



Food Safety Going Forward: Focus on Technology & Transparency

Dairy Forum 2019

S Ostroff MD

Former Deputy Commissioner
US Food and Drug Administration



The Shutdown & FDA

- Continuing food activities
 - Outbreak response & emerging food safety risks (e.g. recalls)
 - Adverse event monitoring and evaluation (signal detection)
 - “Hi-risk” domestic food inspections
 - International and port-of-entry food inspections
- Performed by “excepted” (non-paid) personnel and commissioned officers



Front



Back

The Shutdown & FDA

- What's not happening:
 - “Lo-risk” domestic inspections
 - Guidance and reg work
 - Food additive/GRAS review
 - Nutrition-related work
 - Labeling and standards
 - Communications and consumer information
 - Meetings & stakeholder engagement
 - Research

Will inevitably lead to delays and missed deadlines in many areas.



Front



Back

*“Money talks.
And the only thing mine ever said was goodbye.”*

- Anonymous

*“The best minds are not in government.
If any were, business would steal them away.”*

- Ronald Reagan

The Shutdown & FDA

- Long term impacts
 - Financial & budgetary
 - Both FDA and food industry
 - Slowdowns in productivity and missed deadlines
 - Consumer confidence
 - International engagement
 - Employee morale
 - *Inevitable loss of talented & skilled personnel*
 - *Challenges recruiting and retaining needed talent*



Significant 2018 U.S. Produce Outbreaks

Romaine Lettuce (Yuma, AZ)-E. coli O157:H7:

- 210 cases, 96 hospitalizations and 5 deaths, in 36 states.

Romaine Lettuce (California)-E. coli O157:H7:

- 62 cases, 25 hospitalizations in 16 states

McDonald's Fresh Express Salads-Cyclospora:

- Romaine lettuce & carrots
- 511 cases, 24 hospitalizations, in 16 states.

Pre-cut Melons-Salmonella Adelaide:

- Cantaloupe & watermelon
- 77 cases, 36 hospitalizations, in 9 states.

Del Monte Veggie Trays-Cyclospora:

- Broccoli, carrots, cauliflower
- 250 cases, 8 hospitalizations, in 4 states.



U.S. lettuce industry, wary of E. coli, wants FDA back on the job

By Joel Achenbach
January 15

“.....these are anxious times for the leafy greens industry, and the partial federal government shutdown and furloughing of many Food and Drug Administration officials has deepened the distress.”



Selected 2018 U.S. Non-Produce Outbreaks

Shell Eggs-Salmonella Braenderup:

- 45 cases, 11 hospitalizations, in 10 states
- Recall of 207 million eggs

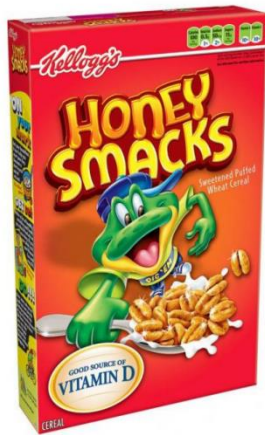


Shell Eggs-Salmonella Enteritidis:

- 14 cases, 2 hospitalizations, in 2 states

Kellogg's Honey Smacks Cereal-Salmonella Mbandaka:

- 130 cases, 34 hospitalizations, in 36 states



Hy-Vee Pasta Salad-Salmonella Sandiego

- 101 cases, 25 hospitalizations, in 10 states

Duncan Hines Cake Mix -Salmonella Agbeni

- 5 cases, 3 states



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



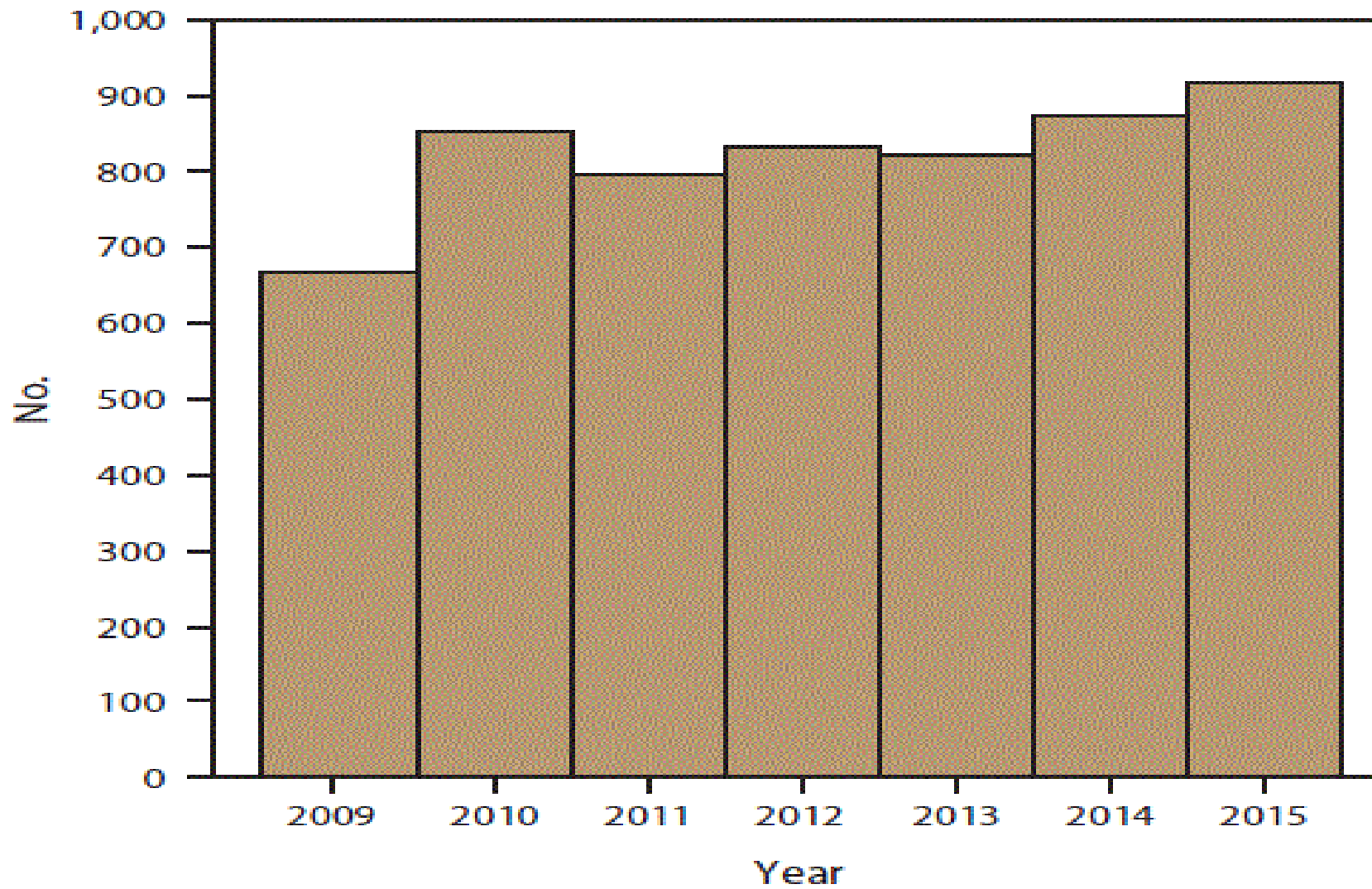
Surveillance for Foodborne Disease Outbreaks – United States, 2009-2015

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

U.S. Foodborne Disease Outbreaks 2009-2015

- Over 7 year period, CDC received reports of 5,760 outbreaks that caused:
 - 100,939 illnesses
 - 5,699 hospitalizations
 - 145 deaths
- Only 3% multi-state, but these resulted in 11% of illnesses, 34% of hospitalizations and 54% of deaths

Number of Foodborne Disease Outbreaks 2009-2015



Outbreaks

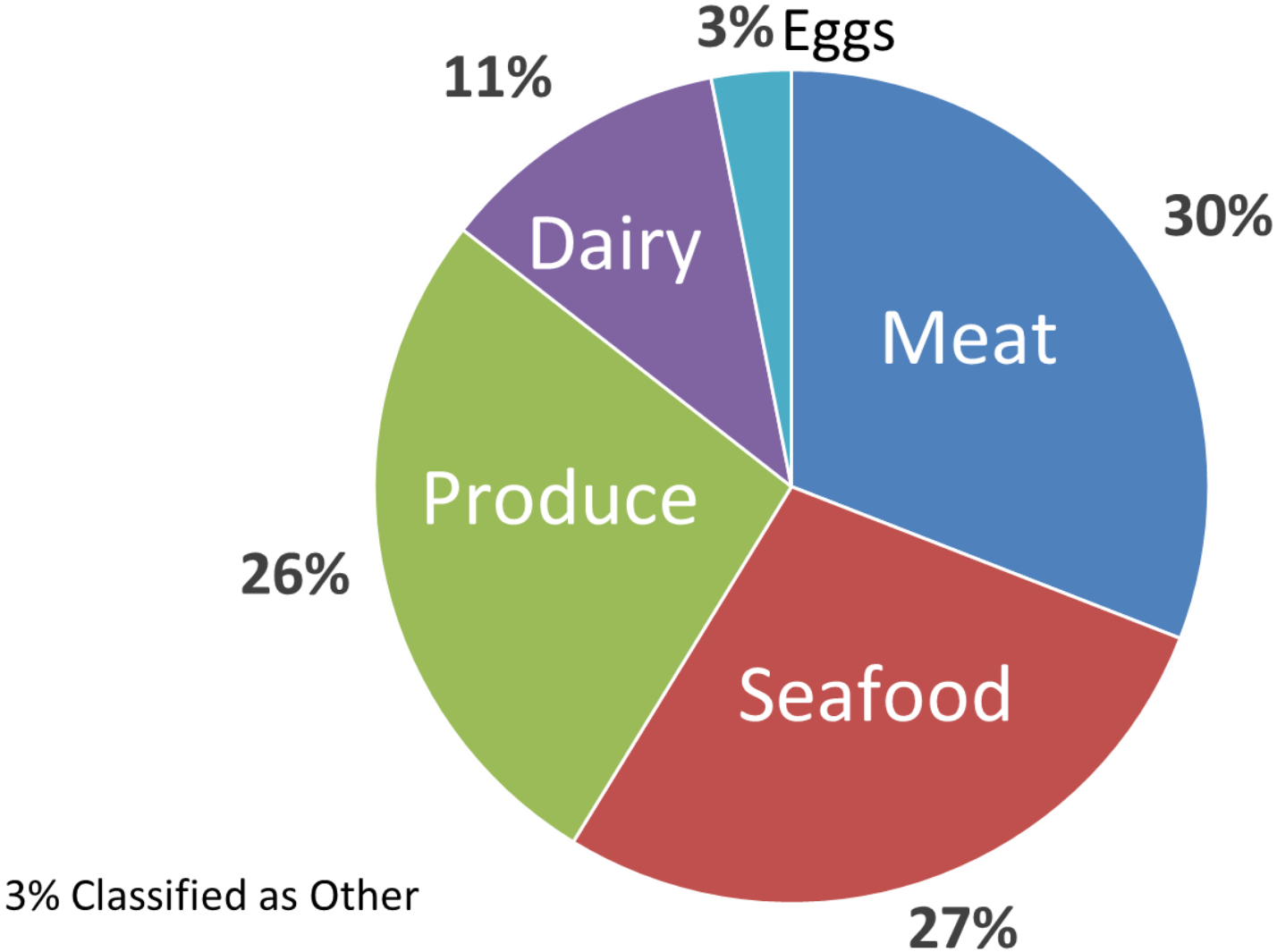
- Numbers increasing
 - Suggesting problem is getting worse
 - ***But is it?***
- During this period:
 - Technology has driven significant improvements in monitoring for foodborne illness
 - Electronic medical records/laboratory data
 - Improved and enhanced diagnostic assays
 - Esp. culture independent diagnostic tests
 - **Molecular fingerprinting**
 - **Esp. whole genome sequencing**

Whole Genome Sequencing

- Jan 2019, CDC transition from PFGE to WGS for major foodborne pathogens
- FDA has sequenced >200,000 food and environmental pathogens
- Both are distributed laboratory networks
- USDA also doing WGS
- Unified database curated by NIH/NCBI
- Powerful resource that will:
 - Inevitably identify more outbreaks faster
 - Enhanced ability for likely attribution
- ***This is the new normal for outbreak detection and molecular epidemiology!!!***

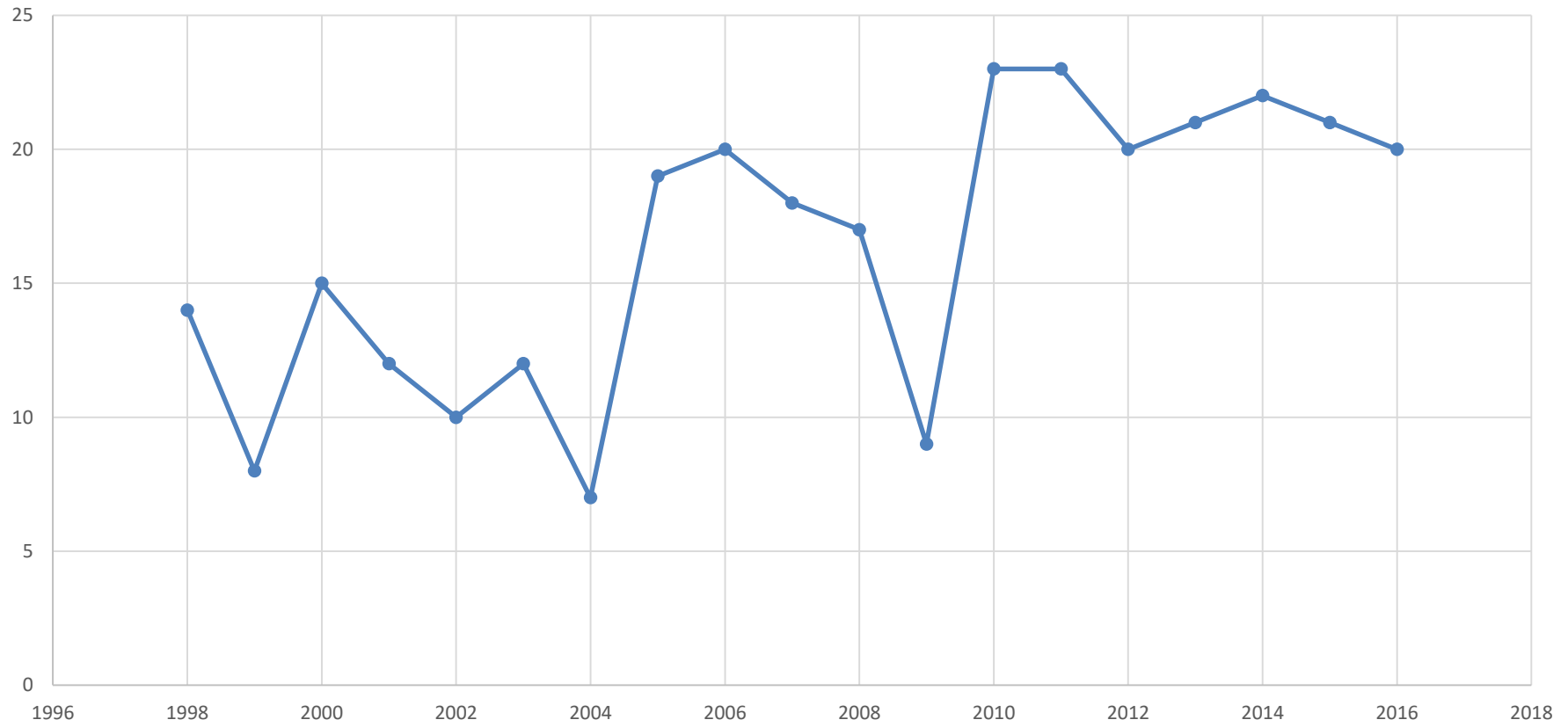


Foodborne Outbreaks Attributed to a Single Commodity Category



Dairy Outbreaks by Year

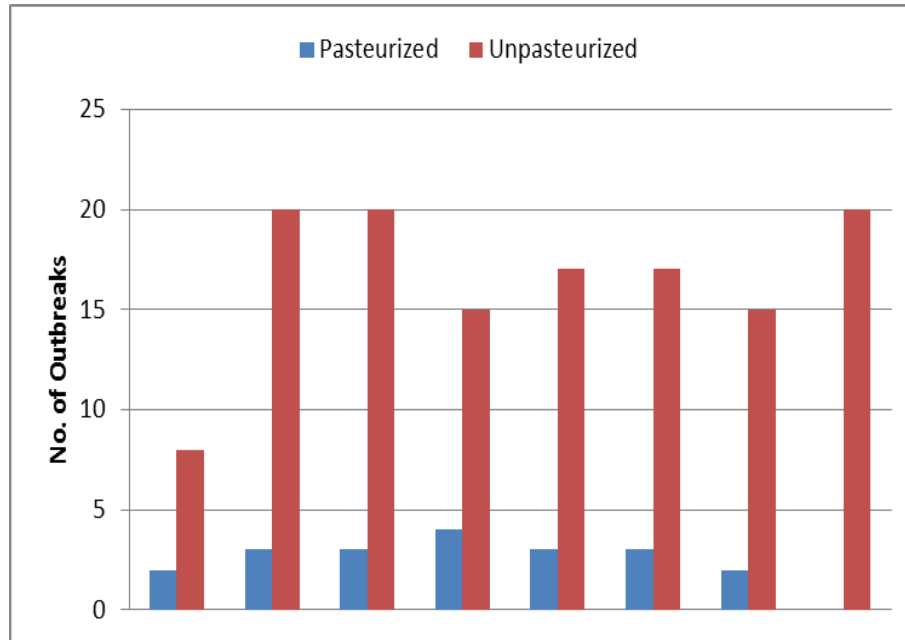
1998-2016



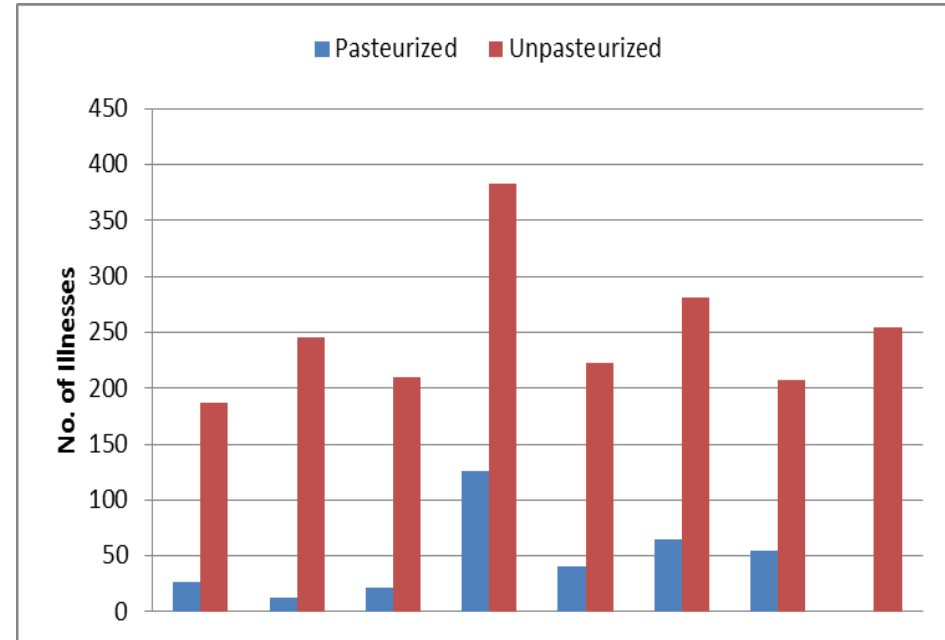
—●— Outbreaks

National Outbreak Reporting System, CDC

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)**

Relevant FDA Food Safety Activities in 2019

- Food Safety Modernization Act:
 - Lab accreditation rule
 - Intentional adulteration rule
 - Compliance date July 2019
 - Part II & III of guidance
 - Traceability rule
- Recall-related retail disclosure
- Listeria
 - Ready-to-eat/not ready-to-eat
 - Compliance policy guide

Traceability

- Major impediment with recent produce outbreaks
 - Has been problem with other commodities
- 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

Traceability (cont'd)

- *Today's technology can achieve traceability needs of the food supply*
- **Examples:**



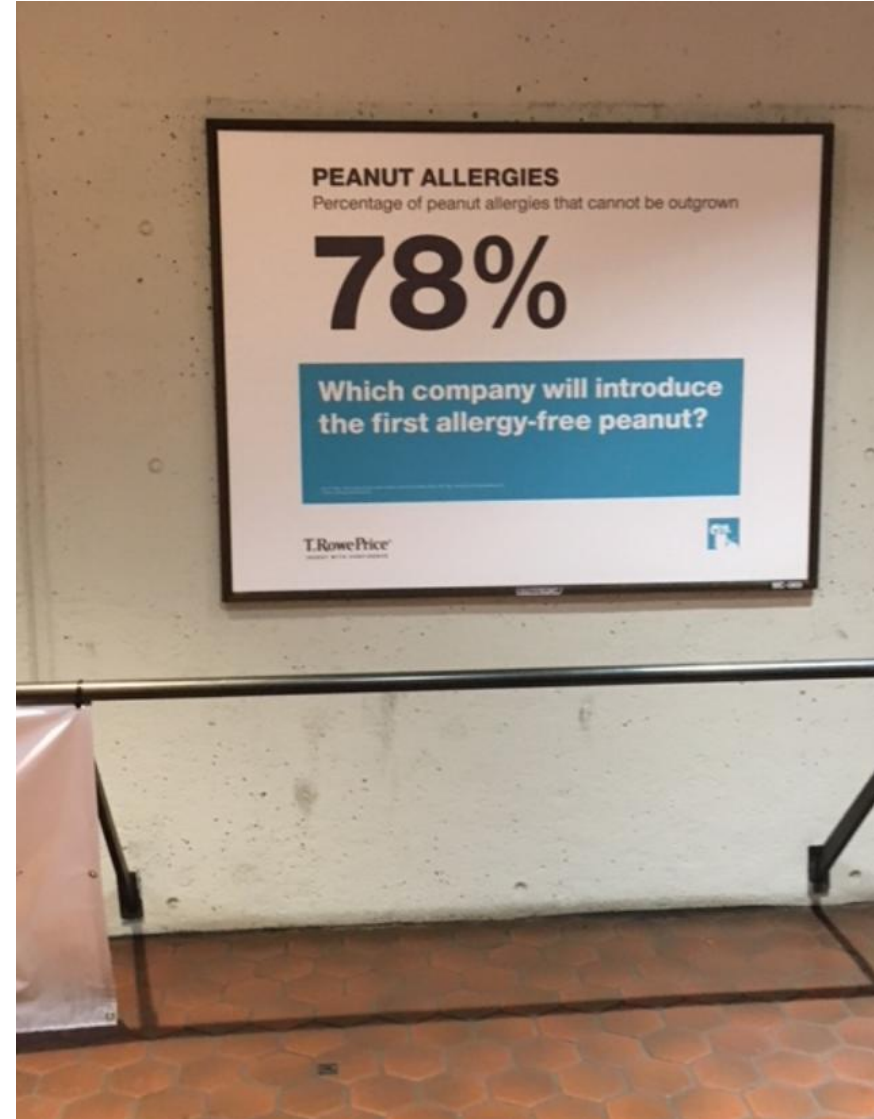
Immutable Ledgers



Edible Barcodes

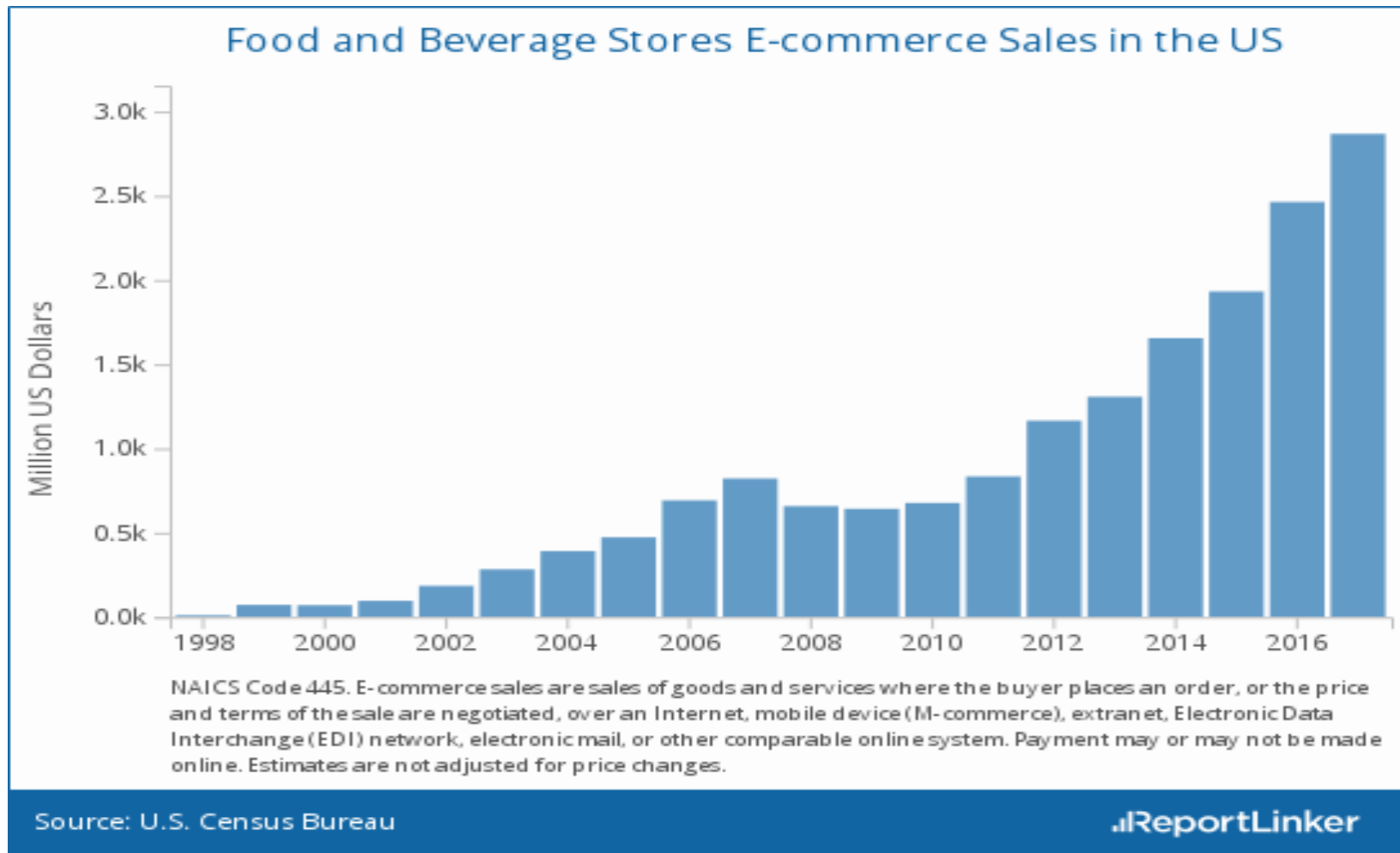
- **In addition to meeting traceability needs, addresses:**
 - **Economically motivated adulteration (food fraud)**
 - **Consumer transparency**

T Rowe Price Ads in DC's Metro Nov 2018



New Modes of Food Delivery

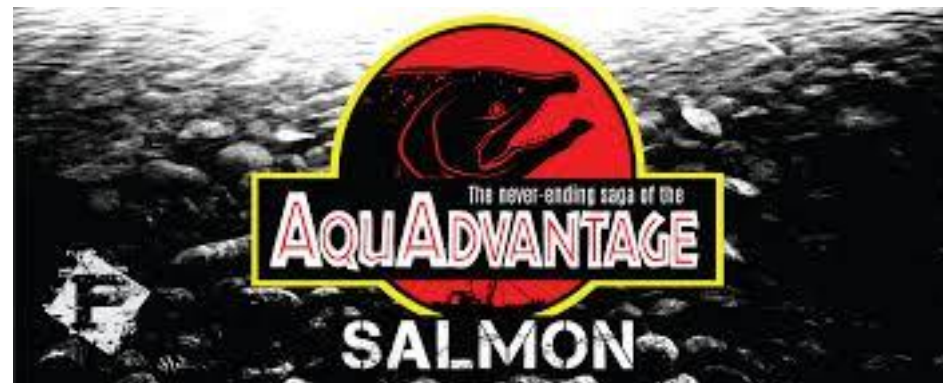




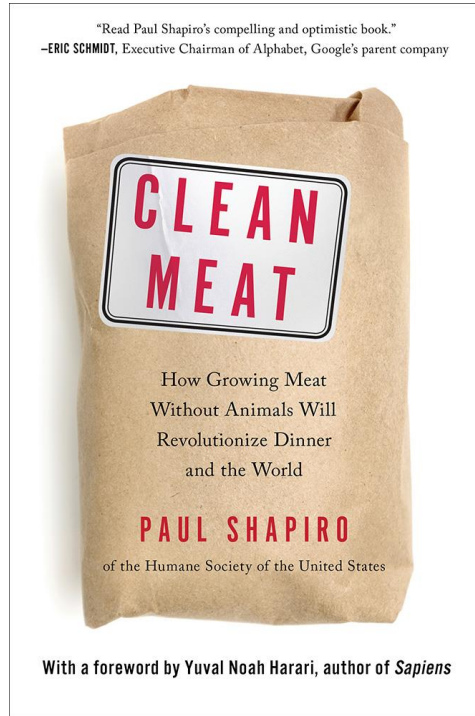
By 2017, 31% of American consumers likely purchase groceries on-line;
 33% of American consumers regularly ordered food delivery on-line.

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

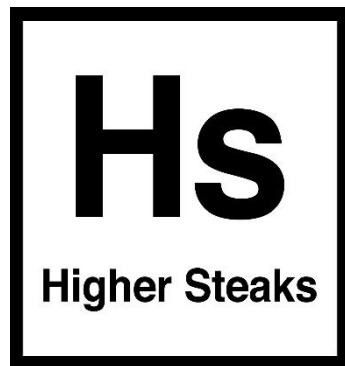
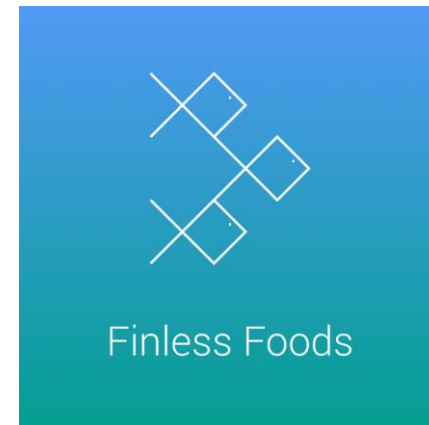
Bioengineered Foods



Synthetic Foods



MEMPHIS MEATS



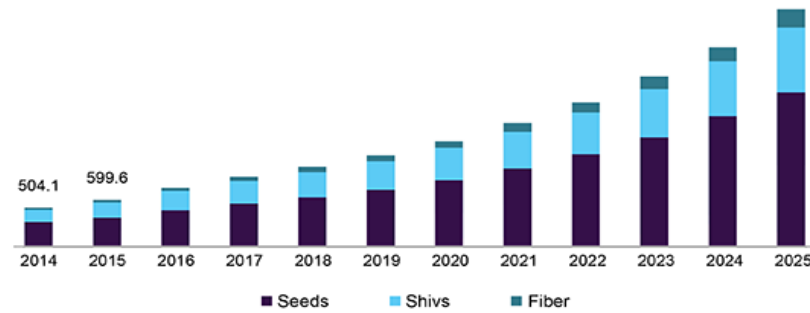
Synthetic Foods

- Food safety considerations
- “Sustainable”/environmentally friendly
- Humane
- Labeling (nomenclature)
- Claims
 - Pathogen-free
 - Antimicrobial use
 - Toxins (mercury)

Hempseed, Industrial Hemp, CBD & Farm Bill



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

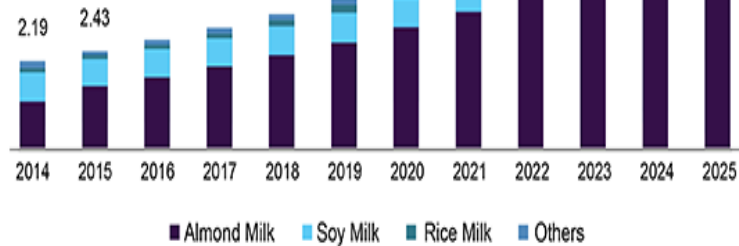


Forbes Sept 27, 2018
Coca-Cola Dipping Into the Cannabis Infused Drink Market



Changing Consumer Demand

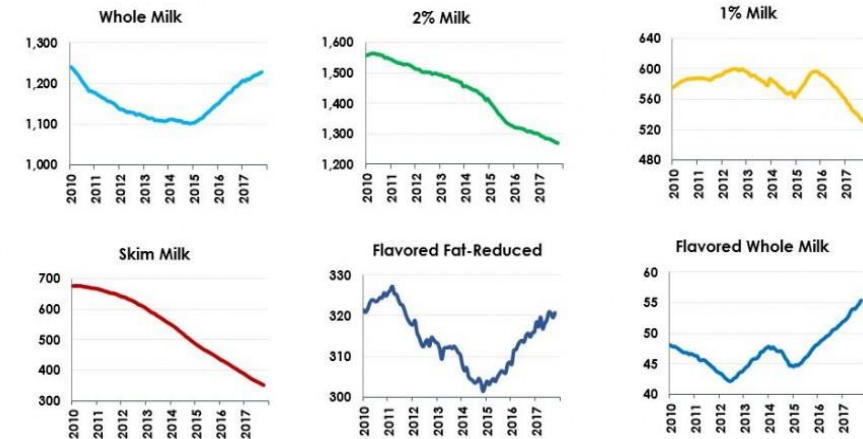
U.S. dairy alternatives market size, by product, 2014 - 2025 (USD Billion)



Source: www.grandviewresearch.com

Figure 2. Conventional Fluid Milk Product Sales in Million Pounds

12-Month Moving Average



Source: USDA AMS

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 – Issuance of 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
- Comment period extended to Jan 27, 2019

Nutrition Innovation Strategy

- Objectives
 - Empower consumers with information to make more informed choices
 - Incentivize innovation for products with more healthful attributes
- Continue work on NFL, menu labeling, sodium
- New work on standards of identity, ingredient listing, health claims

Nutrition Innovation Strategy

- Areas of interest to dairy industry
 - Standards of identity
 - Yogurt
 - Ultra- and micro-filtered milk
 - Natural cheese
 - Ingredient listing
 - Ultra- and micro-filtered
 - Nutrition facts label
 - Sodium reduction

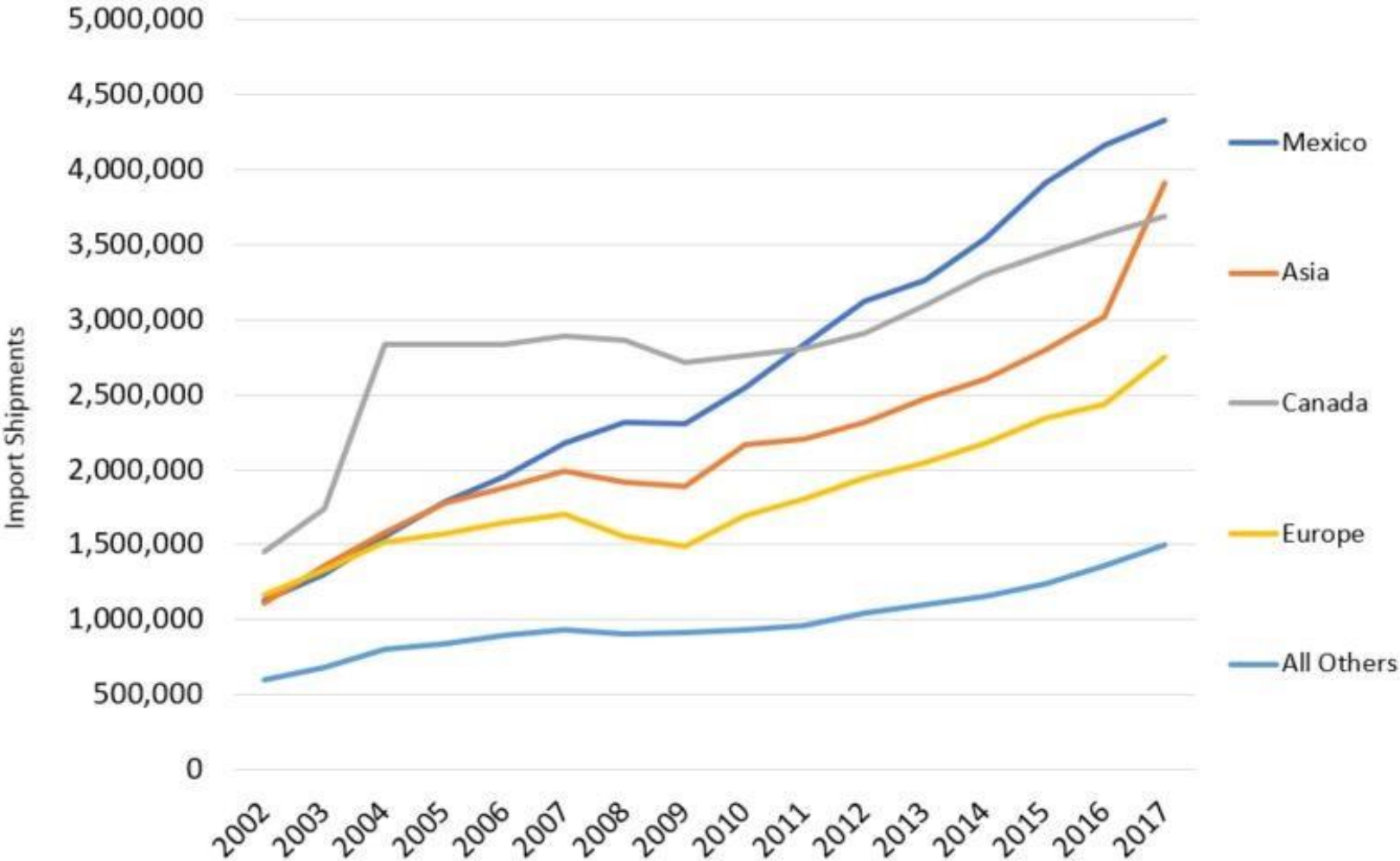


Foods Imported to the U.S.



- U.S. imports about 20 percent of its overall food supply
 - from >200 countries and territories
 - from approx. 125,000 food facilities and farms
- >16 million shipments of food into the U.S.
- 15-year trend of continuously rising import volume

Number of Imported Shipments of Human and Animal Foods, 2002-2017



FDA Import Safety Strategy



Goals of Import Strategy

- 1. Imports meets U.S. food safety requirements**
- 2. FDA border surveillance prevents entry of unsafe foods**
- 3. Rapid and effective response to unsafe imported food**
- 4. Effective and efficient food import program, including performance assessment and continuous improvement**

Goal 1: Imported Food Meets U.S. Food Safety Requirements

- **Optimize use of foreign inspections**
- **Encourage use of verified foreign suppliers**
- **Leverage reliable audits**
- **Leverage oversight efforts of regulatory counterparts**
- **Capacity building**

Goal 2: Border Surveillance

- **Enhance and refine FDA's import screening and entry review processes**
- **Conduct targeted physical examination and sampling**
- **Strategically apply import alerts and certifications**
- **Improve testing methodologies and tools**
- **Leverage state and other partnerships**

Other Issues

- FSMA Inspections
- Grade A/Non Grade A inspection pilot
- Surveillance sampling
- Export certificates
- FDA-USDA interactions
- FDA food program reorganization
- Others.....

“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