



Current Food Safety Landscape



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Overview

- Biggest challenges in food safety
- Approaches to assessing risks
- Approaches to managing risk
- Leveraging technology



Challenges

- Constant innovation
- Consumer demands
 - Low cost
 - Zero risk
 - Exciting flavors
- Economic pressures
- Continued growth
- Being familiar with the current challenges
- Brand protection

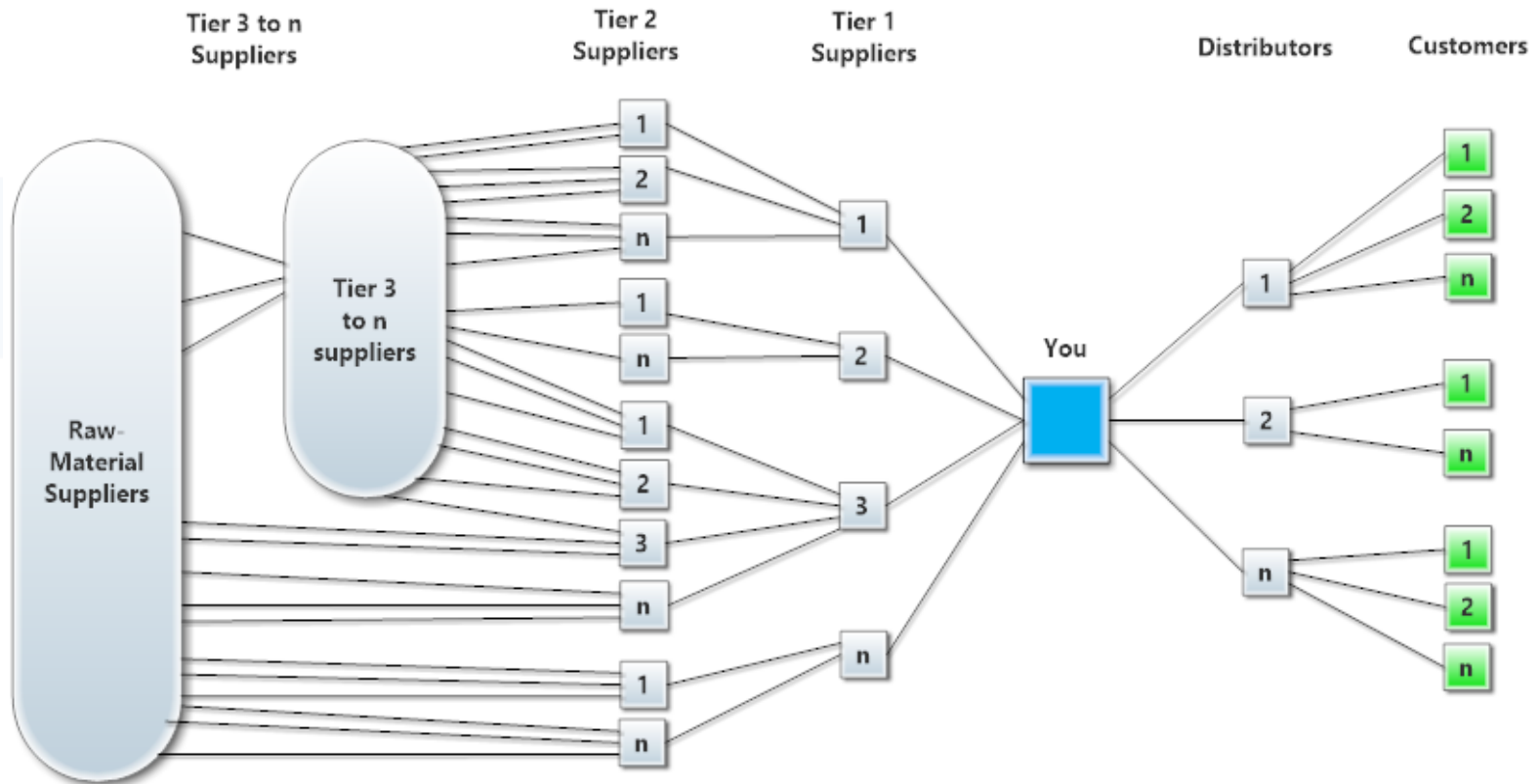


The Changing Food-Safety Landscape

- Complex supply chains
- Consumer demands
- Emerging threats
- Improving epidemiology
- Influence of media
- Litigation
- Regulatory changes
- Criminal prosecutions



Supply Chain Risks



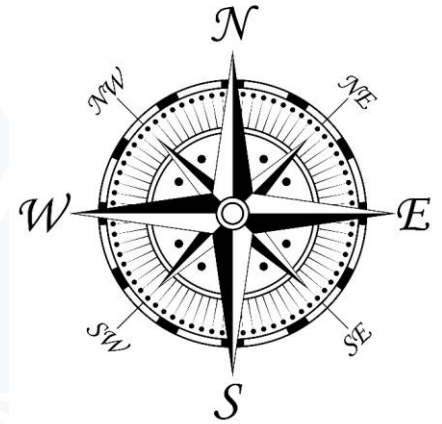
Key Questions

- Do you have adequate understanding of the risks
- Do you know who is really controlling the risk in your supply chain
- Are you able to track all the information you receive
 - Checking COAs
 - Reviewing third party audits
- Who is in charge of the supply chain



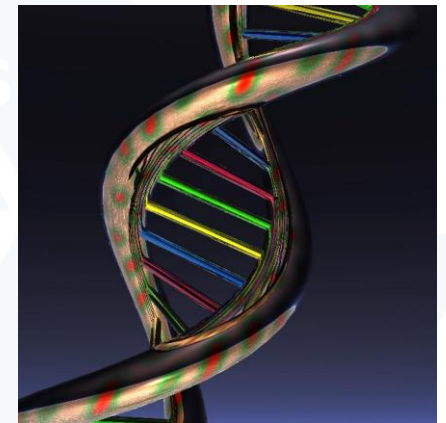
Changing Science of Food Safety

- Drug residues
- Chemicals
- Heavy metals
- New microbes being found
 - E. coli O104
 - E coli 0121
- Antibiotic resistance challenges
- Allergens



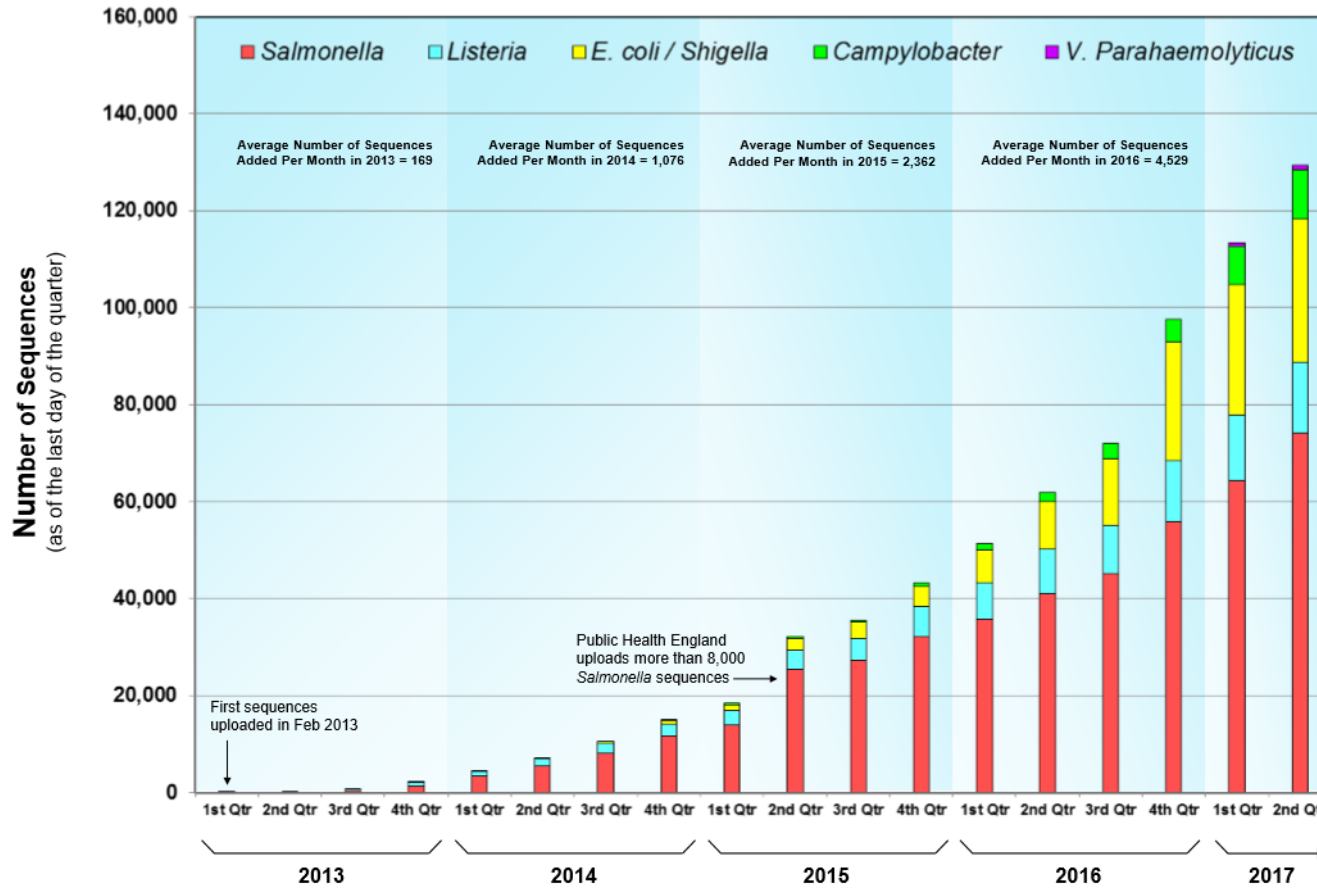
Changing Science of Food Safety

- New risks identified with foods
 - Peanut in flour/cumin
 - Is anything not RTE
- Greater capacity to link food with illness
- Ability to measure lower levels of chemicals
- Whole genome sequencing
- Linking specific isolates with illness



Whole Genome Sequencing

Total Number of Sequences in the GenomeTrakr Database



Whole Genome Sequencing

Labs Outside the U.S. Contributing to GenomeTrakr



WGS Scenario

- February 2016 - regulators find *Salmonella* in your facility in zone 3 during a routine visit.
- September 2017 - CDC uploads the *Salmonella* genome from a single human illness case
- The two isolates match
- What happens next



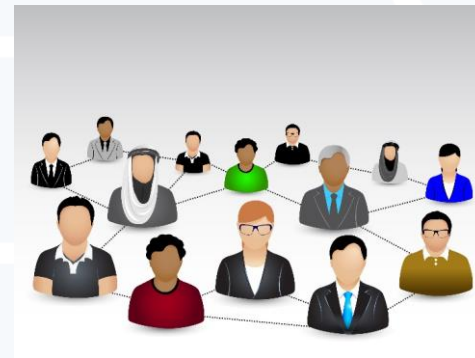
Consumers

- Consumer view of science
- Move toward clean labels
- Understanding risks
 - Preservatives vs no preservatives
- Thought leaders and “agitators”
- Demonization of processed food



Consumer Expectations and Media Influence

- Consumers expect all types of food will be available all the time
- Zero tolerance for unsafe food
- Consumers place responsibility for safe food on the producer
- Increased desire for local and unprocessed food
- Consumers ability to damage a brand
 - Main stream media
 - Social media



New Regulations

- Food Safety Modernization Act in the US
- New regulations in Canada
- Moving from reaction to prevention
- Focusing on corporate responsibility
- Greater consequences
- Holding companies accountable



Other Key Players

- Center for Disease Control
- State regulators
- Consumer organizations
- Congress
- Department of Justice



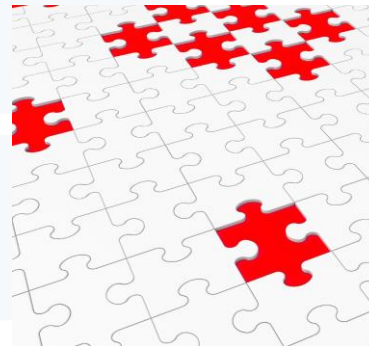
Litigation

- Let CDC do the work
- Going after the deep pockets
- Strict liability
- Doesn't matter where you are in the supply chain



Criminal Investigations

- Peanut Corporation of America - Salmonella
- ConAgra - Salmonella
- Jensen Farms – Listeria
- Iowa egg company - Salmonella
- Bluebell Ice-cream – Listeria
- Chipotle – Norovirus
- Dole – Listeria



High Risks

- Congress has made it a prohibited act to introduce adulterated food into interstate commerce
- This is a strict liability offense, meaning that a company or individual who violates the law and can face misdemeanor charges whether or not it intended to distribute adulterated food



Regulatory Procedures Manual



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Regulatory Procedures Manual

6-5 - PROSECUTION

–Misdemeanor prosecutions, particularly those against responsible corporate officials, can have a strong deterrent effect on the defendants and other regulated entities.....

<https://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074317.pdf>

How Are We Doing?

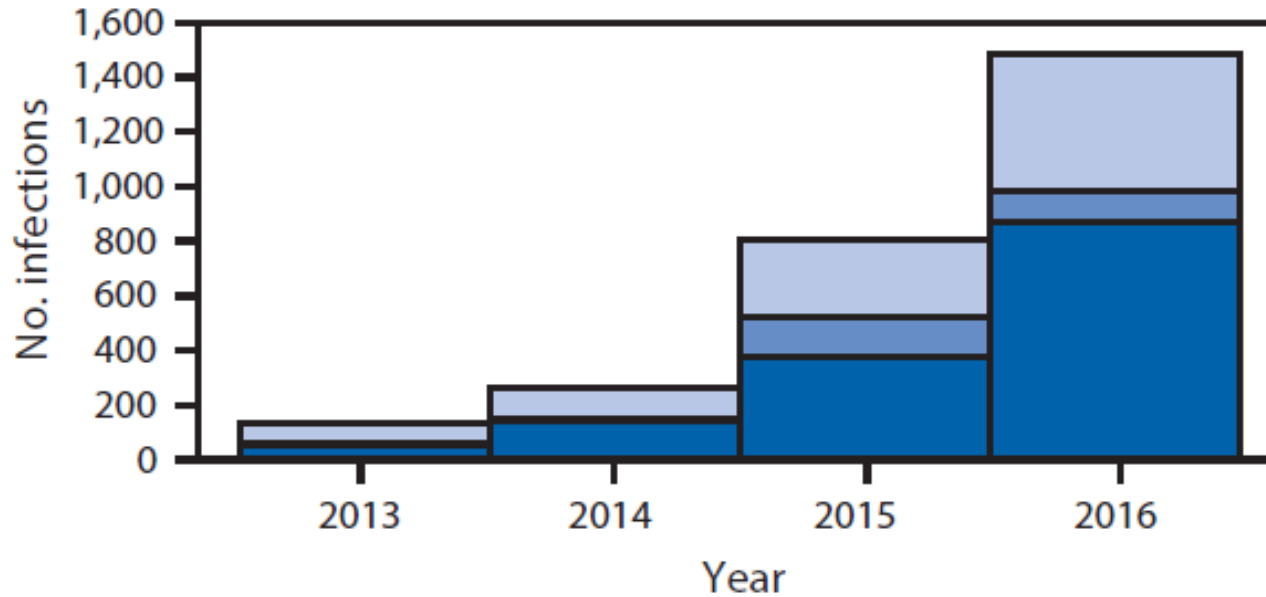
- Centers for Disease Control use FoodNet to track human foodborne illness
- First used in 1996
- Captures illness from nine important foodborne agents
- Tracks illness in approximately 45 million people in 10 states
- Annual report of trends
- Indications for regulatory focus and where the risks are



How Are We Doing?

- 2016 FoodNet data

Salmonella

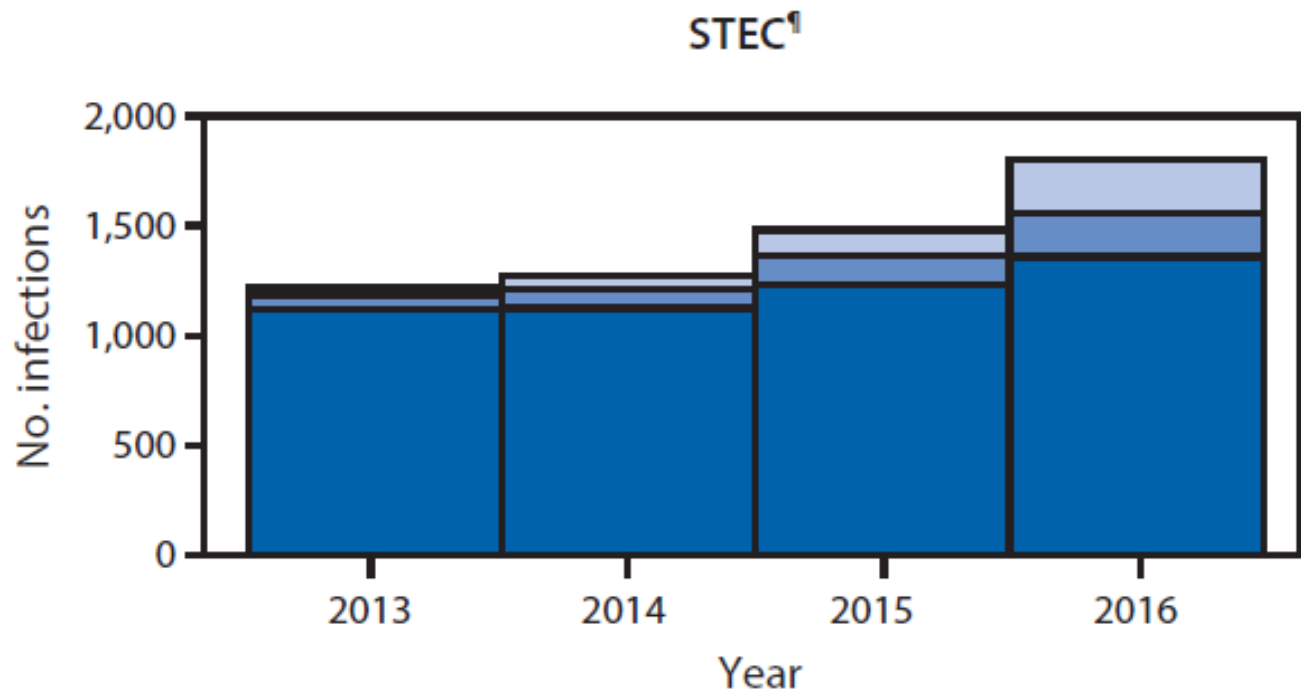


Morbidity and Mortality Weekly Report

April 21, 2017

How Are We Doing?

- 2016 FoodNet data



[Morbidity and Mortality Weekly Report](#)

April 21, 2017

How Are We Doing?

- 2016 FoodNet data – percent changes 2016 vs 2013-2015 averages

Pathogen	2016 IR [¶]	% Change ^{**}
<i>Campylobacter</i>	11.79	-11
<i>Listeria</i> ^{††}	0.26	+4
<i>Salmonella</i>	15.40	+2
<i>Shigella</i>	4.60	+7
STEC ^{¶¶}	2.84	+21
<i>Vibrio</i>	0.45	+2
<i>Yersinia</i>	0.42	+29
<i>Cryptosporidium</i>	3.70	+45

Major Causes of Trouble

- Supply chain failures
- Labeling mistakes
- Environmental contamination of ready to eat foods



Approach to Risk

- Assess risks
- Prioritize risks
- Manage risks



Continuous Improvement

Reactive

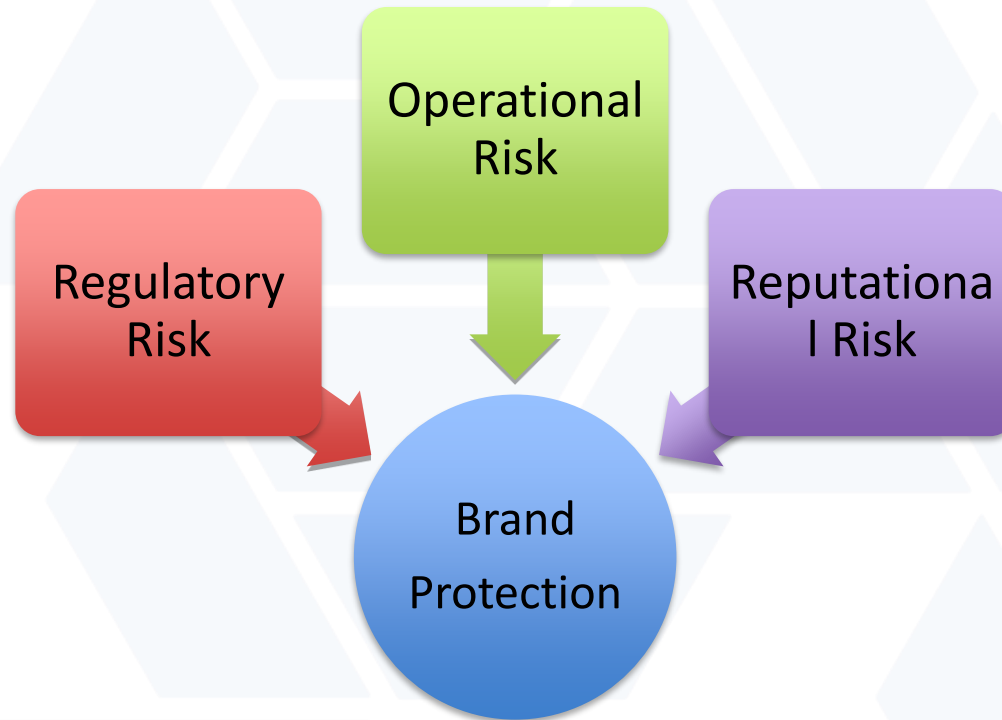
Preventive

Approach to Managing Risks

- Limited resources, so need to identify top priority risks
- Not all risks are the same
- Some risks are tolerable
- Some risks need to be managed aggressively
- How to approach risk
 - Assess the risk
 - Manage the risk



Risk Management Approach



Supply Chain Risk

- How do you determine risk in your supply chain?
- Not all suppliers are equal risk
- How do you differentiate?
- Focus resources on the areas of greatest risk
- Multiple factors impact risk



Managing Risks

Ingredient risk

- Hazard analysis
- History

Supplier risk

- On site information
- Document review
- History

Your use of the ingredient

- Processing
- Volumes
- Exposure

Manage
Supply
Chain
Risk

New Products/New Suppliers

- Work as a team
 - Product development/ R and D
 - Food Safety
 - Procurement
 - Supply chain
- Understand product risk, supplier risk, exposure to you
- Manage the risk accordingly
 - May need more resources
 - May decide not to go there



Current Suppliers

- Track and trend data
 - Timeliness of delivery
 - Meeting specifications
 - COAs
- Take corrective actions
 - Warnings
 - Site visits
 - Change supplier
- Keep records



Environmental Monitoring

- Think like a bug
- Look for trends in your results
 - Too many negatives
 - Too many positives
 - Do you have places you are not looking
- Connect the dots
- Look for trouble
- Where would the regulators test
- React to positive results



Reacting to Positive Results

- Appropriate cleaning and sanitation
- Vectoring
- Root cause analysis
- Re-testing
- Challenge of getting more positive results
- How far do you go to determine cause
- Should you undertake whole genome sequencing
- Look at alternate technology such as HPP



Summary

- Senior executives and food safety professionals have to manage many different aspects of risk
- Leverage new technology such as HPP
- Stay current with multiple challenge areas
- Building relationships
- Prevention focus with strong reactive capabilities
- The need for a strategic and holistic approach
- Setting the right culture



Thank You!