

IDFA Regulatory Roundup

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June 4, 2019



“If you join government, calmly make your contribution and move on. Do your best and when you have to – leave, and be something else.”

- Peggy Noonan



“Descriptive statistics can be like online dating profiles: technically accurate yet pretty darn misleading.”

- Charles Wheelan



**Department of Health and Human Services
Centers for Disease Control and Prevention**

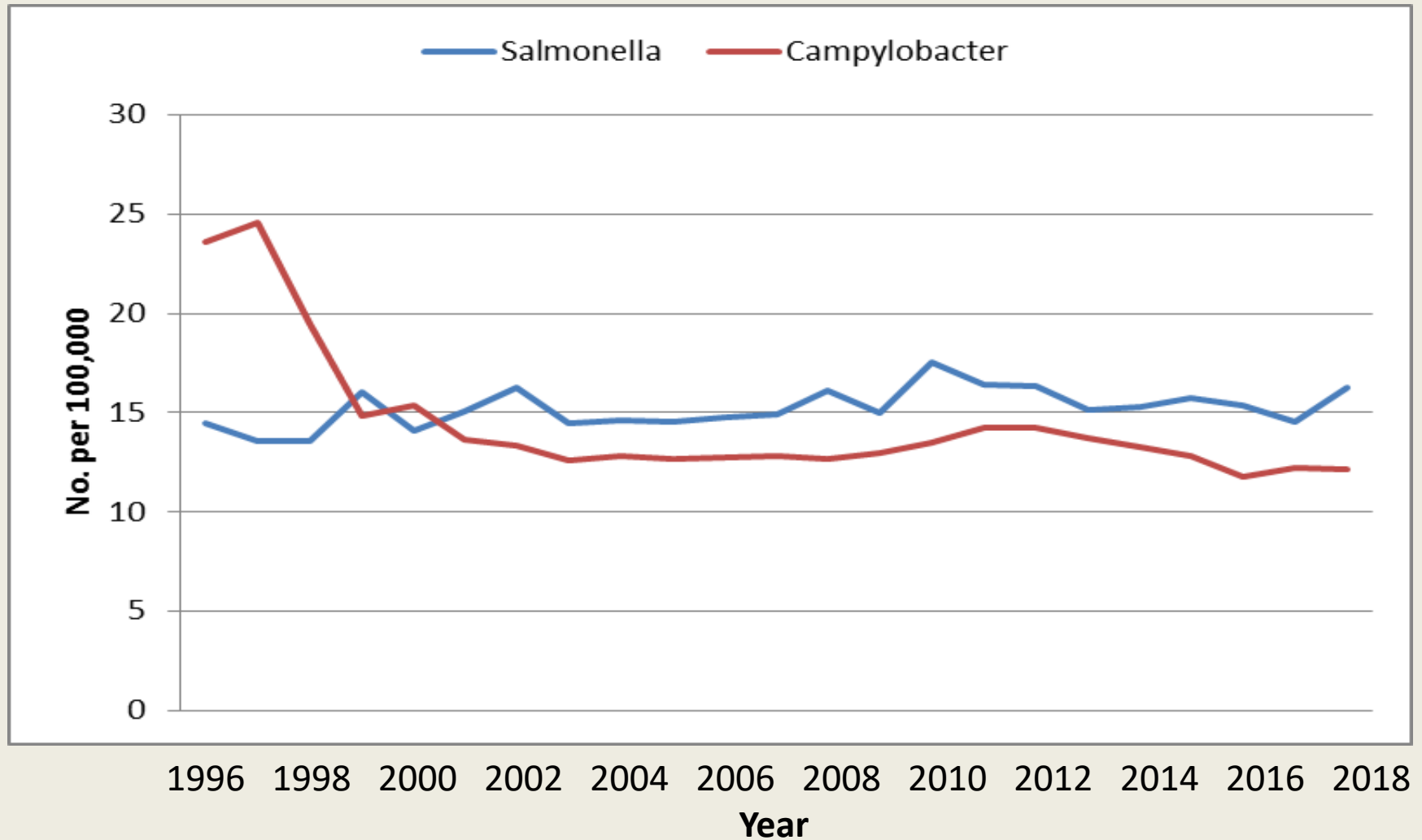
MMWR
Morbidity and Mortality Weekly Report

FoodNet

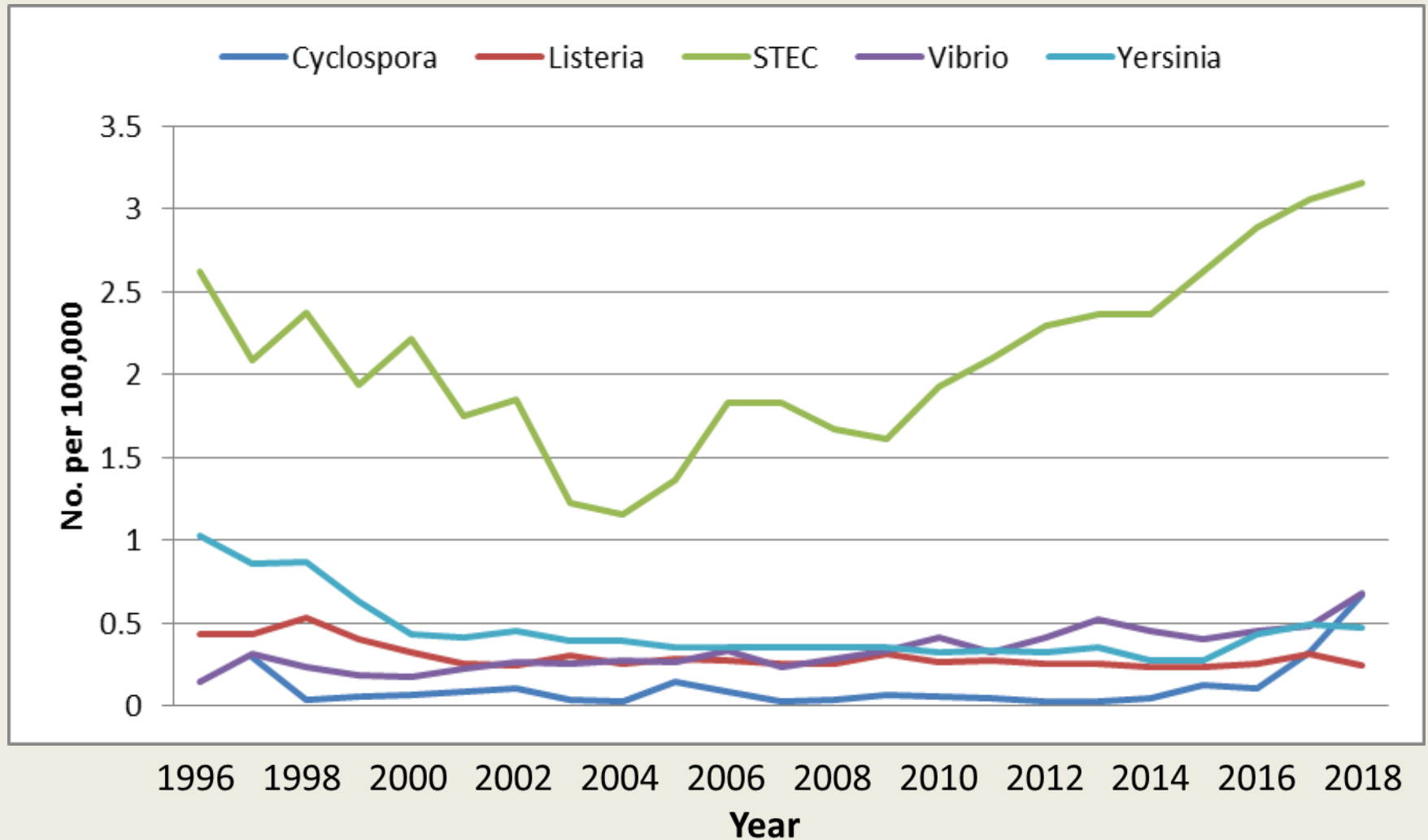
**Preliminary Incidence and Trends of
Infections with Pathogens Transmitted
Commonly Through Food — Foodborne
Diseases Active Surveillance Network, 10
U.S. Sites, 2015–2018**

MMWR: April 26, 2019 –68(16):369-73

Incidence of Culture-Confirmed *Salmonella* and *Campylobacter* Infections, FoodNet, 1996-2018



Incidence of Culture-Confirmed Infections Due to Other Pathogens, FoodNet, 1996-2018

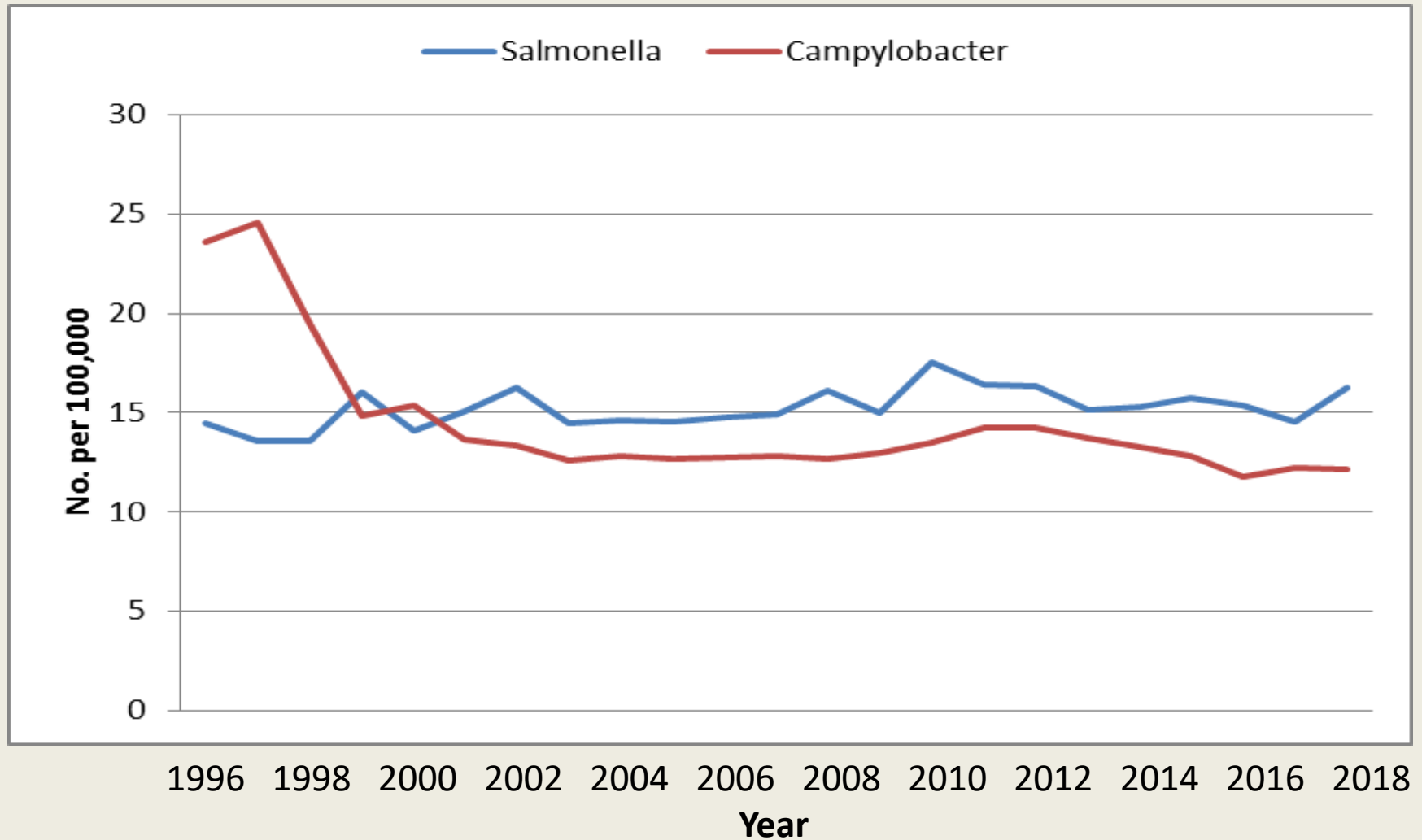


Incidence of Foodborne Pathogens, FoodNet, 2018

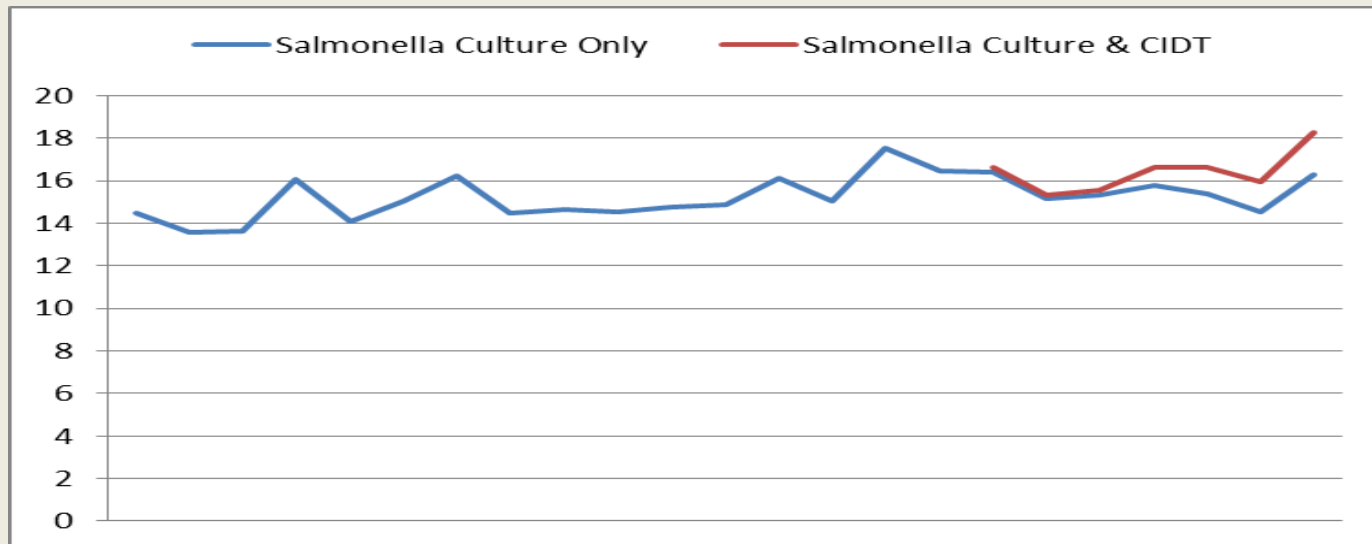
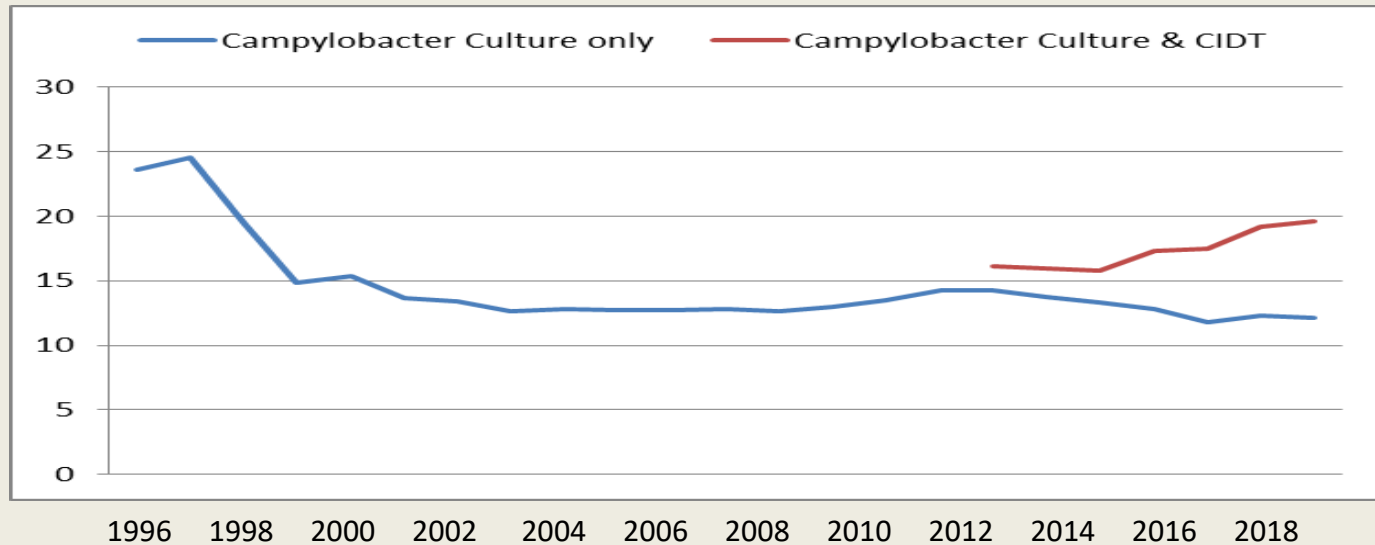
Pathogen	2018 Incidence Rate (per 100,000)	Change in 2018 Compared to 2015-2017*
Campylobacter	19.6	+12%
Salmonella	18.3	+9%
Shiga-toxin Producing E. coli	5.9	+26%
Vibrio	1.1	+109%
Yersinia	0.9	+58%
Cyclospora	0.7	+399%
Listeria	0.3	-4%

***Figures in bold are statistically significant**

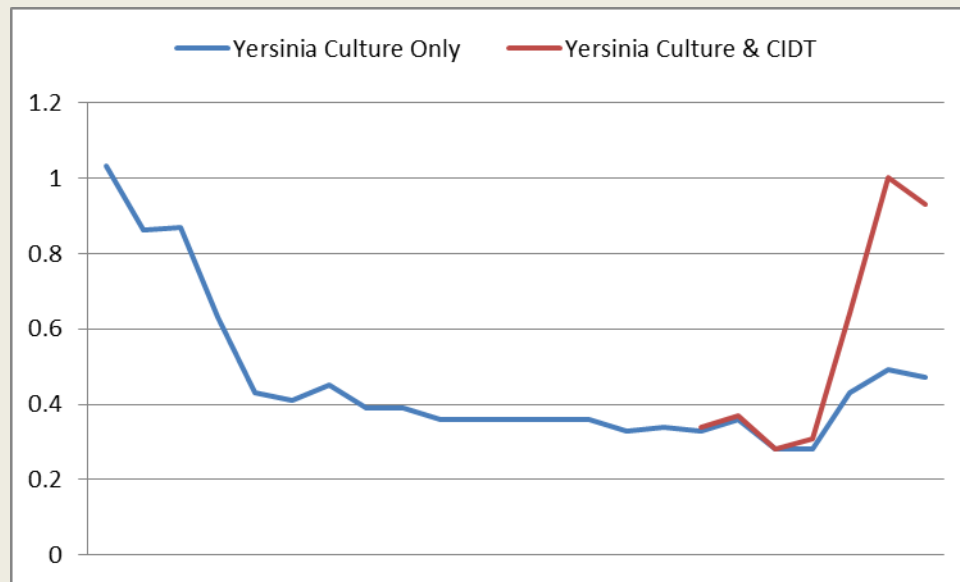
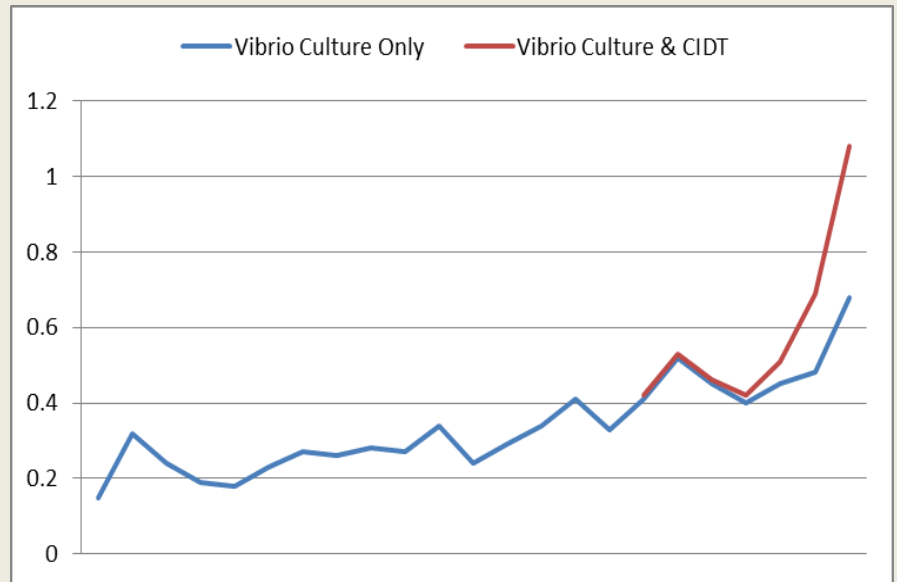
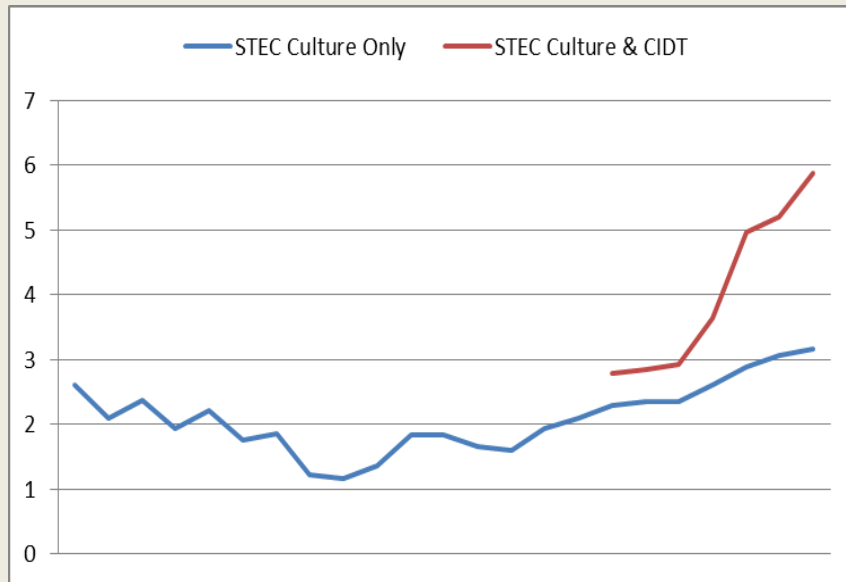
Incidence of Culture-Confirmed *Salmonella* and *Campylobacter* Infections, FoodNet, 1996-2018



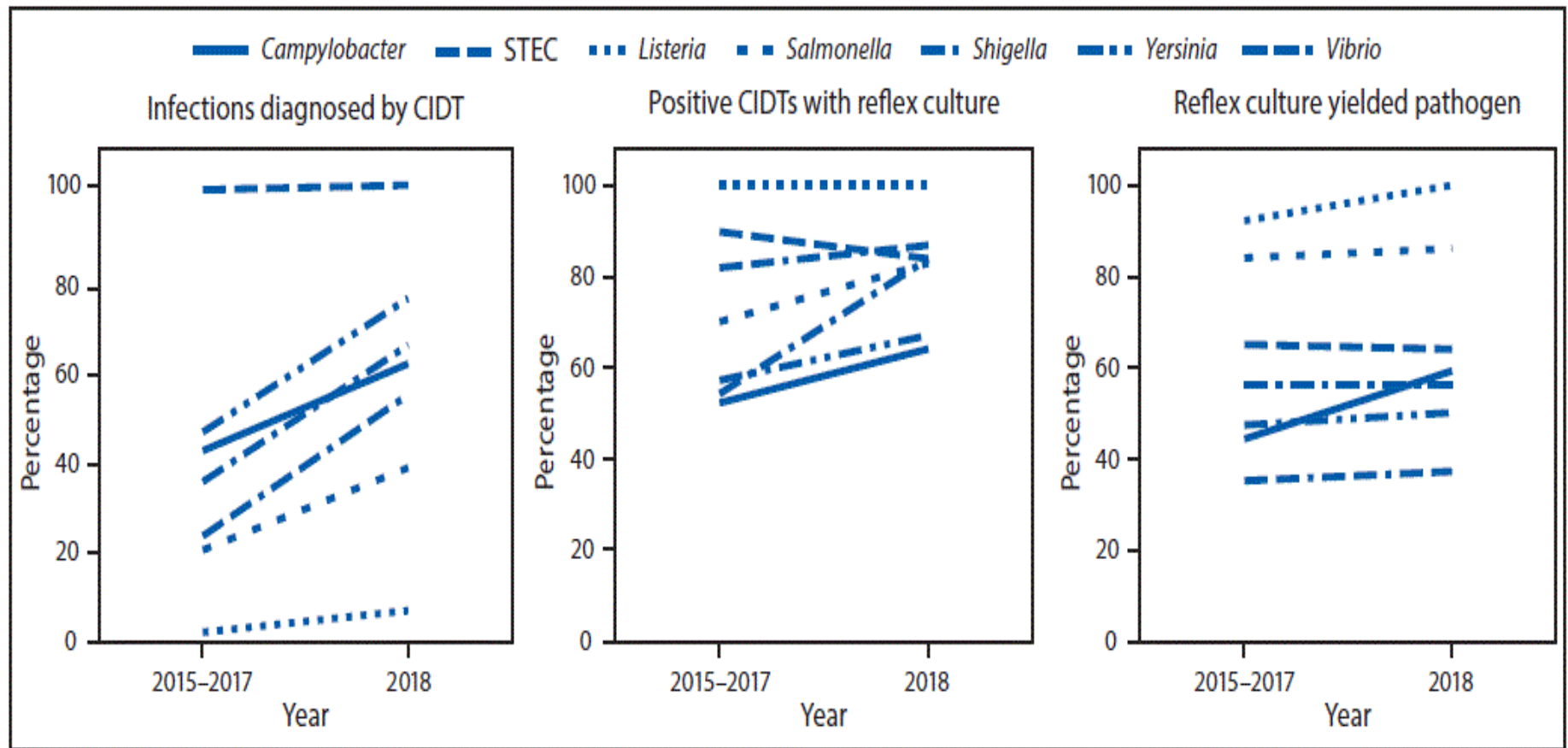
Impact of Culture-independent Diagnostic Tests, Campylobacter and Salmonella, FoodNet



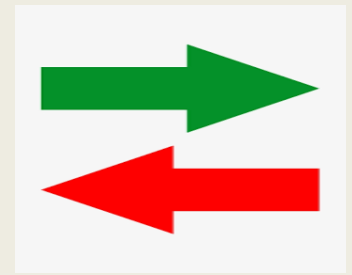
Impact of Culture-Independent Diagnostic Tests, Other Pathogens, FoodNet



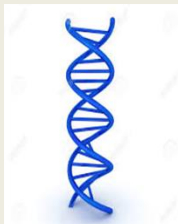
Percentage of infections diagnosed by culture-independent diagnostic tests (CIDTs), positive CIDTs with a reflex culture,* and reflex cultures that yielded the pathogen, by pathogen



Trends in Lab Practices & Impact on Foodborne Illness Data



- CIDs (single or multiplex) becoming the norm for diagnosing foodborne pathogens in clinical settings
 - Big impact on trend data
 - Including accuracy
 - Absent reflex cultures, loss of critical public health information
 - Antimicrobial susceptibility
 - Serotyping (*Salmonella* most impacted)
 - Molecular subtyping
- Whole genome sequencing (WGS) now also the norm for molecular analysis of human, animal and environmental isolates
 - Enhanced ability to identify outbreaks
 - Enhanced ability to identify resident pathogens
 - Enhanced ability for attribution
 - *Need for information sharing of WGS data between clinical, public health, regulators & industry*



Foodborne Outbreaks in the U.S.

- 2018 was the year of produce (esp. leafy greens) outbreaks
 - 2 large *E. coli* O157:H7 outbreaks
 - Multiple *Cyclospora* outbreaks with domestic detection
 - ***No multistate dairy-related outbreaks reported to CDC***
- 2019 so far looks different
 - Ground beef - *E. coli* O103
 - Pre-cut melon – *Salmonella* Carrou
 - Frozen raw tuna – *Salmonella* Newport
 - Tahini – *Salmonella* Concord
 - Flour – *E. coli* O26
 - ***No multistate dairy-related outbreaks reported (so far)***

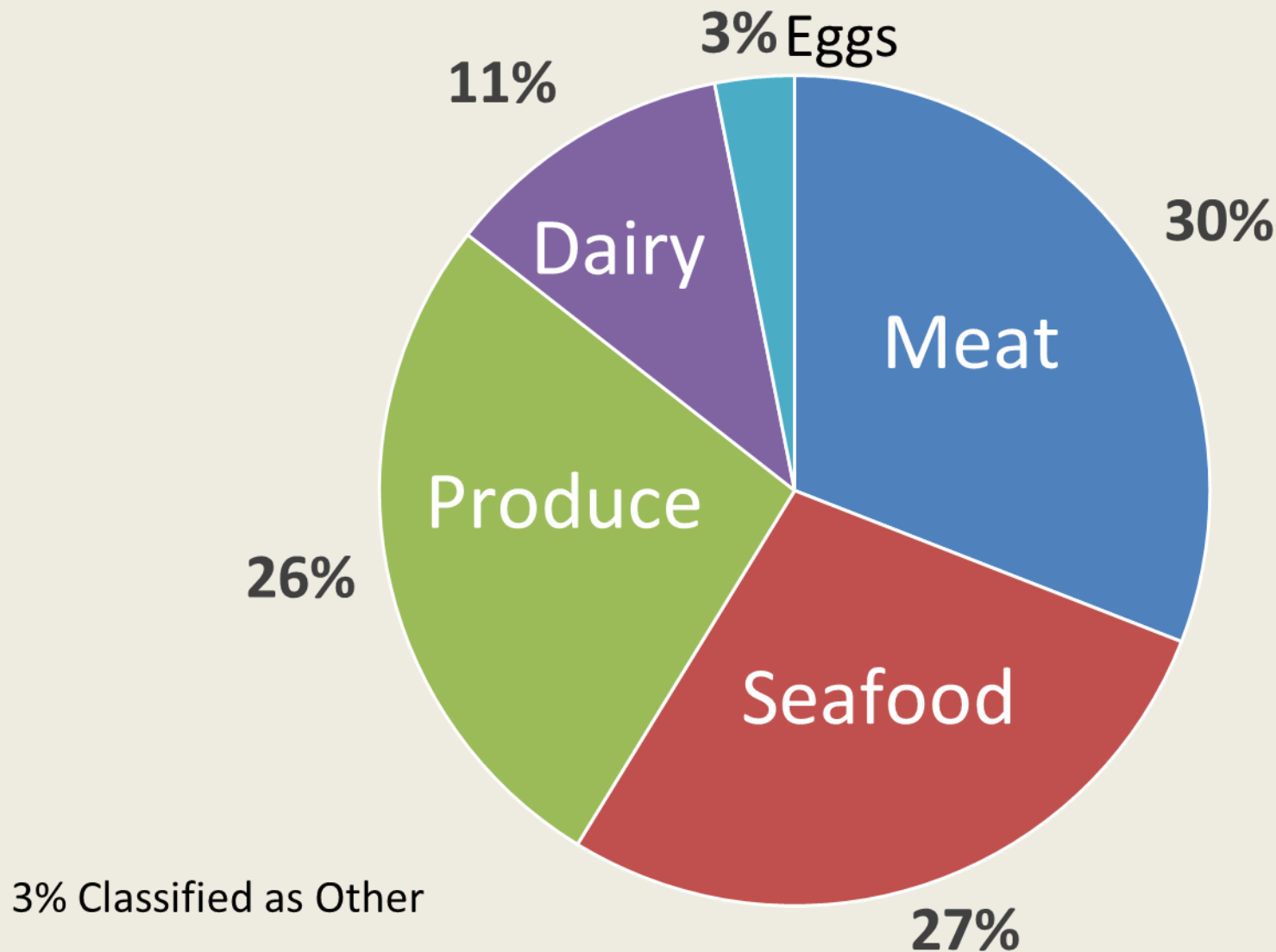
**Department of Health and Human Services
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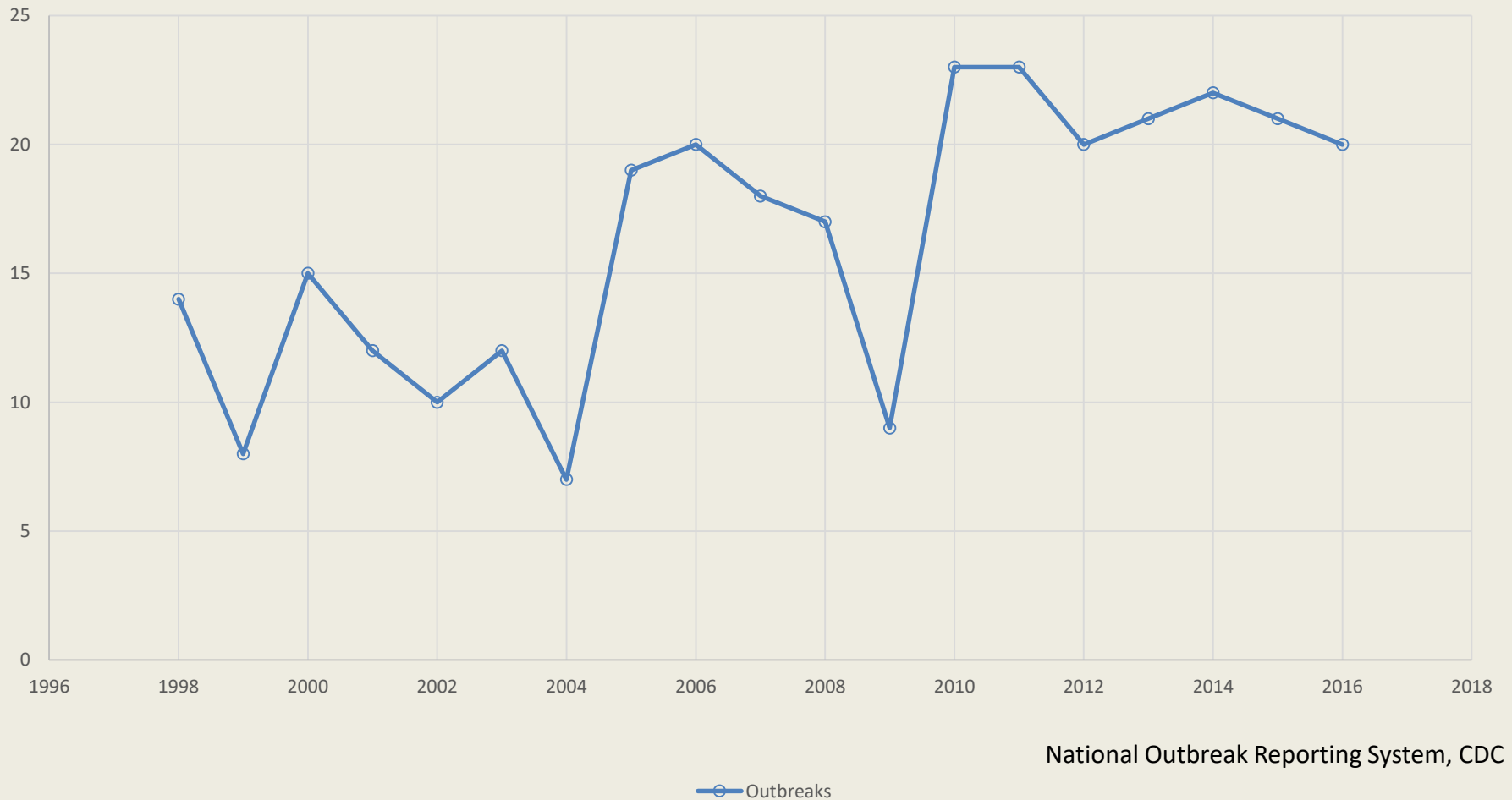
Surveillance for Foodborne Disease Outbreaks – United States, 2009-2015

CDC. MMWR July 27, 2018 Vol 67(10):SS1-11

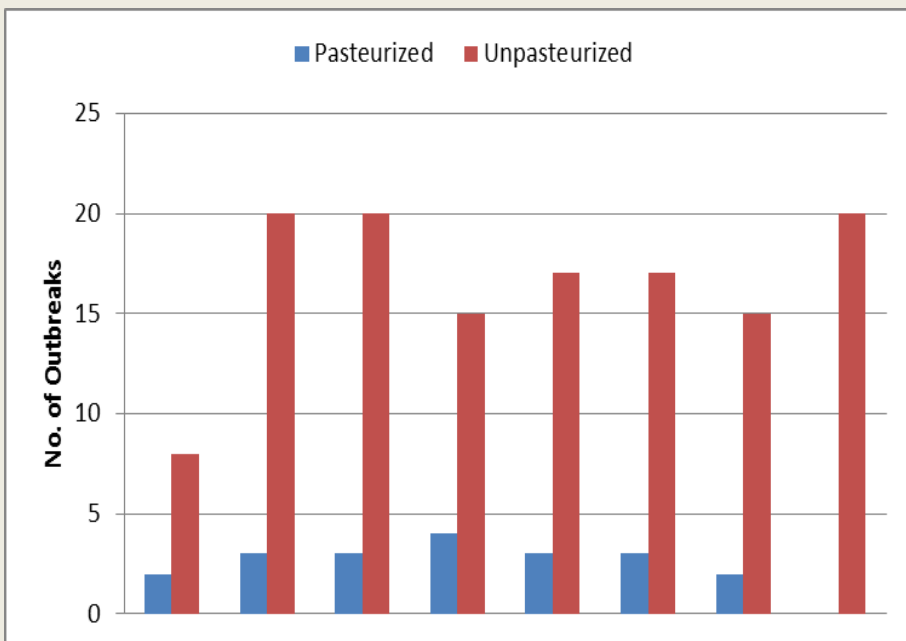
Foodborne Outbreaks Attributed to a Single Commodity Category



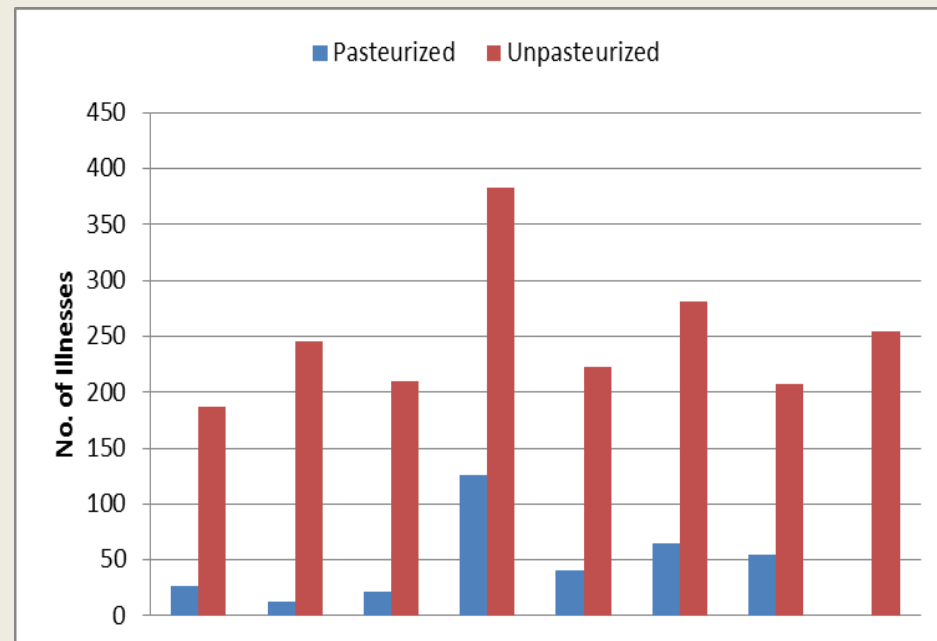
Dairy Outbreaks by Year 1998-2016



Outbreaks – Pasteurized vs. Unpasteurized 2009-2016



2009 2010 2011 2012 2013 2014 2015 2016



2009 2010 2011 2012 2013 2014 2015 2016

**Of 159 outbreaks, 82% due to raw dairy products
(72% due to raw milk)**

**Of 1,991 illnesses, 83% due to raw dairy products
(67% due to raw milk)**

Pot O Gold raw milk linked to Salmonella outbreak in Pennsylvania

October 15, 2018

Deadly Disease Caused by Raw Milk Has Already Put 19 US States on High Alert

February 18, 2019



E. coli in raw milk nearly kills 2 Tennessee children

June 18, 2018

More ill in Listeria, E. coli outbreaks linked to raw milk cheese in France

May 31, 2019



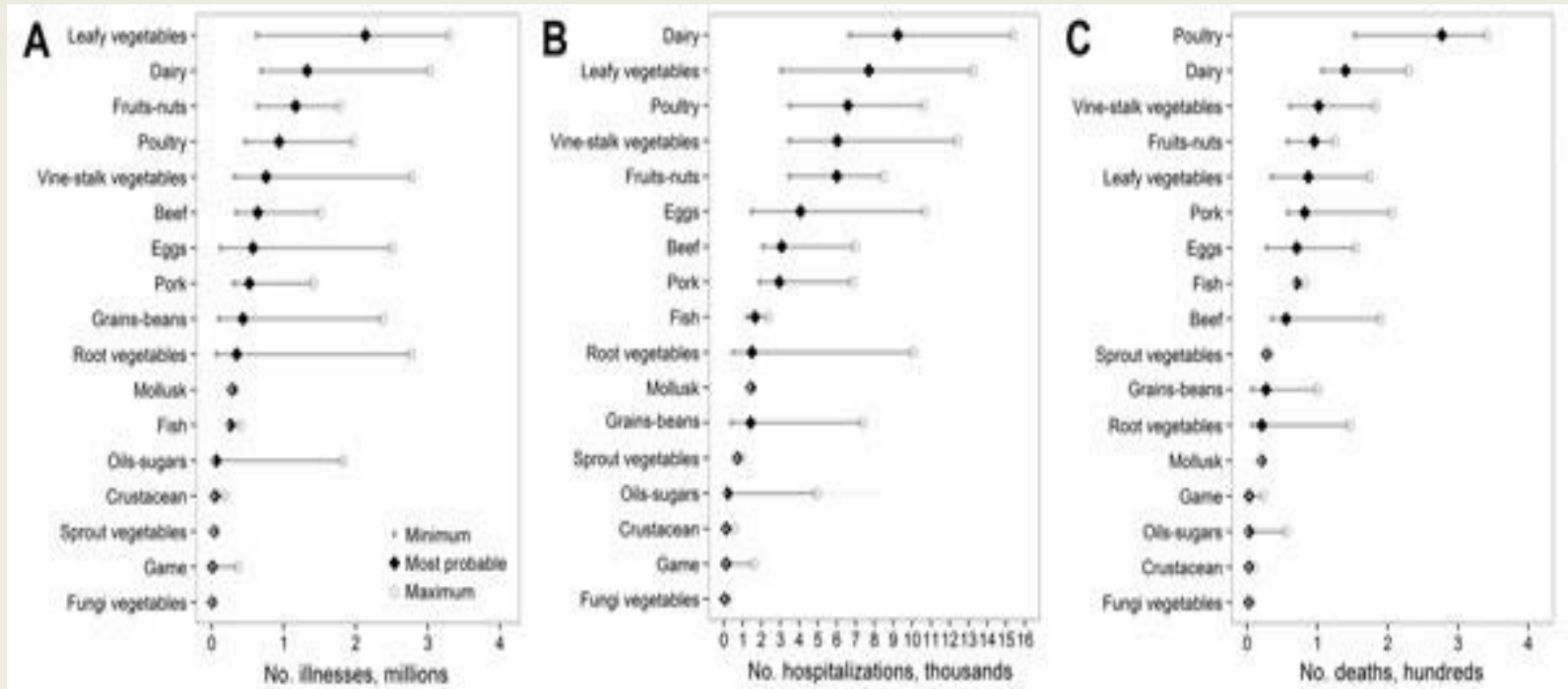
Velvet Ice Cream Company warned for Listeria in production facility

By [Kelsey M. Mackin](#) on May 29, 2019

Velvet Ice Cream Company Inc.'s ice cream manufacturing facility in Utica, OH, was inspected by the FDA from Jan. 23 to Feb. 14 and the results were not good. Lab tests showed the plant was harboring the pathogen *Listeria monocytogenes*.



Attribution of Foodborne Illness, Hospitalizations and Deaths by Food Commodities Using Outbreak Data, United States, 1998-2008



Painter JA, et al. Emerg Infect Dis 2013;19(3):407-15.

Outbreak Attribution Data & FSMA Metrics

- FDA committed to producing metrics to monitor impact/success of regulations
- Preventive controls metrics to be issued first
- Combination of process and outcome measures
- CDC involved in outcome measure methodology, data collection & analysis
 - Refined outbreak attribution methodology
 - For commodities covered by rules

FDA Food Safety Activities in 2019

- Food Safety Modernization Act:
 - Lab accreditation rule
 - Intentional adulteration rule
 - Traceability rule
- Listeria
 - Ready-to-eat/not ready-to-eat guidance
 - Compliance policy guide
- Smarter Food Safety

***“Every once in a while, a new technology,
an old problem, and a new idea turn
into an innovation.”***

- Dean Kamen



Smarter Food Safety

- Modern technologies for traceability
 - Need for tracing that is:
 - Rapid, reliable & reproducible (the 3 Rs)
 - End-to-end across the supply chain
 - Affordable
 - Can FSMA tracing requirements achieve these goals?
 - Written prior to current technologies
 - Restricted to designated “high risk” commodities
- Data analytics/artificial intelligence
 - Initial focus on improved oversight of food imports
- Evolving modes of food delivery
 - e.g. e-commerce



Public meeting planned on the strategy

“Ideas are like rabbits. You get a couple and learn how to handle them, and pretty soon you have a dozen.”

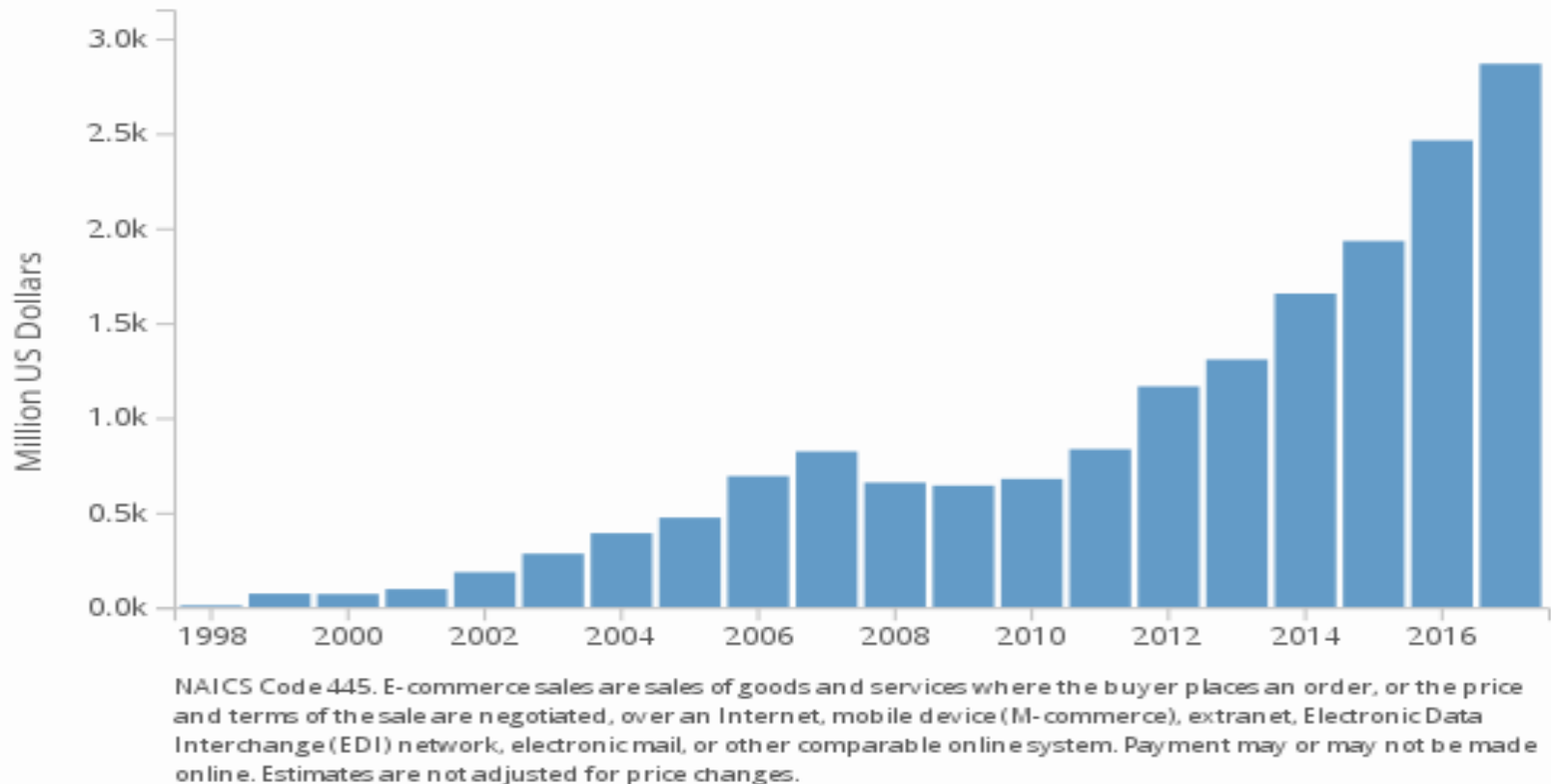
- John Steinbeck



New Modes of Food Delivery



Food and Beverage Stores E-commerce Sales in the US



Source: U.S. Census Bureau

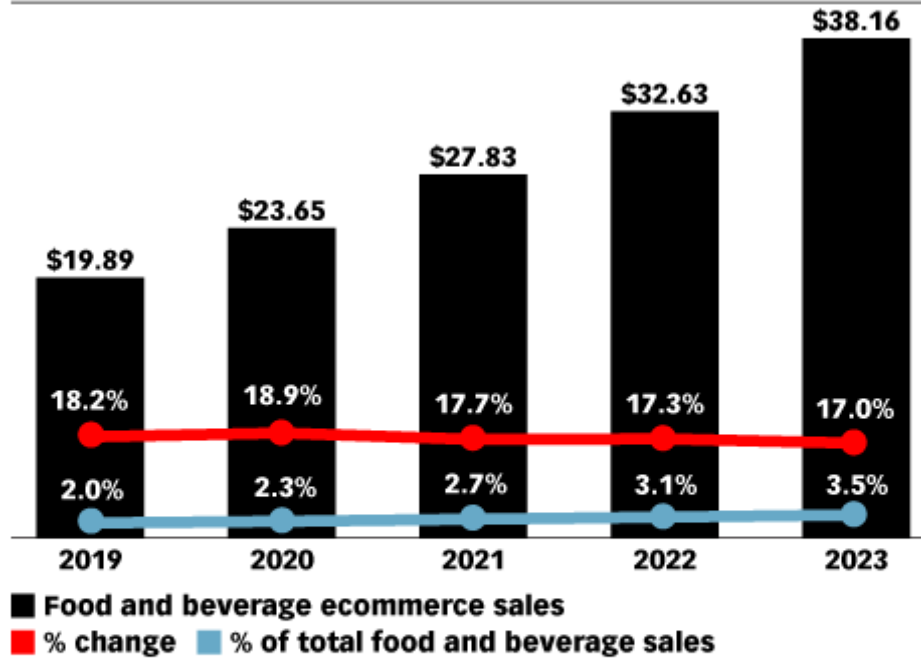
ReportLinker

By 2017, 33% of American consumers regularly order food delivery on-line.

<https://totalfood.com/how-e-commerce-transforming-food-industry/>

US Food and Beverage Ecommerce Sales, 2019-2023

billions, % change and % of total food and beverage sales

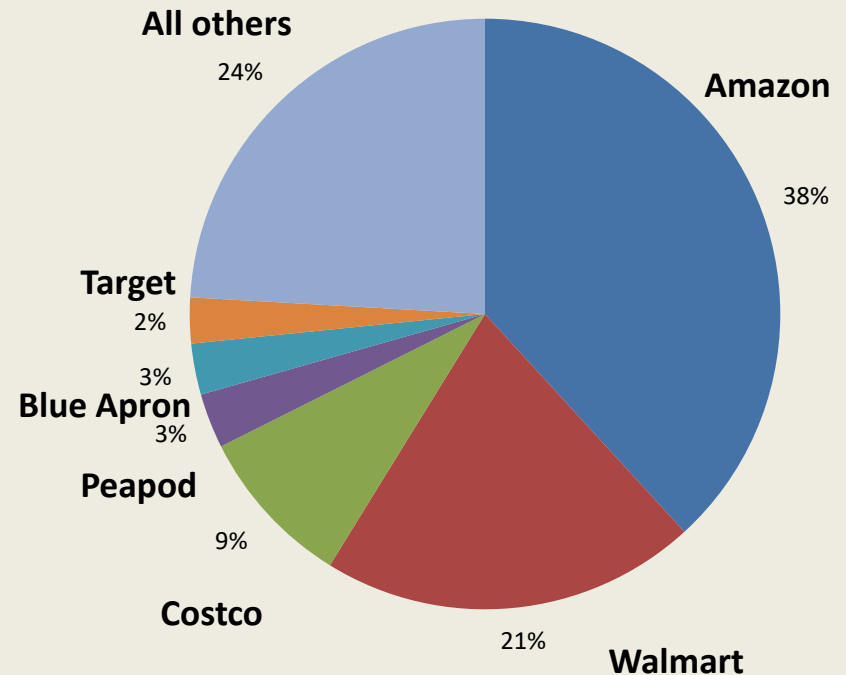


Note: includes products or services ordered using the internet via any device, regardless of the method of payment or fulfillment; includes packaged foods, fresh foods and beverages; eMarketer benchmarks its retail and retail ecommerce sales figures against US Department of Commerce data, for which the last full year measured was 2017
 Source: eMarketer, March 2019

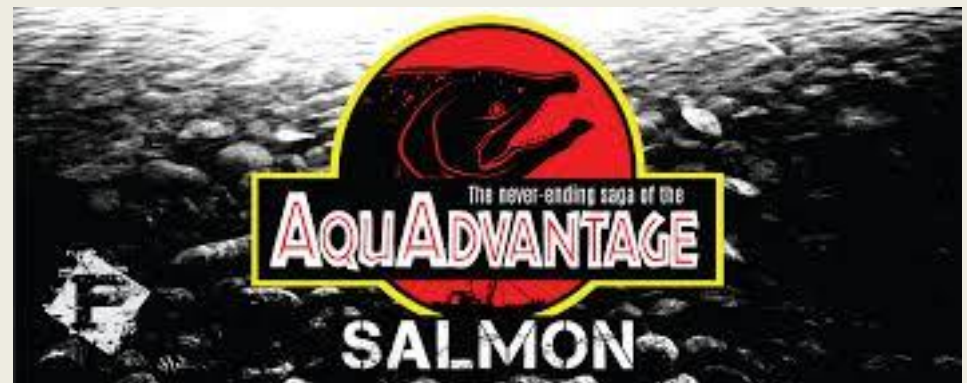
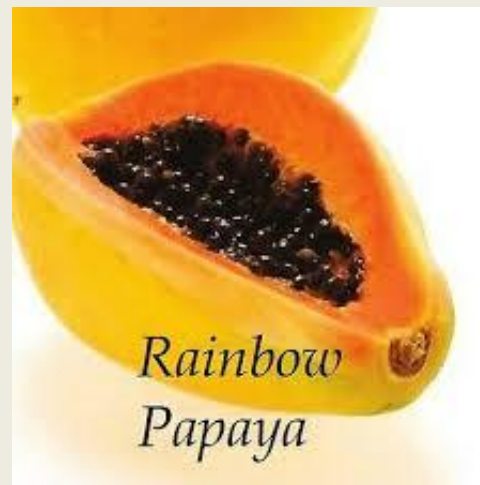
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www.eMarketer.com

Percentage of E-commerce Food Market, 2017



Bioengineered Foods



Bioengineered Foods

- USDA Bioengineered Food Disclosure regulation (Dec 2018)
 - Initial voluntary compliance date Jan 1, 2020
 - Mandatory compliance date Jan 1, 2022



- FDA final voluntary labeling guidance (Mar 2019)

Synthetic Foods - Plant Based



CNBC (5/29) – Impossible Whopper boosts Burger King traffic by 18%





Changing Consumer Demand

U.S. dairy alternatives market size, by product, 2014 - 2025 (USD Billion)

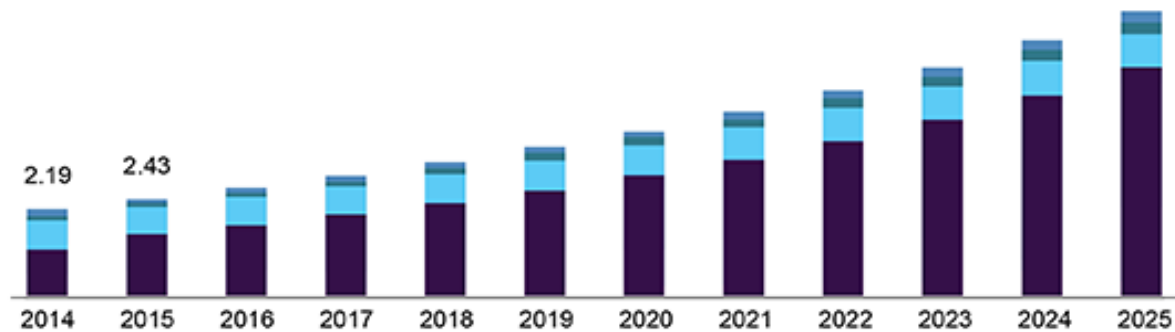
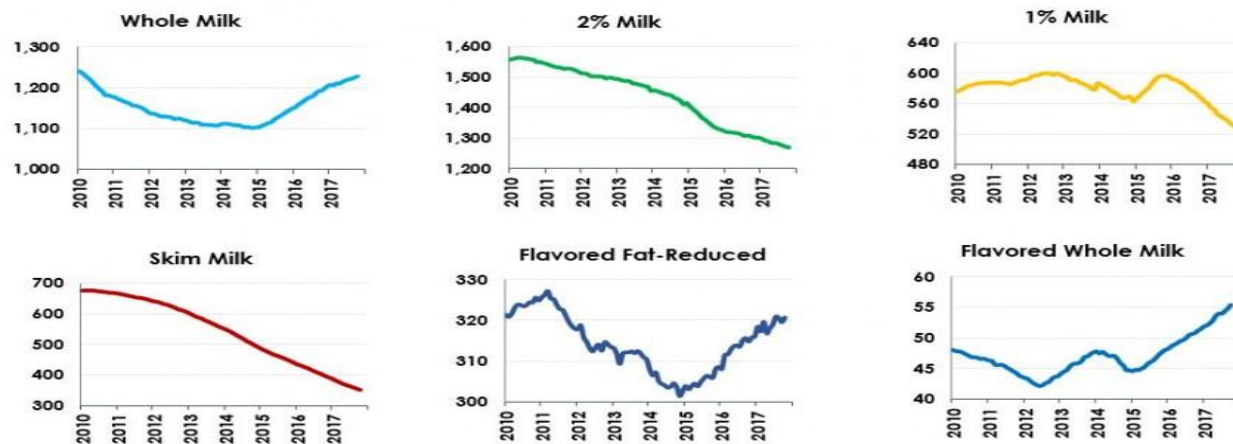


Figure 2. Conventional Fluid Milk Product Sales in Million Pounds
12-Month Moving Average



Synthetic Foods – Lab Grown

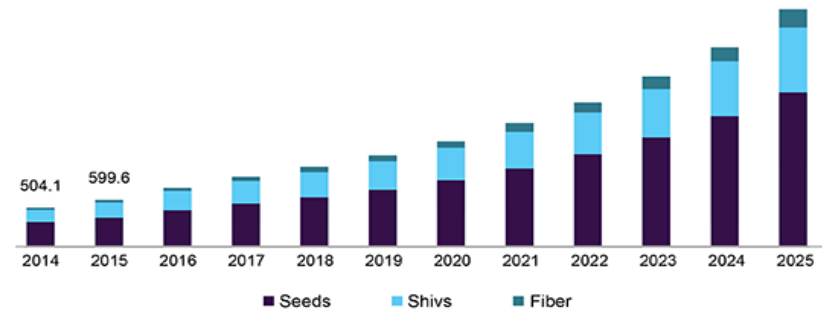


**NEW AGE
MEATS**

Hempseed, Industrial Hemp, CBD & Farm Bill



U.S. industrial hemp market size, by product, 2014 - 2025 (USD Million)



CSP May 23, 2019
Sheetz Launches
CBD Line

Forbes Sept 27, 2018
Coca-Cola Dipping Into the
Cannabis Infused Drink
Market

CBD

- 2018 Farm Bill de-scheduled industrial hemp (<0.3% THC on a dry weight basis)
 - Did not remove FDA regulatory oversight
- May 31 Part 15 hearing
 - 140 speakers
 - Support for CBD in food supply
 - Concerns
 - Extraction and manufacturing process
 - Quality and quantity
 - Presence of contaminants (e.g. lead)
 - Presence of synthetic CBD
 - Potential for drug interactions and adverse events
- FDA to review information and identify next steps
- Advise

Synthetic Foods

- Food safety considerations
- Sustainable/environmentally friendly
- Humane
- Labeling (nomenclature)
- Claims
 - Healthier
 - Pathogen-free
 - Antimicrobial use
 - Toxins (mercury)
 - For CBD products – drug claims

Plant-based Dairy Substitutes

- Complex issue from regulatory and industry perspective
 - Standard of truthful and not misleading
 - Standard of identity for dairy products & naming
- Sept 2018 – Jan 2019 – Req. for Information (RFI)
 - How and why consumers use these products
 - Consumer understanding of these products
 - Basic nature, characteristics, ingredients, nutritional content
- Information on adverse nutritional health consequences
- Use feedback as basis for identifying pathway forward
- In meantime, continue to seek and submit examples of deceptive or untruthful labeling.

Lab Grown Products

- Also complex regulatory and labeling issues
- Added challenge of USDA amenable products
- Non-amenable products entirely overseen by FDA
- Last year's public meetings led to March agreement between USDA & FDA on regulatory oversight for livestock and poultry



Cell collection, banking,
growth & differentiation

Harvest

Food manufacture,
labeling



FDA

USDA

Innovation in the Food Supply

- There's lots of innovation going on in the food supply
- Challenges between innovation and traditional products
- Difficult for regulatory system to keep pace
- Political dimension
- Inevitably the marketplace will decide as long as consumers can make informed decisions

Other dairy issues

- Natural cheese
- Microfiltered milk
- PFOS
- Export certificates
- Standards of identity
 - In particular, yogurt standard

2020 Budget

- In late May, House Appropriations Ag Subcommittee markup of FDA budget
- Two significant increases:
 - \$17.5 million for veterinary food and feed
 - \$40.5 million for enhanced outbreak response and FSMA state-based inspection activities

**“When the winds of change blow,
some people build walls while
others build windmills.”**

- *Chinese Proverb*

