution	75.9%							24.2%									

*Based on a model using outbreak data that gives equal weight to each of the most recent five years of data (2015-2019) and exponentially less weight to each earlier year (1998-2014).

https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2019-report-TriAgency-508.pdf

E. coli O157 Attribution to Food Categories, 2019



	Vegetable Row Crops	Beef	Dairy	Fruits	Other Produce	Other Meat/ Poultry	Seeded Vegetables	Pork	Sprouts	Grains-Beans	Other Seafood	Chicken	Game	Fish	Turkey	Eggs	Oils-Sugars
% attribution	55.9	23.4	4.7	3.6	2.6	1.8	1.5	1.5	1.4	1.1	0.8	0.7	0.7	0.3	< 0.1	--	--
cumulative attribution	79.3%		20.7%														

*Based on a model using outbreak data that gives equal weight to each of the most recent five years of data (2015-2019) and exponentially less weight to each earlier year (1998-2014).

https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2019-report-TriAgency-508.pdf

Attribution of *Salmonella* and *E. coli* O157 to Selected Vegetable Categories

Estimated Percentage of Foodborne Illnesses		
Agent	**Seeded Vegetables**	**Vegetable Row Crops**
Salmonella	12.6%	4.2%
E. coli O157	1.5%	55.9%

Estimated Number of Foodborne Illnesses		
Agent	**Seeded Vegetables**	**Vegetable Row Crops**
Salmonella	130,000	43,000
E. coli O157	1,000	35,000

https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2019-report-TriAgency-508.pdf

FSMA Final Rule on Produce Safety

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

1. Agricultural Water
2. Biological Soil Amendments
3. Sprouts
4. Domesticated and Wild Animals
5. Worker Training and Health and Hygiene
6. Equipment, Tools and Buildings

https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety

Microbiological safety evaluations and recommendations on sprouted seeds

- Sprouted seeds potential for pathogen growth during production.
- Soak viable seed in water and place seed in a warm, humid environment 3 to 7 days for germination and sprout growth.
- Ideal conditions for exponential growth of bacteria.
- If pathogens present on/in seed, conditions may allow for proliferation.

National Advisory Committee on Microbiological Criteria for Foods, Microbiological Safety Evaluations and Recommendations on Fresh Produce.

Food Control.1999;10:117–143.

Microbiological safety evaluations and recommendations on sprouted seeds

- Food safety knowledge
  - lack of fundamental food safety knowledge along continuum from seed production through sprout consumption…general perception that sprouted seed industry was producing an agricultural commodity and not a “ready-to-eat” food.
- Seed production
  - multiple opportunities during seed production and harvest for contamination with foodborne pathogenic microorganisms.

National Advisory Committee on Microbiological Criteria for Foods, Microbiological Safety Evaluations and Recommendations on Fresh Produce.

https://doi.org/10.1016/S0168-1605(99)00135-X

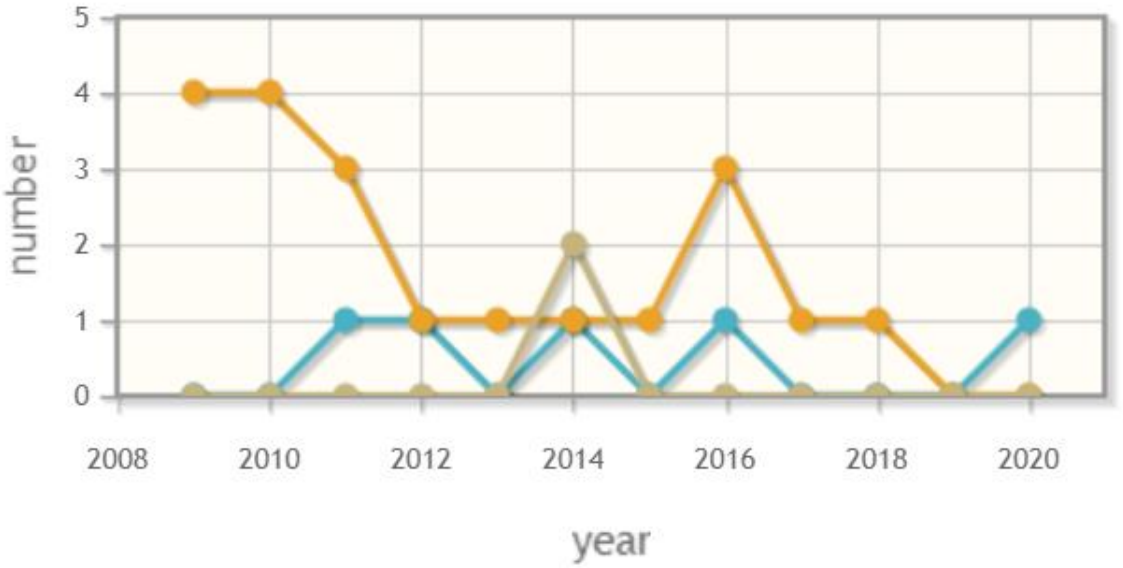
Microbiological safety evaluations and recommendations on sprouted seeds

- Seed handling
  - seeds can be contaminated during post-harvest operations such as transport, conditioning, grading, storage, and packaging.
- Seed treatment
  - treatments shown to reduce levels of pathogenic bacteria present on seeds, but not eliminated pathogenic microorganisms.
- Sprout production
  - procedures and practices used by sprout producers have substantial impact on likelihood that pathogenic bacteria will survive and proliferate in sprouts.

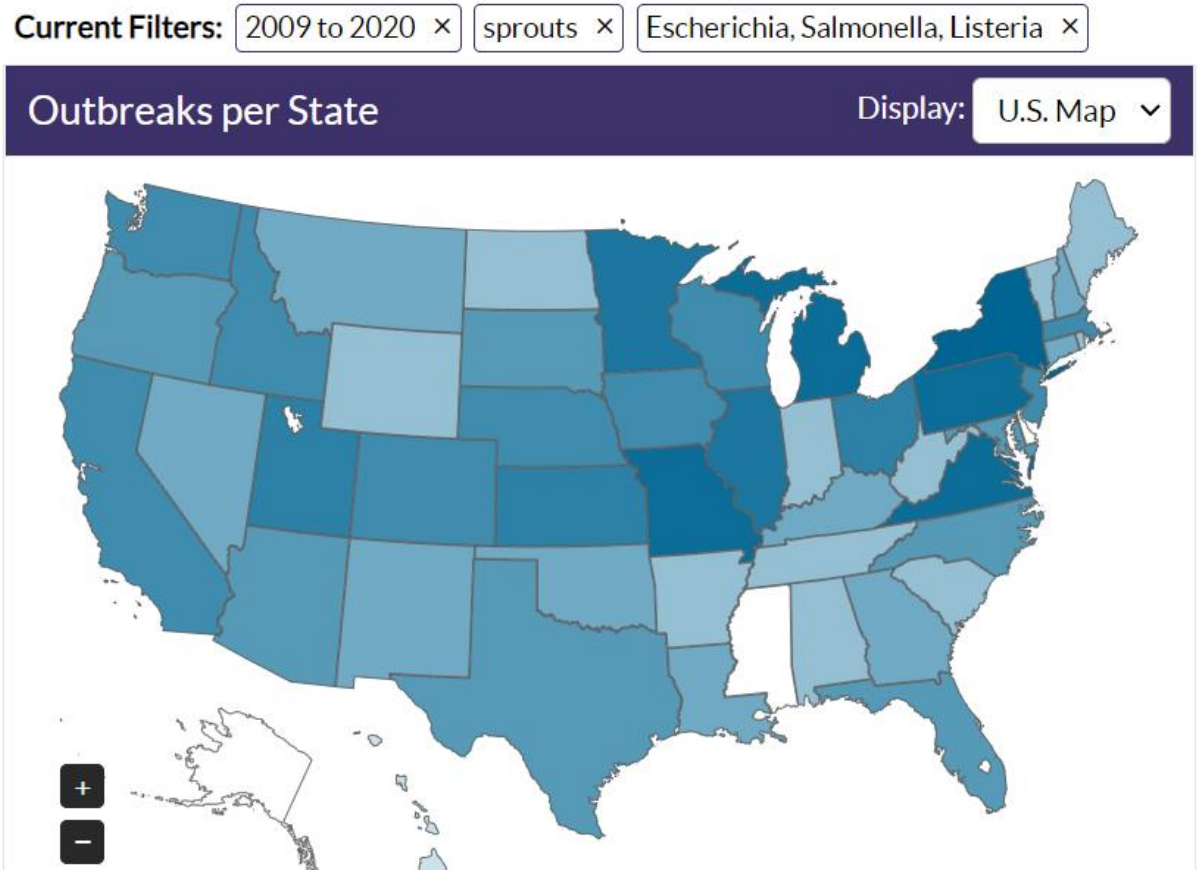
National Advisory Committee on Microbiological Criteria for Foods, Microbiological Safety Evaluations and Recommendations on Fresh Produce.

https://doi.org/10.1016/S0168-1605(99)00135-X

Outbreaks Associated with Sprouts Reported to FDOSS, 2009-2020

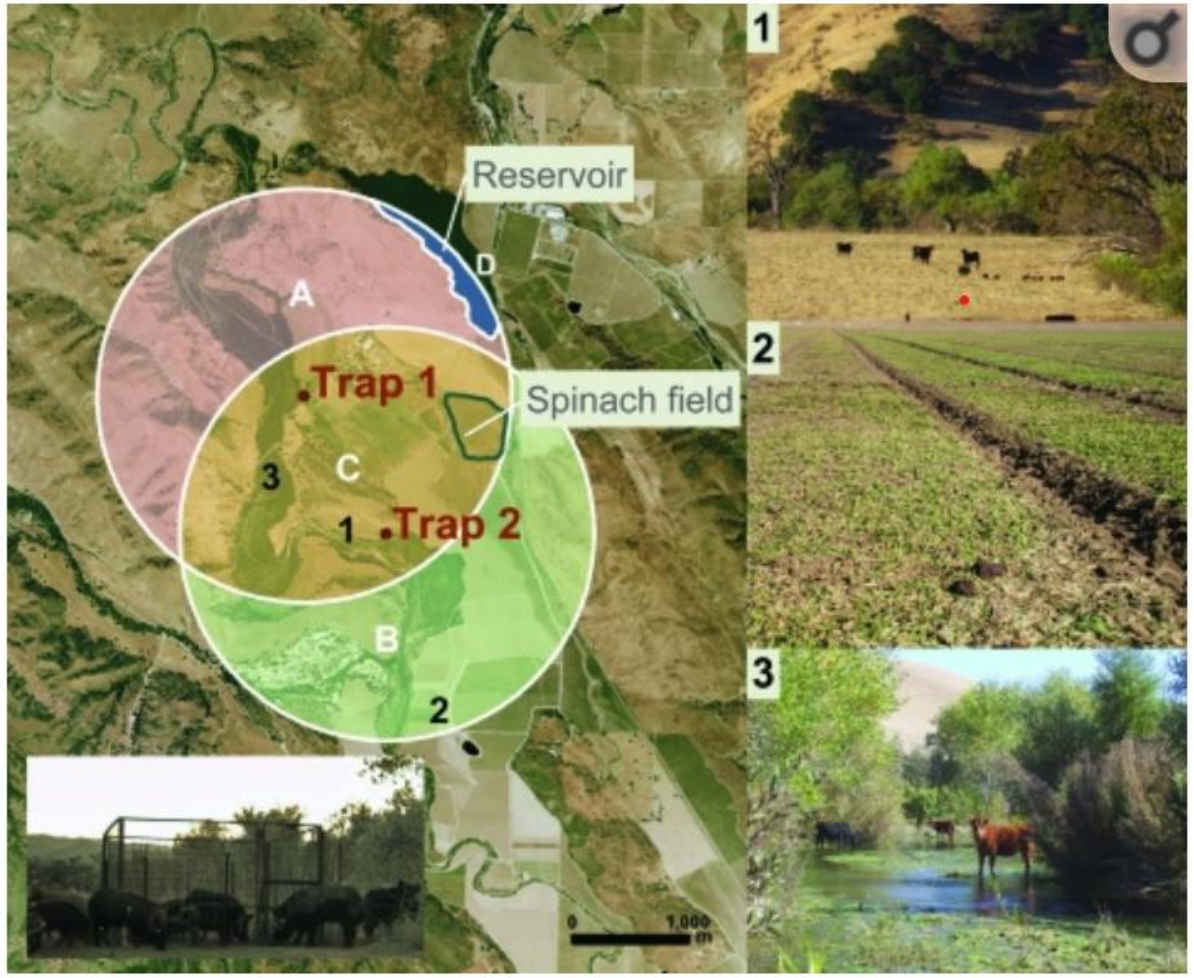


Salmonella =20
STEC = 5
Listeria = 2



https://wwwn.cdc.gov/norsdashboard/

Escherichia coli O157:H7 in Feral Swine near Spinach Fields and Cattle, Central California Coast



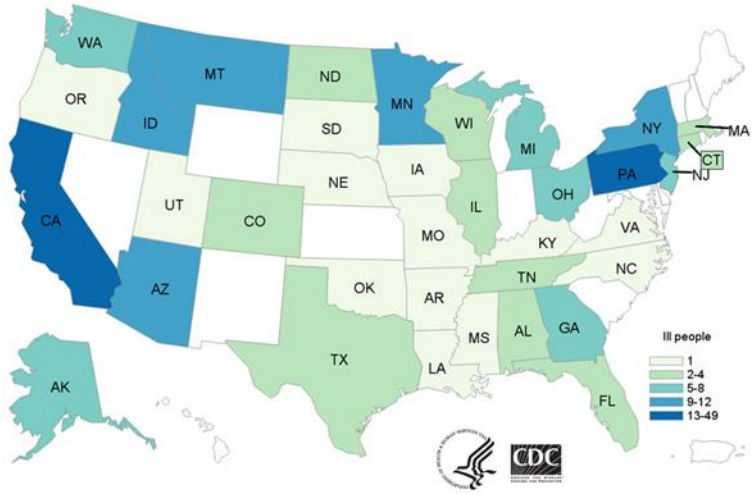
Potential risk factors for *Escherichia coli* O157:H7 contamination of spinach at ranch A:

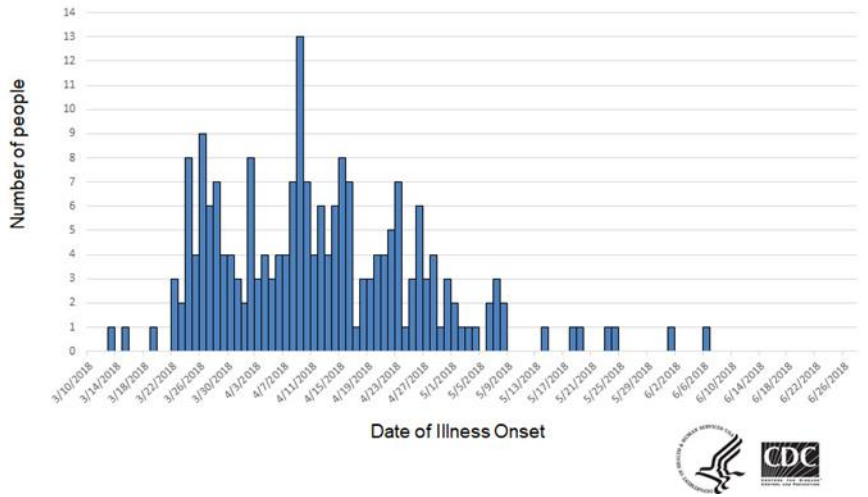
1) Feral sow and piglets sharing rangeland with cattle;
2) Feral swine feces, tracks, and rooting in a neighboring spinach field;
3) Cattle in surface water.

Emerg Infect Dis. 2007 Dec; 13(12): 1908–1911. doi: 10.3201/eid1312.070763

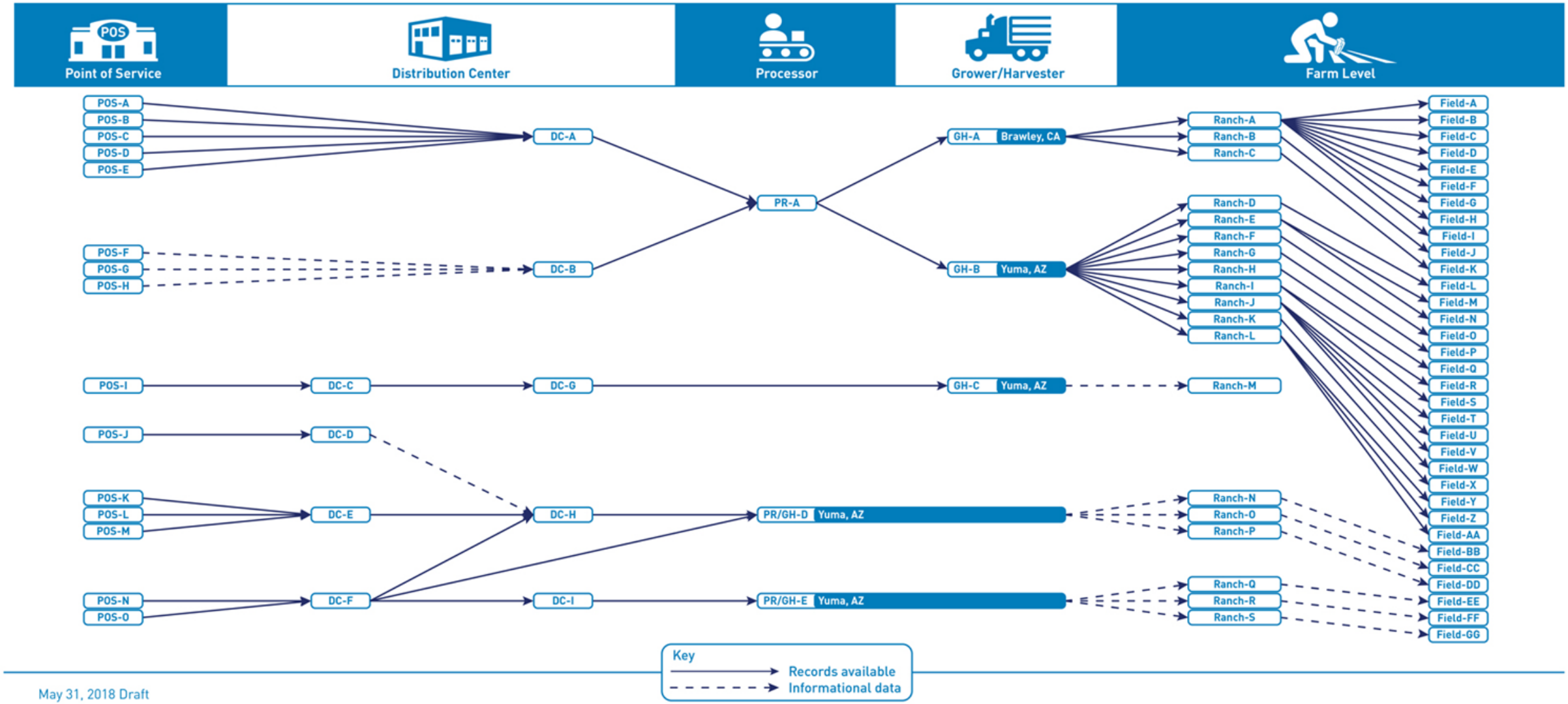
Multistate Outbreak of E. coli O157:H7 Infections Linked to Romaine Lettuce

- 210 people with outbreak strain reported from 36 states.
- 96 people hospitalized, 27 HUS.
- 5 deaths from Arkansas, California, Minnesota (2), New York.
- Ill people 1 to 88 years, median 28
- 67% female.
- 87% of 166 interviewed reported eating romaine lettuce (46% background).
- Traceback to Yuma, AZ growing region.
- Outbreak strain identified in canal water samples from Yuma growing region.





Redacted draft traceback diagram for FDA investigation of multistate outbreak of E. coli O157:H7 infections linked to romaine lettuce from Yuma growing region.



https://www.fda.gov/news-events/fda-voices-perspectives-fda-experts/fda-update-traceback-related-e-coli-o157h7-outbreak-linked-romaine-lettuce

Outbreak-pathogen-positive irrigation water samples:

- Upstream
- Adjacent
- Downstream of CAFO

https://www.fda.gov/media/117512/download

Environmental Assessment of Factors Potentially Contributing to the Contamination of Romaine Lettuce Implicated in a Multi-State Outbreak of *E. coli* O157:H7

- Known reservoirs of *E. coli* O157:H7 assessed in Yuma growing:
  - ruminant animals, water, soil and biological soil amendments of animal origin.
- Outbreak strain in 3 samples of water collected along a 3.5 mile stretch of irrigation canal.
- No other environmental samples yielded outbreak strain of *E. coli* O157:H7.
- FDA considers most likely way romaine lettuce contaminated was use of water from irrigation canal.
  - among Yuma area farms identified in traceback, irrigation canal water only directly applied during germination.
  - aerial and ground-based spraying of crop protection pesticides diluted with irrigation canal water occurred at various times during the growing season including after freeze event in late February.
  - freeze event likely led to damage of some portion of the romaine lettuce crop, which may have rendered it more susceptible to microbial contamination.

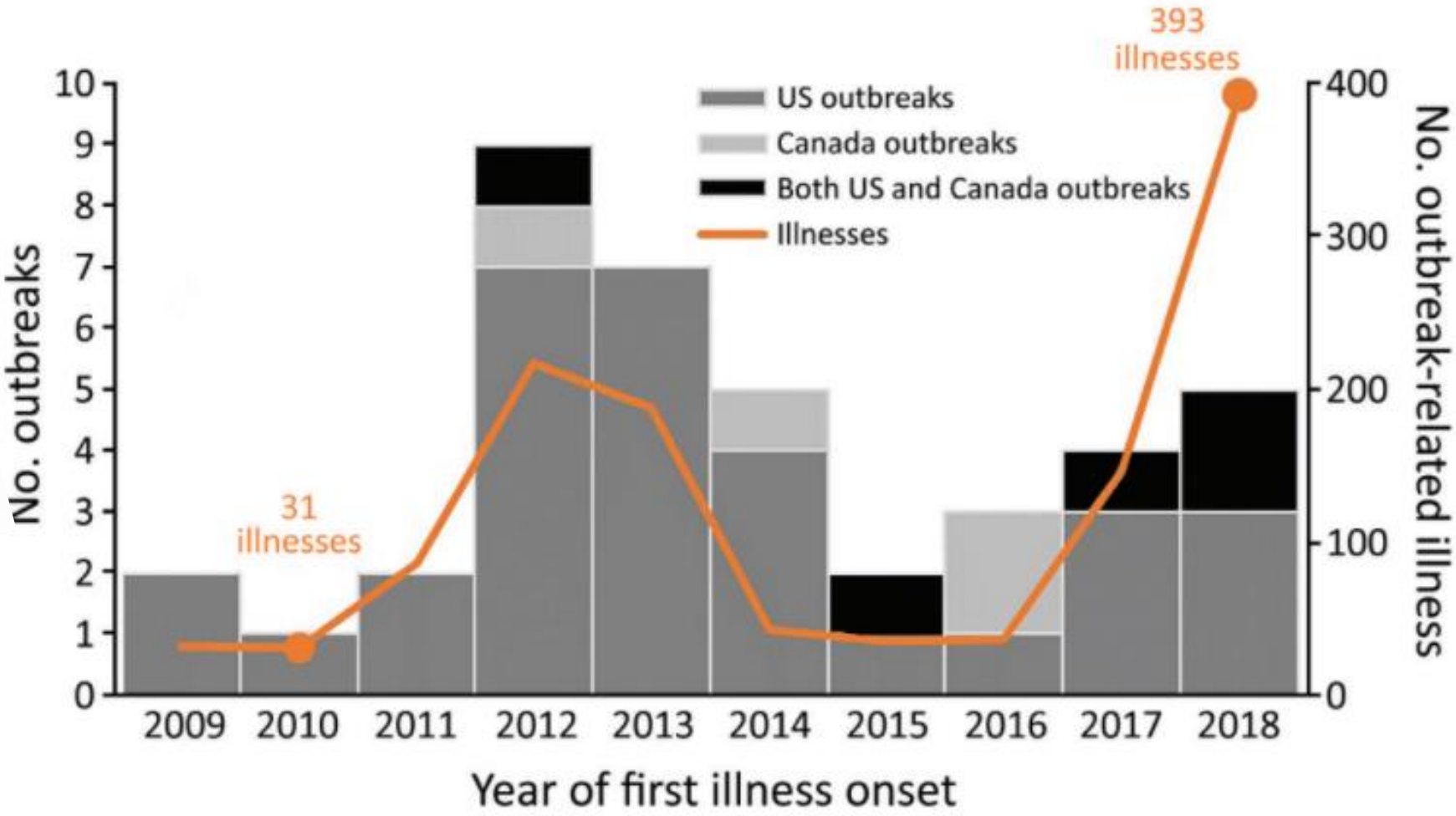
https://www.fda.gov/food/outbreaks-foodborne-illness/environmental-assessment-factors-potentially-contributing-contamination-romaine-lettuce-implicated

Independent Review of FDA's Foodborne Outbreak Response

- FDA traceback identified 36 growing fields on 23 farms in AZ and CA as potential sources of contaminated lettuce.
- Environmental assessment (EA) reviewed traceback leg associated with the grower, crops grown on adjacent fields, source of irrigation water, source of water of chemical applications, application of chemicals after a freeze in late February, use of biological soil amendments, evidence of animal intrusions, and unusual weather events for 21 farms.
  - 13 used water from contaminated canal for irrigation.
  - 7 of these used canal water to formulate chemical applications and applied chemicals to fields after a freeze in late February that may have damaged plants and increased their susceptibility to contamination.
  - **At least one such farm was represented on each of the major legs of the traceback.**
- This combination of conditions provides a reasonable pathway for contamination that caused the outbreak.

https://www.fda.gov/media/154484/download

Shiga toxin-producing *E. coli* Outbreaks Linked to Leafy Greens in the US and Canada, 2009-2018



Emerg Infect Dis. 2020 Oct;26(10):2319-2328. doi: 10.3201/eid2610.191418.

Shiga toxin-producing *E. coli* Outbreaks Linked to Leafy Greens in the US and Canada, 2009-2018

Table 2. STEC outbreaks linked to leafy greens by type of leafy green implicated, United States and Canada, 2009–2018*

Leafy green type	Outbreaks with information for type of leafy green†	Outbreaks with single known type of leafy green implicated	Outbreak-related illnesses attributed to outbreak with single type of implicated leafy green
Romaine	16 (40)	13 (54)	617 (84)
Iceberg	7 (18)	4 (17)	54 (7)
Spinach	5 (13)	4 (17)	32 (4)
Cabbage	1 (3)	1 (4)	16 (2)
Kale	1 (3)	1 (4)	7 (1)
Green leaf	1 (3)	1 (4)	5 (0.7)
Butter lettuce	1 (3)	NA	NA
Radicchio	1 (3)	NA	NA
Spring mix	1 (3)	NA	NA
Unknown	11 (28)‡	NA	NA
Total	40	24	731

*Values are no. (%) except as indicated. NA, not applicable; STEC, Shiga toxin–producing *Escherichia coli*
†More than 1 type of leafy green may have been reported for a given outbreak.
‡This includes two outbreaks that occurred in both the US and Canada. In 2015, the US investigation identified romaine lettuce as the outbreak source, and the Canadian investigation was not able to determine a specific type of leafy green. In 2017, the Canadian investigation linked an outbreak of STEC O157 to romaine lettuce, and the US investigation did not result in enough epidemiologic evidence to implicate a specific type of leafy green. For the purposes of this study, the leafy green type for these outbreaks was classified as unknown. For 1 outbreak, multiple leafy green types, including kale, spinach, and romaine, were reported and traced back but the leafy green type remained unknown.

Emerg Infect Dis. 2020 Oct;26(10):2319-2328. doi: 10.3201/eid2610.191418.

Food Source Information

COLORADO INTEGRATED FOOD SAFETY CENTER OF EXCELLENCE

Food Source Information
COLORADO INTEGRATED FOOD SAFETY CENTER OF EXCELLENCE

Worldwide, the United States is the 8th largest producer of cantaloupes/other melons.

Physical characteristics of rind and flesh make cantaloupes susceptible to pathogen contamination and growth.

Cantaloupe Production

- Cantaloupes often planted in raised beds, irrigation water to roots, melon remains dry.
  - Fruit contact with moist soil could produce “ground spot”.
    - Area on rind that is thin, poorly developed, soft, and appears lighter in color.
    - Presence of ground spot increases the risk for microbial growth and pathogen contamination.
    - Cantaloupes with ground spot may be more susceptible to internalization by pathogens during post-harvest handling.
- Cantaloupe irrigation can vary from weekly to daily.

Cantaloupe Harvest

- Cantaloupes harvested by hand when melons are mature/ripe and fruit begins to easily separate from the stem with a twist or pull.
  - Over 10–14-day period, fields harvested 8 to 10 times.
  - If pathogens present, can become attached to the cantaloupe rind, particularly where the stem was removed (the stem scar).
- Cantaloupes harvested, packed, inspected, graded in the field, transported to storage facility maintained at 36-40°F before shipped.
  - Some producers harvest the melons into field bins and move them directly into shipping boxes once in the packing house.
  - Rapid removal of field heat is necessary.

Consumption of Foods in Past 7 Days, FoodNet Population Survey, 2018-2019

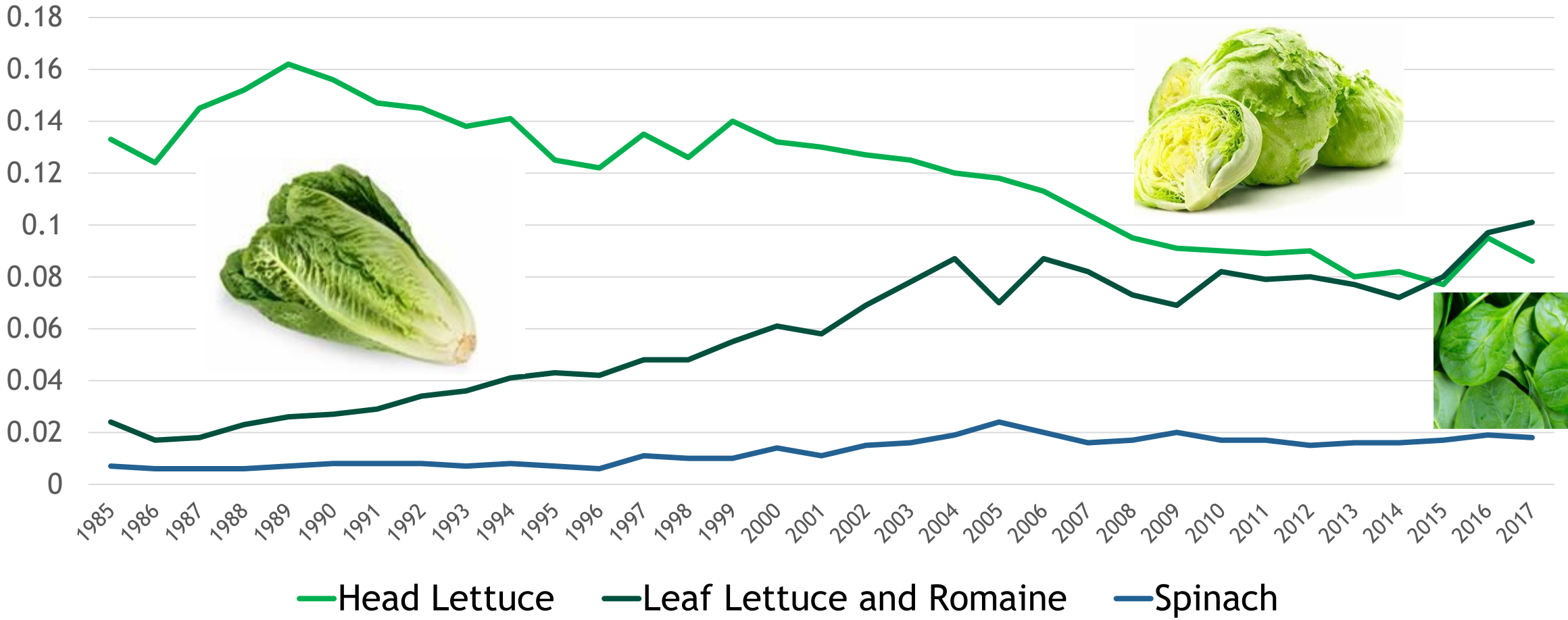
Fruit	%
Cantaloupe	19.4
Honeydew Melon	9.4
Watermelon	23.8
Peaches, *et al*	26.1
Strawberries	50.3
Raspberries	21.6
Blueberries	39.4
Mango	18.7

Vegetables	%
Leafy greens	80.5
• Iceberg lettuce	• 55.1
• Romaine lettuce	• 49.1
• Spinach	• 45.7
Sprouts	8.7
Tomatoes	71.7
• Cherry tomatoes	• 34.5
• Salsa, pico de gallo	• 25.2
Green onions	37.4
Bell peppers	55.4
Hot chili peppers	27.8

Consumption of Foods in Past 7 Days, FoodNet Population Survey, 2018-2019

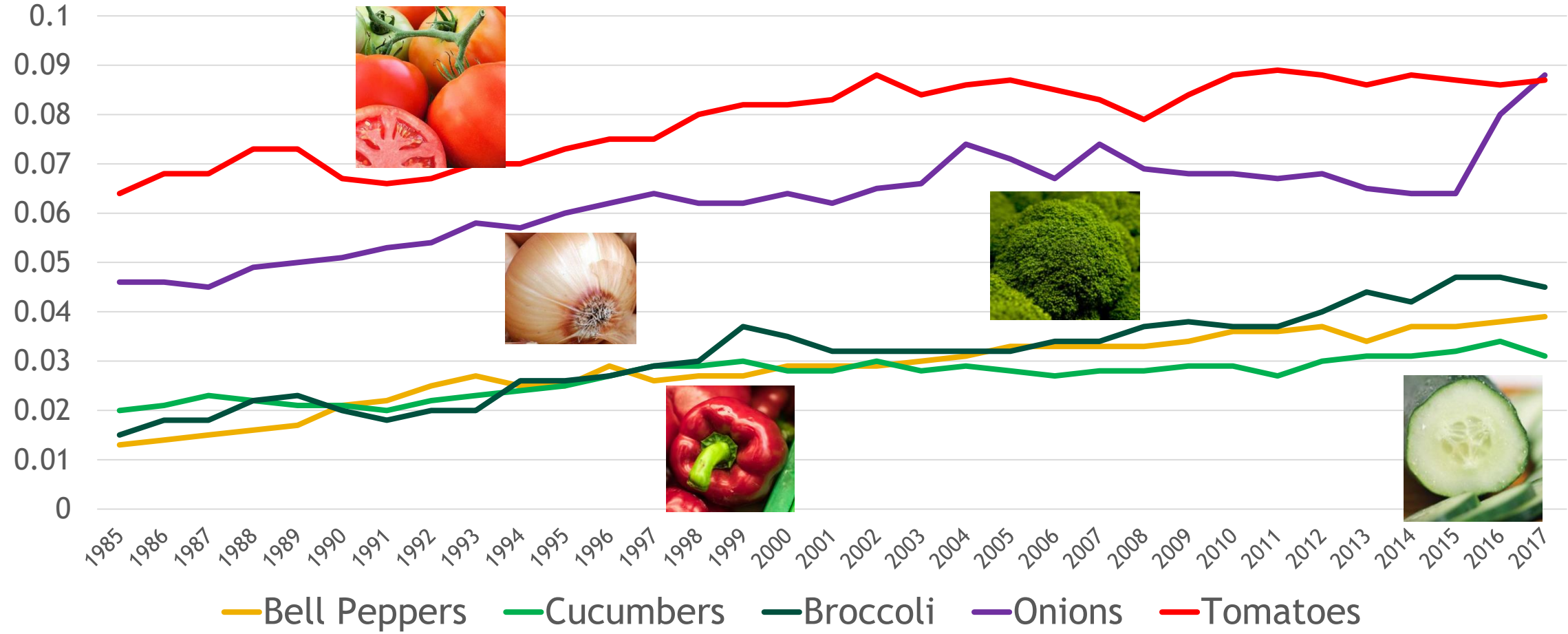
Vegetables	%
Avocado or guacamole	43.4
Pre-packaged salad	38.1
Arugula	13.8
Kale	18.8
Cucumber	50.1
Broccoli or cauliflower	55.3
Basil	22.2
Parsley	19.1
Cilantro	28.4
Other fresh herbs	28.8

Average daily per capita cup-equivalents from the U.S. food availability, adjusted for spoilage and other waste.



https://www.ers.usda.gov/data-products/food-availability-per-capita-data-system/

Average daily per capita cup-equivalents from the U.S. food availability, adjusted for spoilage and other waste.



https://www.ers.usda.gov/data-products/food-availability-per-capita-data-system/

Average daily per capita cup-equivalents from the U.S. food availability, adjusted for spoilage and other waste.





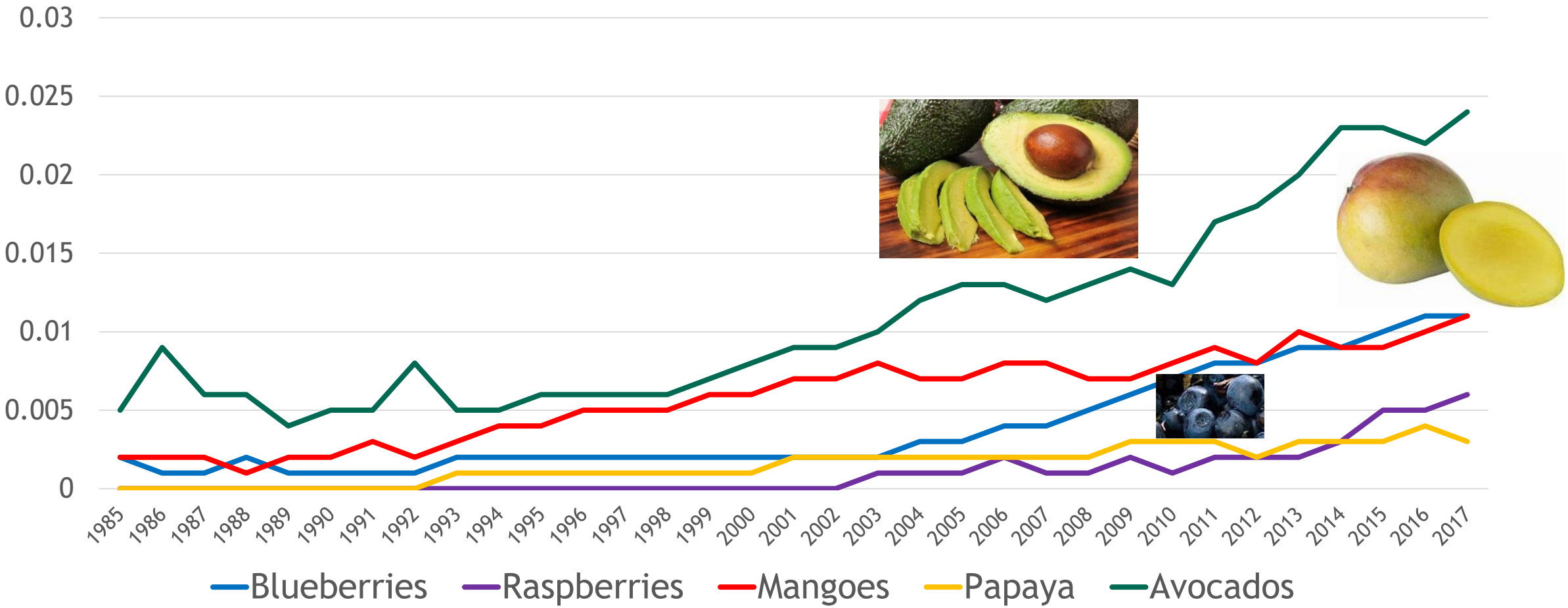
0.05
0.045
0.04
0.035
0.03
0.025
0.02
0.015
0.01
0.005
0

1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017

Cantaloupe Honeydew Watermelon Strawberries Peaches

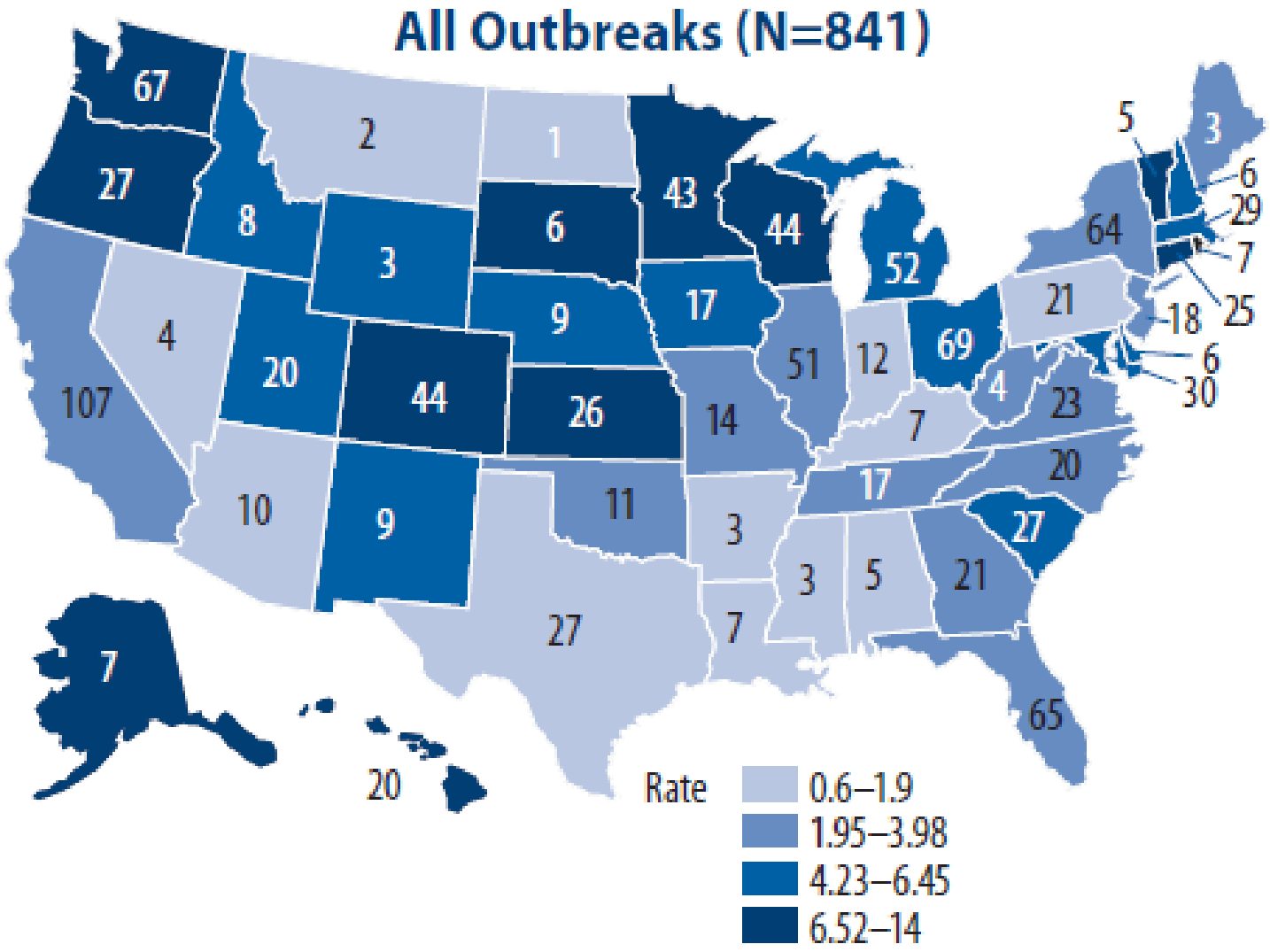
https://www.ers.usda.gov/data-products/food-availability-per-capita-data-system/

Average daily per capita cup-equivalents from the U.S. food availability, adjusted for spoilage and other waste.



https://www.ers.usda.gov/data-products/food-availability-per-capita-data-system/

Figure: Rate of reported foodborne disease outbreaks per one million population* and number of outbreaks,† by state‡ and confirmed and suspected etiology§ — Foodborne Disease Outbreak Surveillance System, United States, 2017.



https://www.cdc.gov/fdoss/pdf/2017_FoodBorneOutbreaks_508.pdf

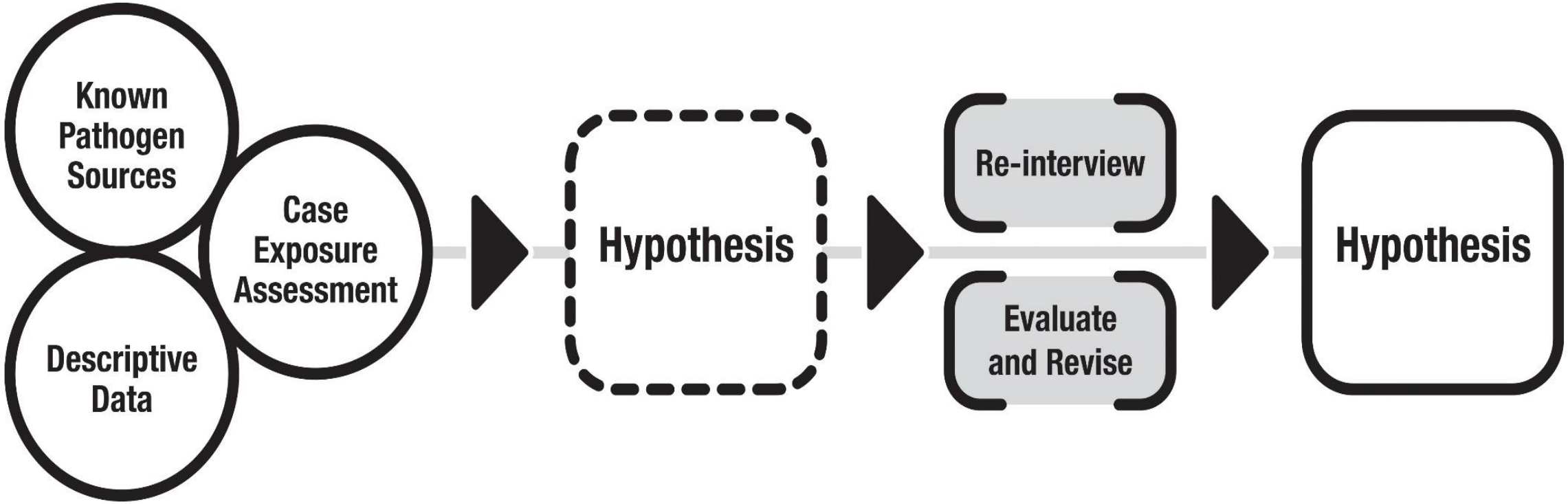
Progression of Public Health System Awareness

- Initial outbreak investigations demonstrate that a particular transmission pathway is possible
- Repeated investigations lead to an acceptance that it occurs
- Further repeated investigations lead to an expectation that it occurs

Hypothesis Generation

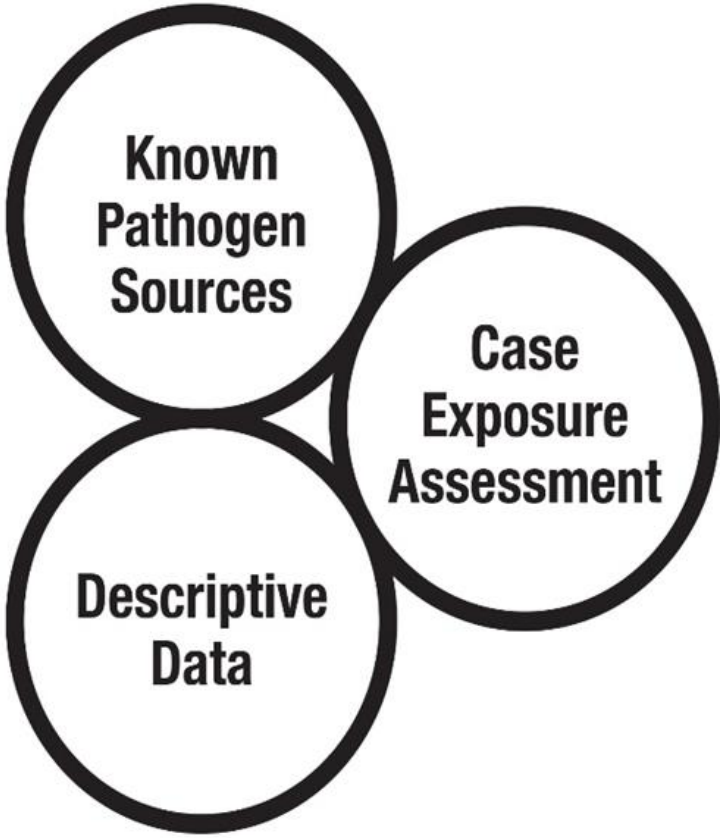
- To narrow the focus of an investigation and most effectively use time and resources, investigators should begin to generate hypotheses about potential sources of the outbreak during the earliest stages of the investigation and refine them as they receive information

Model framework for hypothesis generation



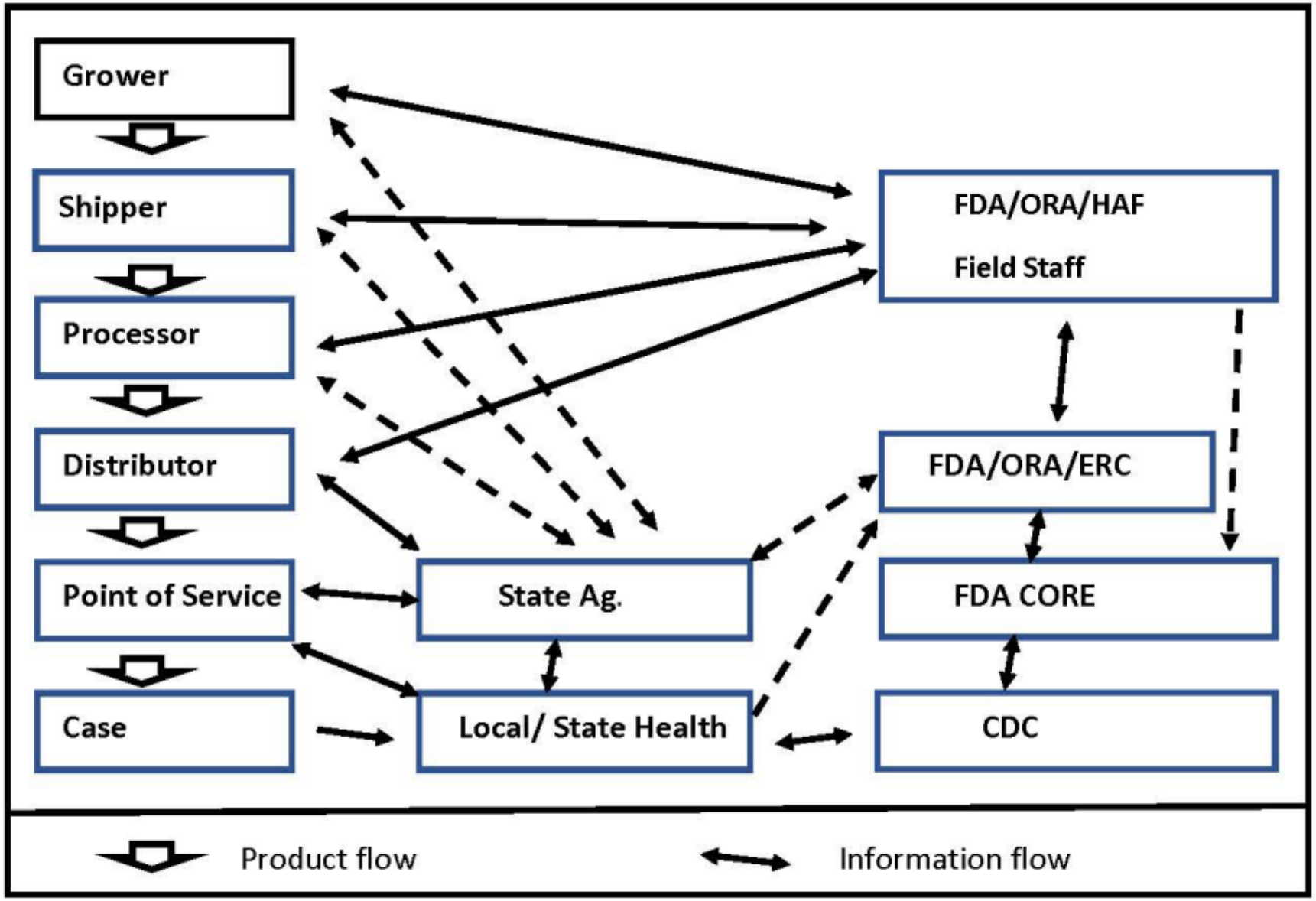
White et al. *Am J Epidemiol*. 2021 Oct 1;190(10):2188-2197

Case exposure assessment



- Rapidly collecting detailed food histories from cases in an outbreak is the most critical step in identifying commonalities between these cases

Figure 2. Schematic of information flow in traceback investigation.



Summary of key takeaways

- Inherent ambiguity in tracebacks due to patient dining preferences, inadequate documentation of exposure source details, and comingling of raw ingredients from multiple sources.
- Limited number of tracebacks conducted during investigation increases likelihood that information errors on any leg of the traceback could mask convergence across the legs of the traceback.
- Increasing number of tracebacks and assessing maximum likelihood of tracebacks based on probability distributions across supply chain would increase opportunities to use traceback data to evaluate environmental assessment and microbiological testing results in epidemiologic manner.

https://www.fda.gov/media/154484/download

Summary of key takeaways

- Introduction of foodborne pathogens into fresh produce systems may happen on sporadic basis from environmental reservoirs that limit the ability of detect the presence of the agent in subsequent environmental assessments.
- Frequent finding of pathogens associated with animals, and animal production on land adjacent to produce farms suggests a likely causal pathway from contamination.
- Consistency of findings in aggregate compensates for the uncertainty in individual observations

https://www.fda.gov/media/154484/download

Big 6 Produce: IFSAC Category: What are we missing?

• Leafy greens	Vegetable Row Crops	Celery, broccoli
• Sprouts	Sprouts	
• Tomatoes	Seeded Vegetables	Cucumbers, snow peas
• Peppers		
• Onions	Root-underground	
•	Herbs	Basil, cilantro
•	Fungi	Specialty mushrooms
• Melons	Fruits (Melons)	
•	Fruits	Other fruits