

Improving Public Health Through Collaboration & Innovation

# **FDA Office of Partnerships' Update**

Ushering in New Era of Smarter Food Safety...  
Building on a Solid Foundation of Success



#SmarterFoodSafety

**Alan Tart**  
Deputy Director  
Office of Partnerships



A black and white scanning electron micrograph (SEM) showing a dense population of various bacterial cells. The cells are mostly rod-shaped (bacilli) and some are spherical (cocci). They are arranged in clusters and chains, with some showing flagella. The background is dark, and the cells are highlighted in shades of gray.

**Are we WINNING  
the battle against  
foodborne disease?**

# Foundational Successes

## FDA FOOD SAFETY MODERNIZATION ACT



## Voluntary National Retail Food Regulatory Program Standards



## Food Code

U.S. Public Health Service



## Manufactured Food Regulatory Program Standards



The collection of information has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 and has been assigned OMB control number 0910-0001.

To request a copy of the standards go to:  
[www.fda.gov/MFRPS](http://www.fda.gov/MFRPS)

U.S. Department of Health and Human Services  
Food and Drug Administration  
Office of Regulatory Affairs

OMB Control No. 0910-0001  
Expiration Date: 09-30-2019

## AFRPS Animal Feed Regulatory Program Standards

U.S. Department of Health and Human Services  
Food and Drug Administration  
Office of Regulatory Affairs  
Publication Date: January 30, 2014

Approved by the Office of Management and Budget (OMB)  
0910-0001

**RAPID  
RESPONSE  
TEAMS**

# Regulatory Program Standards

Establish a uniform foundation for the design & management of effective, quality  
SLTT HAF regulatory programs

## MFRPS

### Manufactured Food Regulatory Program Standards

- 43 enrolled jurisdictions from 40 states
- 30 programs are in full conformance with all 10 standards
- FY19 Funding: \$10.5M

## AFRPS

### Animal Feed Regulatory Program Standards

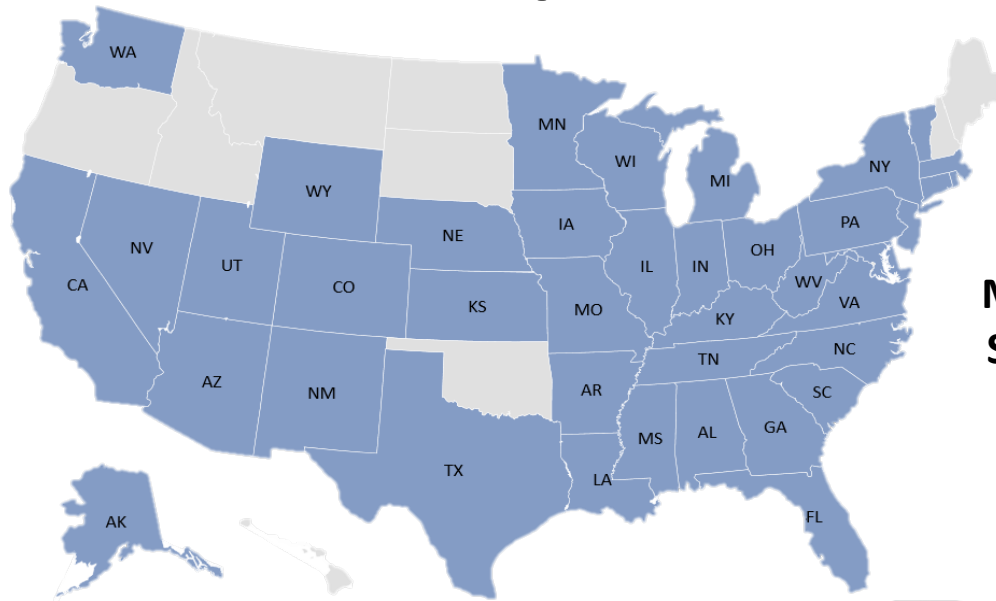
- 23 states enrolled under the CAP
- 5 programs are fully implementing all 11 standards
- FY19 Funding: \$10.7M

## VNRFRPS

### Voluntary National Retail Food Regulatory Program Standards

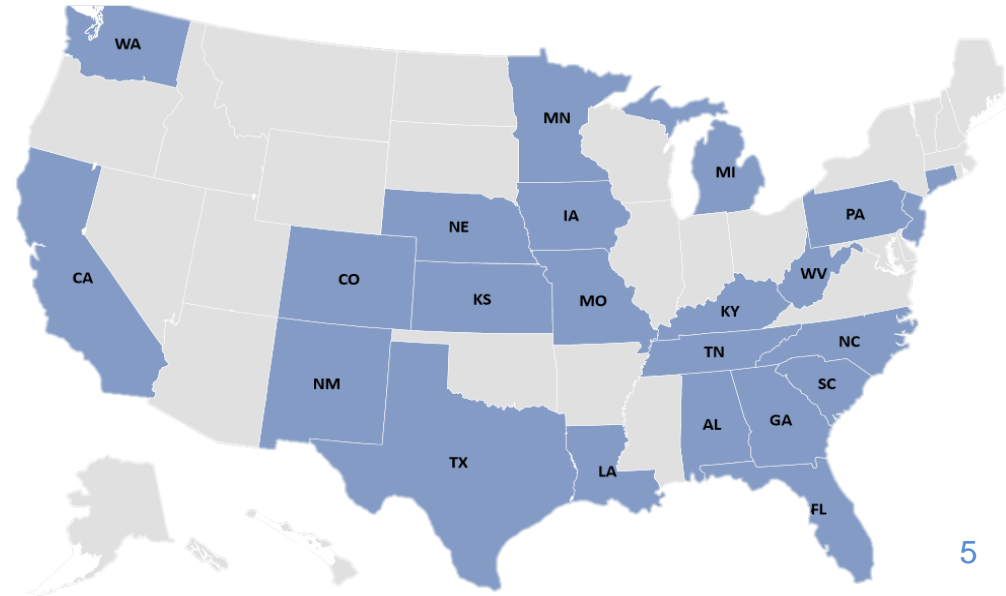
- 865 regulatory jurisdictions enrolled
- 5 programs are in full conformance with all 9 standards
- FY19 Funding: \$6.4M

# MRFPS & AFRPS Enrollment (as of Jan 2020)



**Manufactured Food Regulatory Program  
Standards (MFRPS):** 43 Programs from 40  
States

**Animal Food Regulatory Program  
Standards (AFRPS):** 23 States

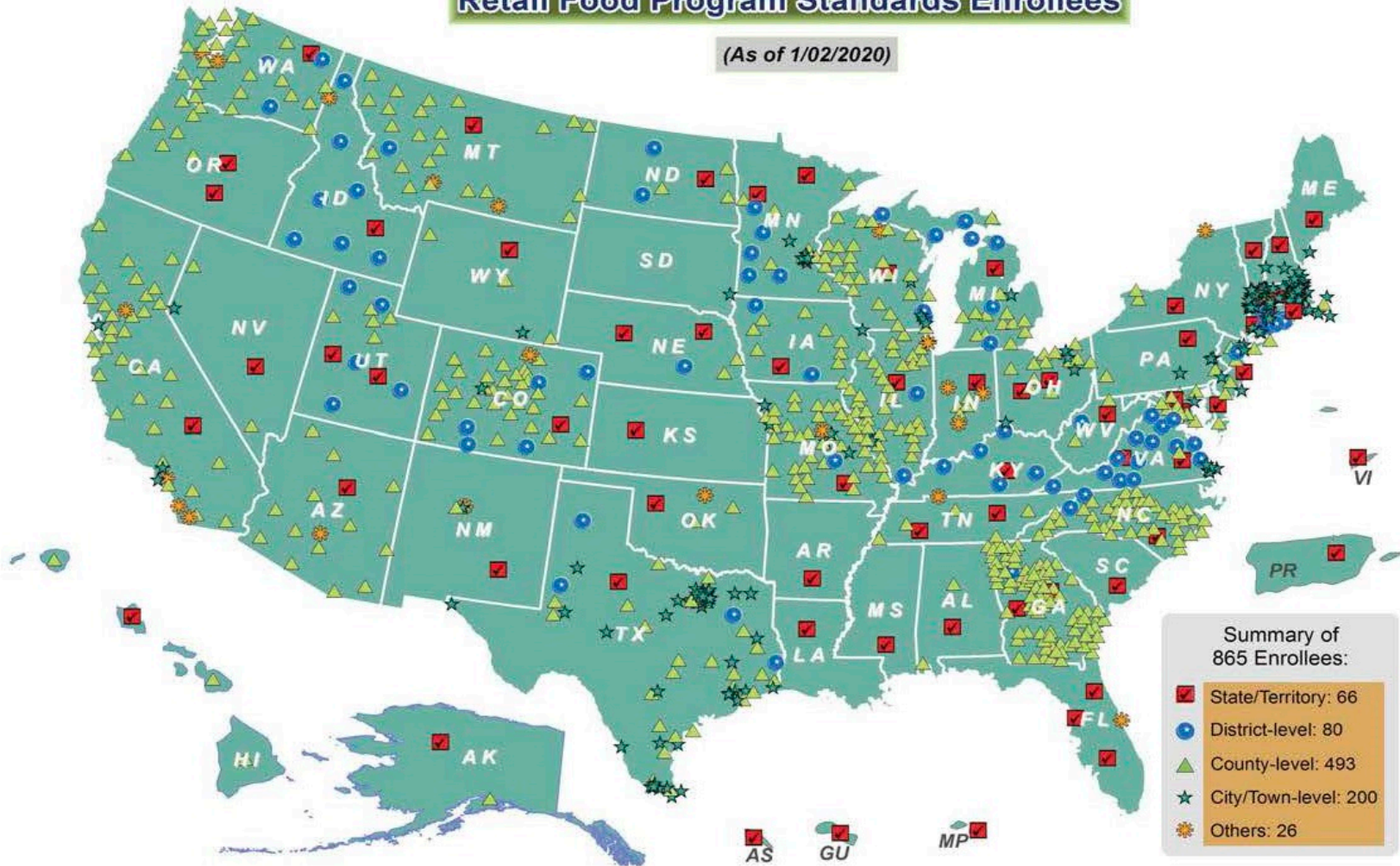




# VNRFRPS Enrollment (as of Jan 2020)

## Retail Food Program Standards Enrollees

(As of 1/02/2020)





# Other Regulatory Program Standards Under Development

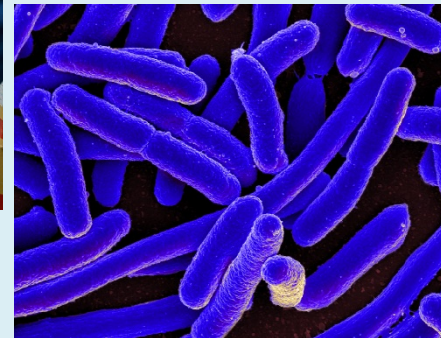


- **Egg Safety Regulatory Program Standards**
  - Cooperative agreement with CA & IA completed
  - Developed recommendations for egg safety standards using MFRPS/AFRPS
  - NERO board voted in FY19 to move forward with developing egg standards
- **Shellfish Sanitation Standards**
  - ISSC developed w/ input from FDA
  - Being piloted in 4 states - MA, VA, FL, & LA
- **Produce Safety Standards**
  - Soon to be developed as an output of a CAP with NASDA via a subaward to AFDO



# Rapid Response Teams (RRTs)

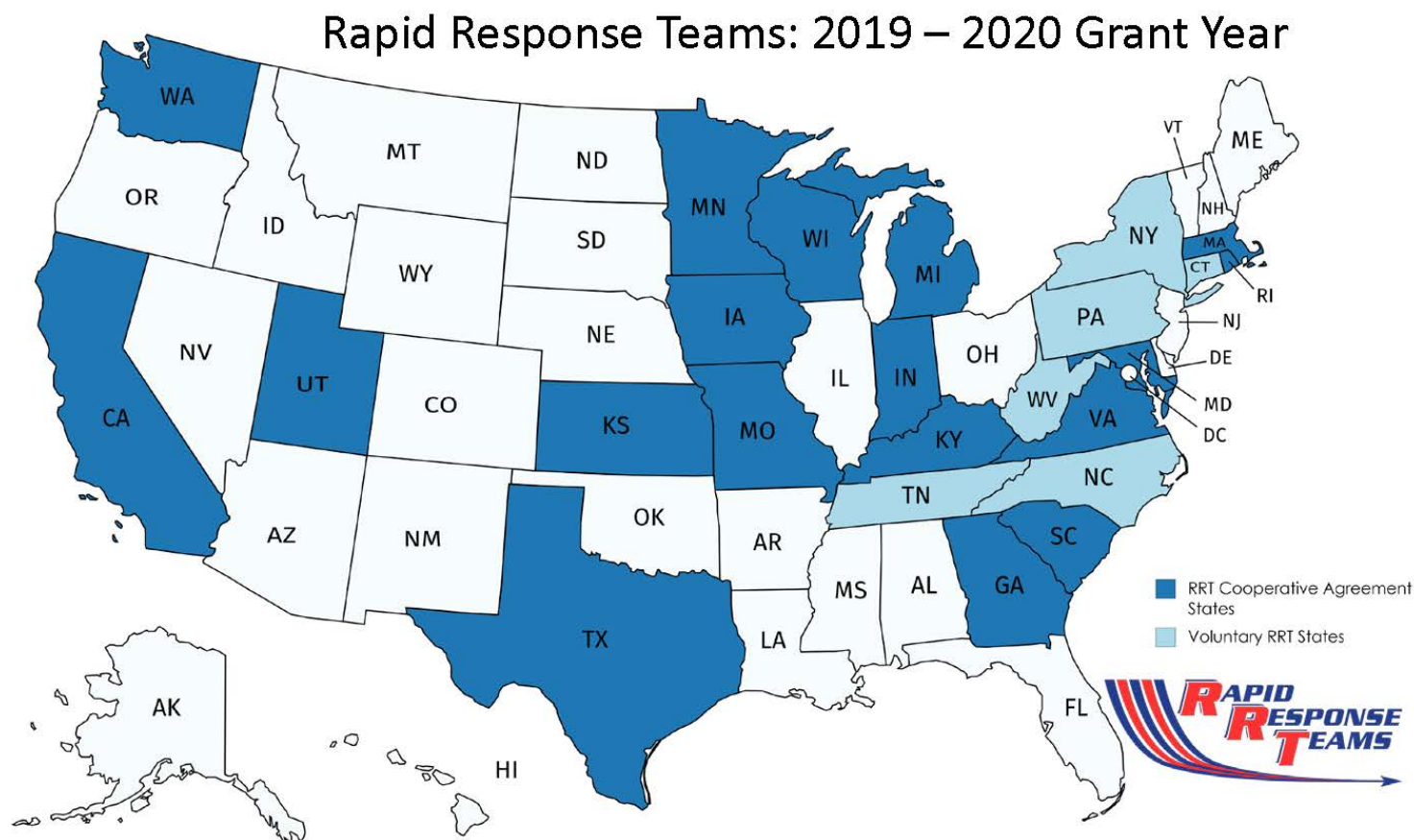
- Began in 2008 with 6 pilot states
- Purpose: Build multi-disciplinary RRTs with capacity to respond to human & animal food emergencies
- Currently, 24 states participate (18 funded, 6 unfunded/voluntary), involving 11 FDA HAF Divisions
- FY19 Funding - \$4.3M
- RRTs can apply for up to \$300k per year for development and maintenance





# RRT Enrollment

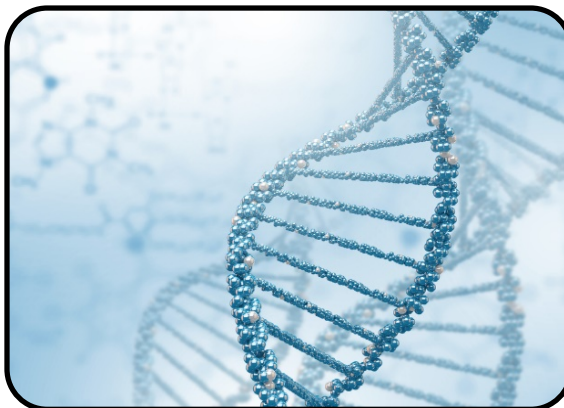
Updated: October, 2019



**Rapid Response Teams (RRTs):**  
 24 States  
 (18 funded, 6 voluntary)

# Building Laboratory Capacity

(FERN CAP & ISO Lab Accreditation/Whole Genome Sequencing CAP)



## Food Emergency Response Network (FERN) CAP

Began in 2007 with 14  
awardees

Provides funding for:

- \* Equipment service contracts
- \* Increasing high volume sampling assignments
- \* Staff
- \* New technology

## ISO Lab Accreditation/Whole Genome Sequencing CAP

Assists labs with  
gaining/maintaining ISO 17025  
accreditation or expanding  
methods

Whole Genome Sequencing  
(WGS) identifies foodborne  
pathogens during outbreaks

## FY19 Funding

FERN: \$8.9M  
26 total state labs  
(14 micro, 14 chemistry, 5  
radiological)

ISO: \$6.8M  
42 state labs

**Laboratory Flexible Funding  
Model Funding Opportunity  
Announcement has posted!**



## ORA's Largest Cooperative Agreement: State Support for Produce Rule

- **State Produce Implementation CAP**
  - Assists states in creating a produce infrastructure and/or inspection program
  - FY19 funding: \$27.1M
- **Produce Association CAP**
  - Partnership with NASDA
  - Provides a National Consortium to assist states & territories in establishing or enhancing their produce safety regulatory programs
  - Creates a forum for states to exchange ideas & receive input from their colleagues
  - FY19 funding: \$1.3M



# Food Safety Report Card

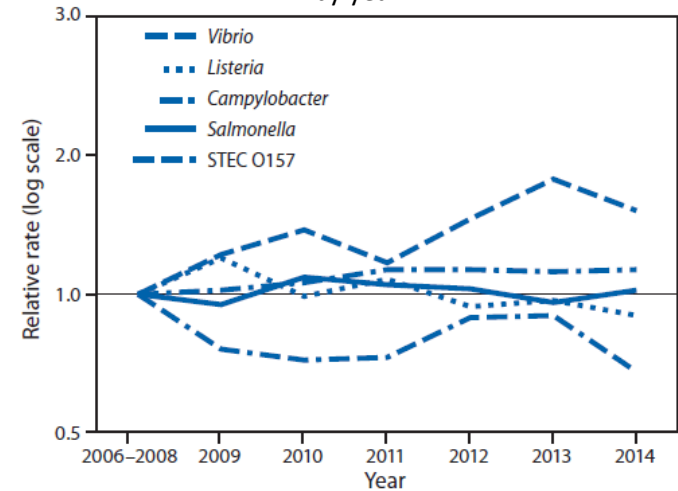
**Foodborne disease infections are on the rise. Here are the most common.**

By: Denise Powell, CNN  
April 25, 2019

**Little progress made on targeting incidences of foodborne illness, according to new CDC report**

April 2019

Relative rates of Infections compared with 2006-2008, by year



## 2014 FOOD SAFETY PROGRESS REPORT

Pathogen	Healthy People 2020 target rate	2014 rate*	Change compared with 2006-2008†	
<i>Campylobacter</i>	8.5	13.45	↑ 13% increase	☹️
<i>E. coli</i> O157 <sup>s</sup>	0.6	0.92	↓ 32% decrease	😊
<i>Listeria</i>	0.2	0.24	No change	😐
<i>Salmonella</i>	11.4	15.45	No change	😐
<i>Vibrio</i>	0.2	0.45	↑ 52% increase	☹️
<i>Yersinia</i>	0.3	0.28	↓ 22% decrease	😊

## 2018 FOOD SAFETY PROGRESS REPORT

Pathogen	Healthy People 2030 target rate	2018 rate	Change compared with 2015-2017	
<i>Campylobacter</i>	TBD	19.6	↑ 12% increase	☹️
<i>E. coli</i> O157 <sup>s</sup>	TBD	5.9	↑ 26% increase	☹️
<i>Listeria</i>	TBD	0.3	↓ 4% decrease	😐
<i>Salmonella</i>	TBD	18.3	↑ 9% increase	☹️
<i>Vibrio</i>	TBD	1.1	↑ 109% increase	☹️
<i>Yersinia</i>	TBD	0.9	↑ 58% increase	☹️

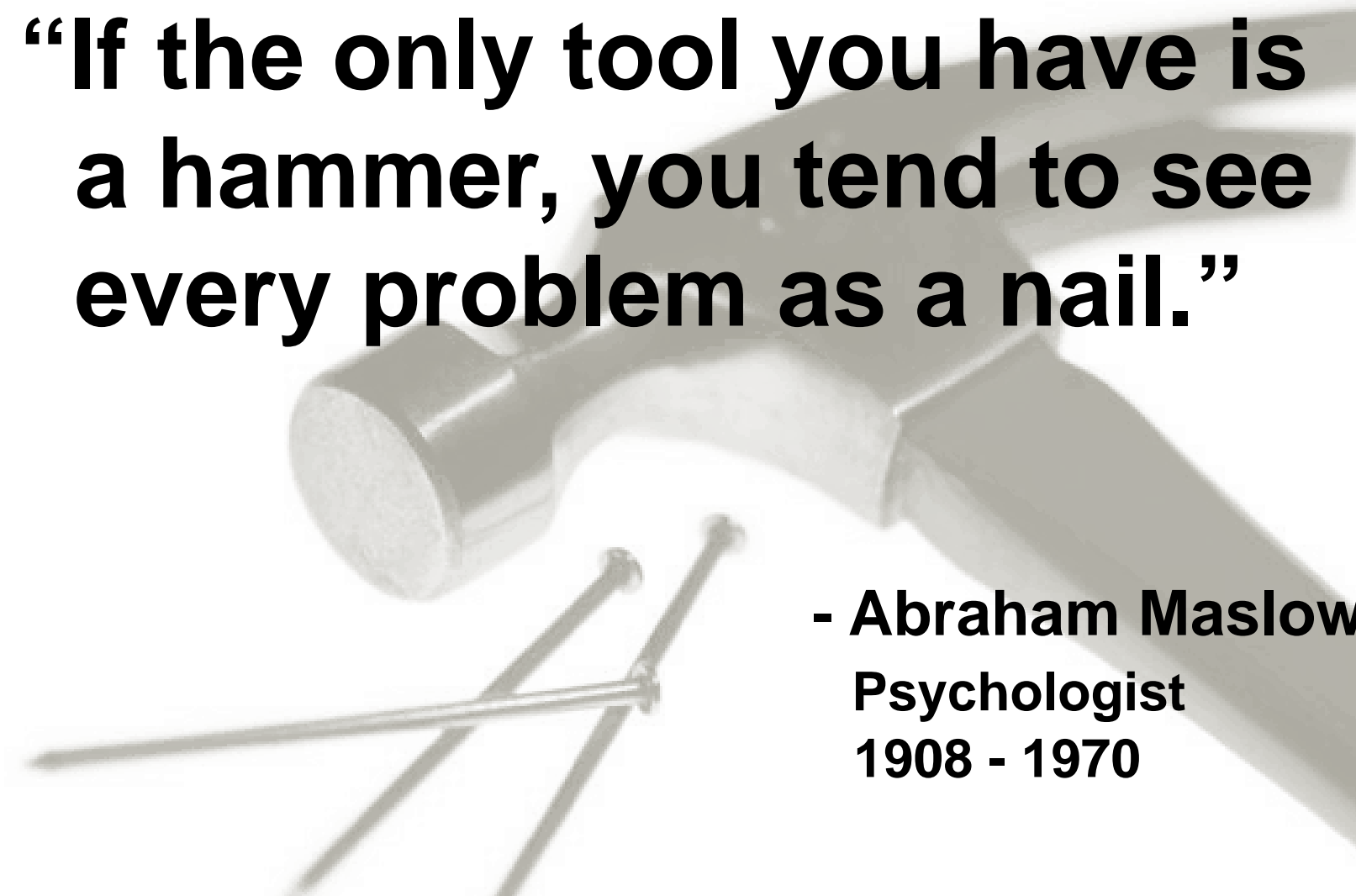
Cyclospora: 399% increase

WGS

## Exposing the Foodborne Illness Iceberg?

~5% cases (Outbreaks)

~95% cases (Sporadic)

A grayscale image of a claw hammer and three nails. The hammer is positioned diagonally across the frame, with its head in the upper left and handle extending towards the bottom right. Three nails are scattered in the lower left area, some overlapping each other. The background is plain white.

**“If the only tool you have is  
a hammer, you tend to see  
every problem as a nail.”**

**- Abraham Maslow  
Psychologist  
1908 - 1970**



FOOD SAFETY

SMARTER

BLUEPRINT

DIGITAL

FUTURE

STRATEGIES

UPGRADE

NEW TOOLS

TRACEABILITY

MACHINE LEARNING

COLLABORATION

EVOLVING

SAFER

INITIATIVES

VISION

PROGRESS

JOURNEY

EMERGING TECHNOLOGIES

REGULATORY FRAMEWORK

LEADERSHIP

SENSORS

SMARTER ERA

FUTURE

FDA

## People-Led \* FSMA-Based \* Technology-Enabled

## Tech-enabled Traceability and Outbreak Response



## Smarter Tools and Approaches for Prevention



## New Business Models and Retail Modernization



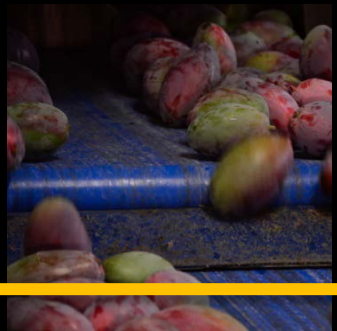
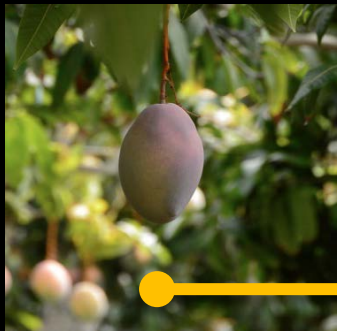
## Food Safety Culture

New Era of Smarter Food Safety Pillar #1

## Tech-enabled Traceability and Outbreak Response







New Era of Smarter Food Safety Pillar #2

## Smarter Tools and Approaches for Prevention



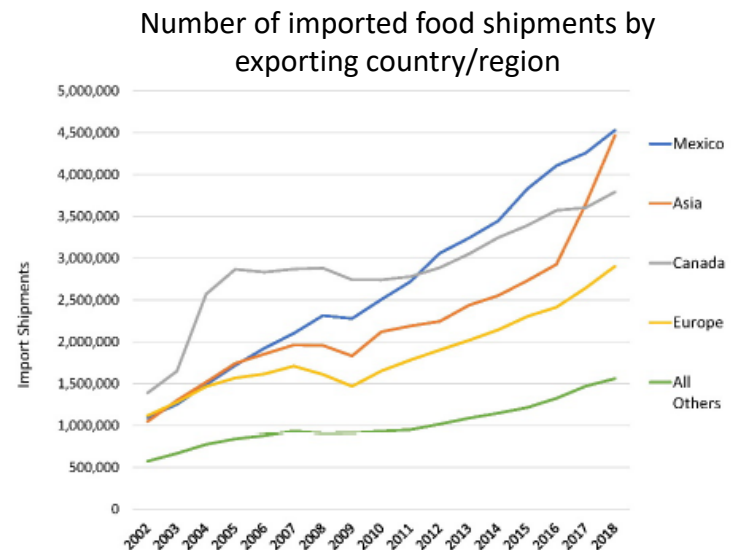


# Americans told to toss romaine lettuce over E. coli fears





# Using AI to Prevent Violative Imported Foods from Entering Commerce



# Mutual Reliance

- A seamless partnership
- FDA & states with comparable regulatory public health systems (trusted partners)
- Fully rely on, coordinate with, & leverage one another's work, data, & actions
- Outcome: Safer national food supply





# Recent Advancements in Mutual Reliance & Next Steps





**MEP** • MANUFACTURING  
EXTENSION PARTNERSHIP®

**FSPCA**  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

# Innovative Partnership to Advance Prevention

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New Era of Smarter Food Safety Pillar #3

## New Business Models and Retail Modernization



Online Share of

# Grocery Basket



retail grocery  
└───→

**80%**  
**20**

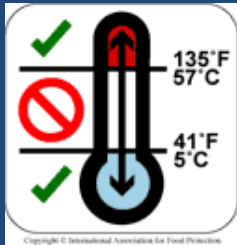
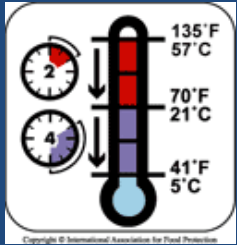
↑ online grocery

By **2022-2024**, could reach

**\$100 Billion**

annually

# Foodborne Illness Risk Factors & Facility Types with Statistically Significant Improvement (1998 – 2008)



Despite improvements, this risk factor continues to have a high % Out of Compliance (still in need of priority attention)



- Hospitals

# Foodborne Disease Outbreak Surveillance System (FDOSS) (2009 – 2015)

**FACT:** Of the ~9.4 million illnesses each year in the U.S. traced to known foodborne disease agents, only a small subset of illnesses are associated with recognized outbreaks.

**5,760 outbreaks  
reported**

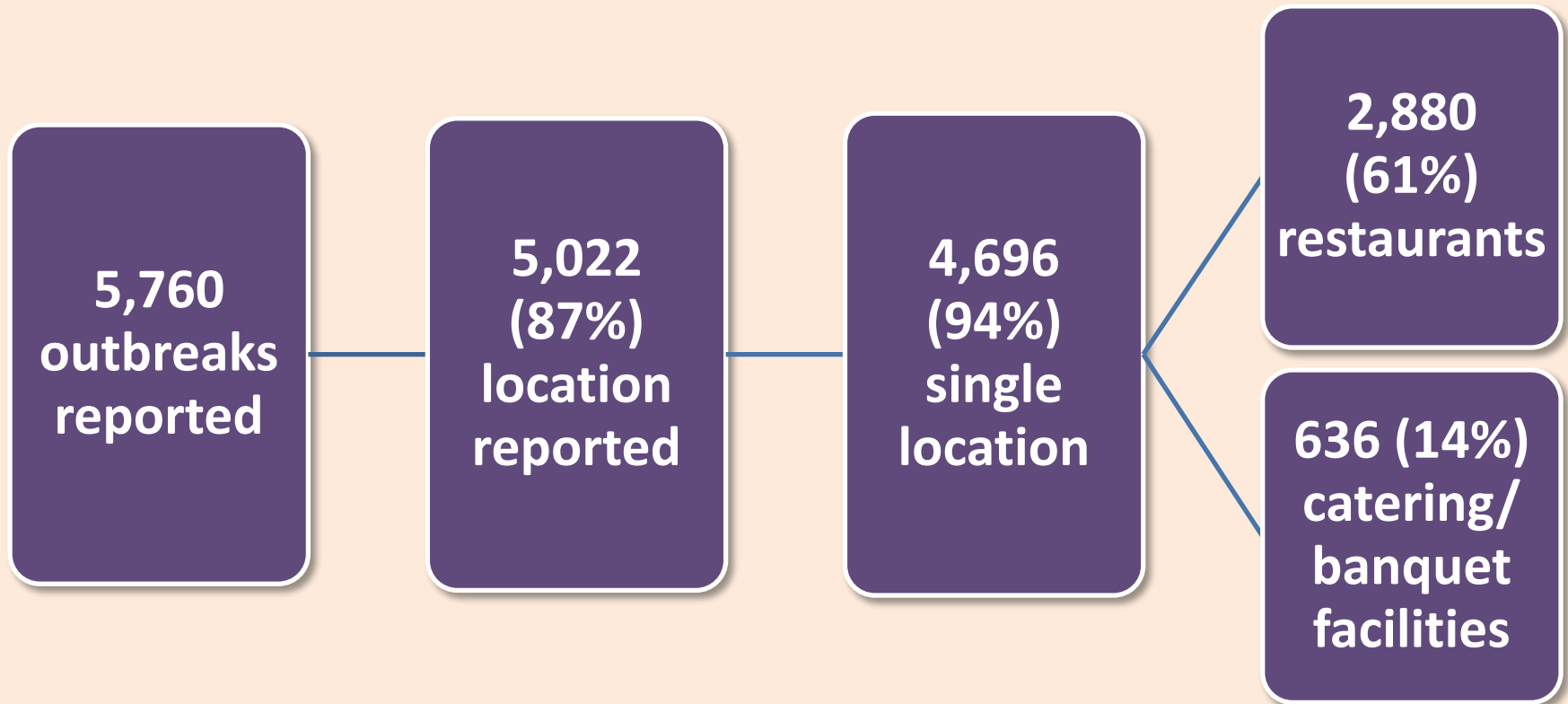
**101K illnesses**

**5.7K  
hospitalizations**

**145 deaths**



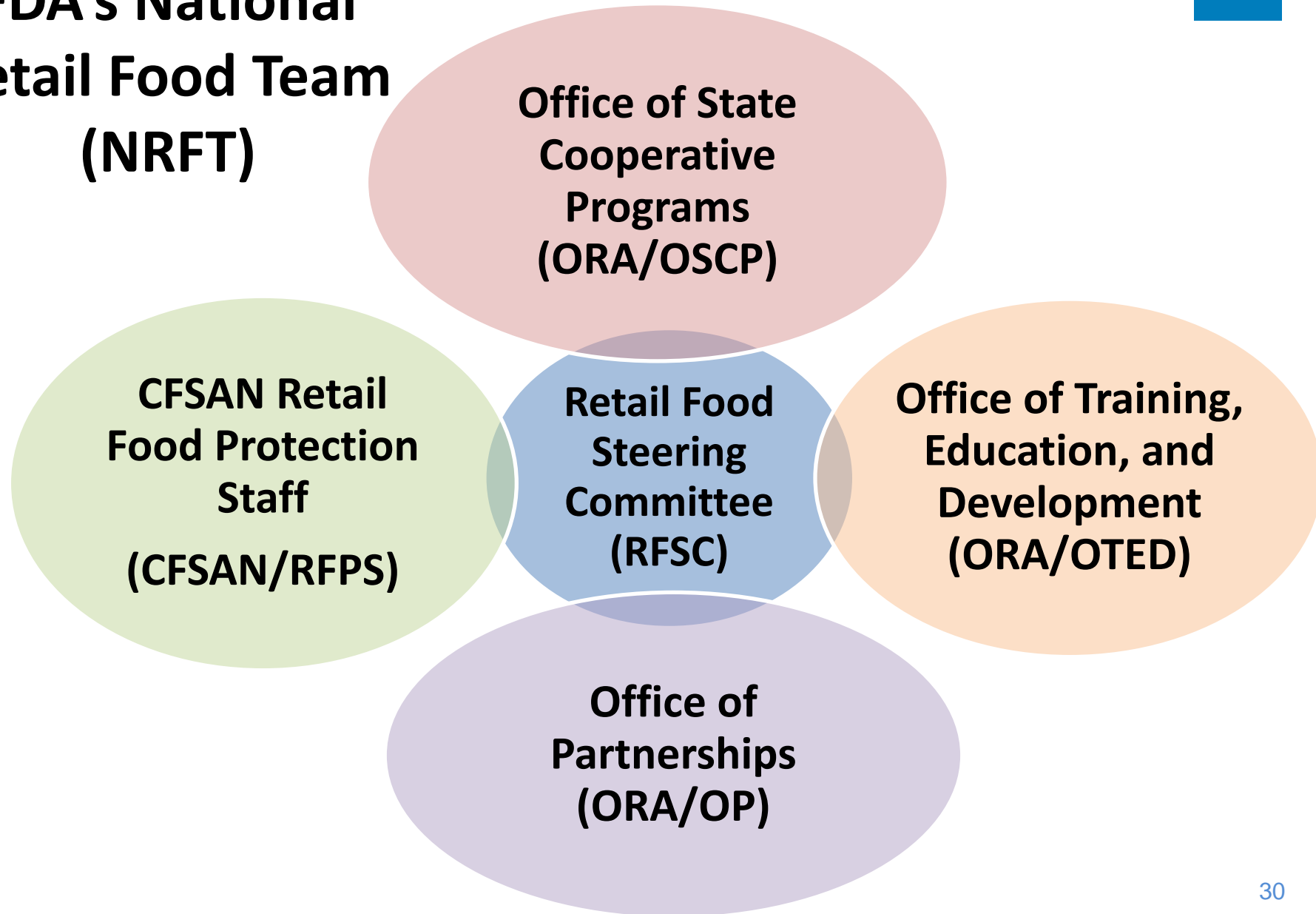
# Foodborne Disease Outbreak Surveillance System (FDOSS) (2009 – 2015)



Of the 101K illnesses,

- Restaurants – 33.5K [43%]
- Catering or banquet facilities – 18.1K [24%]
- Institutions – 9.8K [13%]

# 4 Components of FDA's National Retail Food Team (NRFT)



# NRFT Strategic Goal & Objectives

## GOAL: Reduce the occurrence of foodborne illness risk factors in food establishments

(Metric: FDA Foodborne Illness Risk Factor Study & State, Local, Tribal, & Territorial (SLTT) Risk Factor Studies)

### 1. Increase uniformity, consistency, and capacity of SLTT retail food protection programs

- Technical Assistance
- Food Code Development/Research & Adoption
- Retail Program Standards
- Training & Standardization
- Funding Opportunities
- Leveraging Regulatory Associations (“Multiplier Effect”)
- Enhancement of FBI Surveillance & Response Systems (Std. 5)
- Data collection to inform decision making
- Sharing of best practices

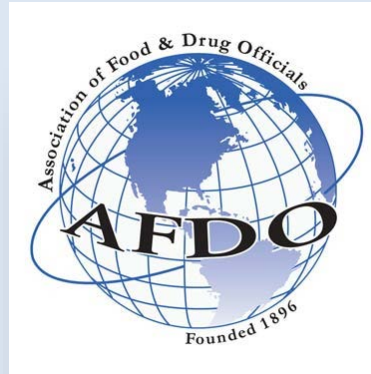
### 2. Promote industry’s active managerial control of foodborne illness risk factors & promote a culture of food safety

- Implementation of Intervention Strategies
- Behavior modification
- Guidance
- Industry Partnership Group Activities
- Leveraging Industry Associations (“Multiplier Effect”)
- Consistent Nutrition/Menu Labeling

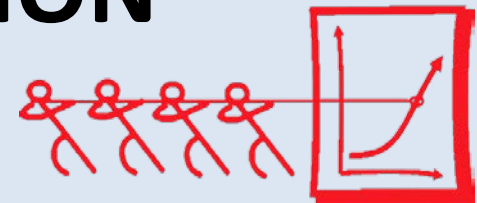
### 3. Maintain a strong NRFT work force

- NRFT Operations & Efficiencies
- NRFT Culture
- NRFT Knowledge & Skills
- NRFT IT Infrastructure

# “Working Together to Bend the Curve on Foodborne Illness”



## RETAIL REGULATORY ASSOCIATION COLLABORATION





# Collaborative's Priorities after Incorporating the Objectives from AFDO's Roadmap to HP 2030 Meeting



## Increase Food Code adoption

- Develop Food Code adoption toolkit
- Develop/implement national strategy to promote adoption
- Increase # of establishments that have a certified food protection manager

## Improve regulatory approach, competency, & food safety culture in regulatory community

- Increase application of risk-based inspection methods
- Improve field staff's use of root cause analysis during inspections
- Identify, assess, promote implementation of regulatory intervention strategies

## Increase participation & conformance with the Retail Program Standards

- Increase enrollment, active participation, & conformance
- Develop national strategy to provide a "multiplier effect" for Retail Standards technical assistance
- Develop a way to aid/fund jurisdictions that need assistance the most

# Collaborative's Priorities after Incorporating the Objectives from AFDO's Roadmap to HP 2030 Meeting



## Improve outbreak investigations

- Increase and improve environmental assessments (includes identification of contributing factors and environmental antecedents)

## Enhance communication

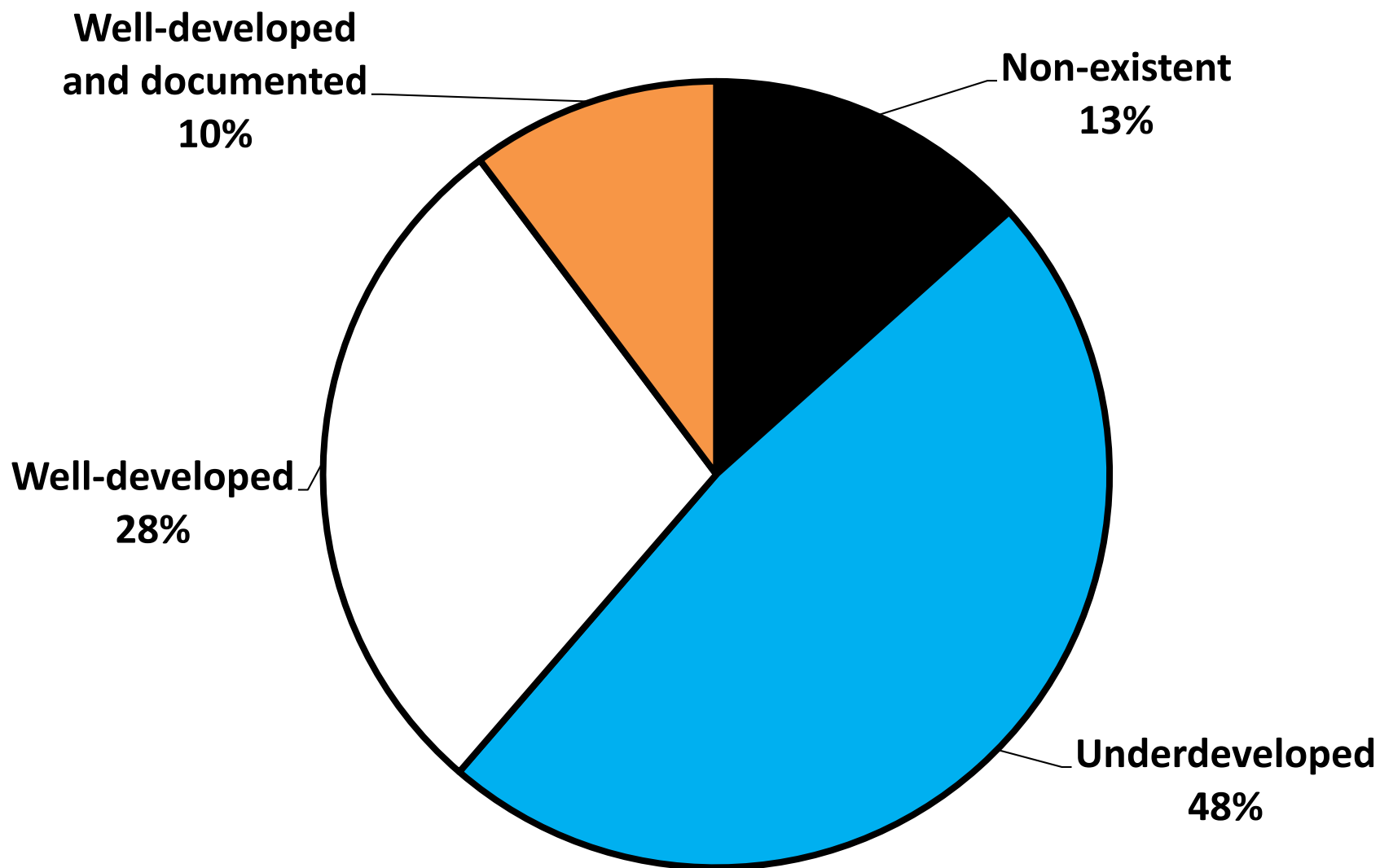
- Develop strategy to enhance communication & better tell our public health story ("putting a face on food safety")
- Issue joint recommendations on emerging issues
- Develop a way to easily share information, food safety resources, tools, & best practices

## Improve active managerial control by industry operators

- **Increase # establishments that have a well-developed & implemented food safety management systems (FSMS)**
- Increase # of establishments that have trained food handlers
- Improve effective handwashing using technology & incentive programs
- Identify, assess, & promote industry intervention strategies

# FSMS Results

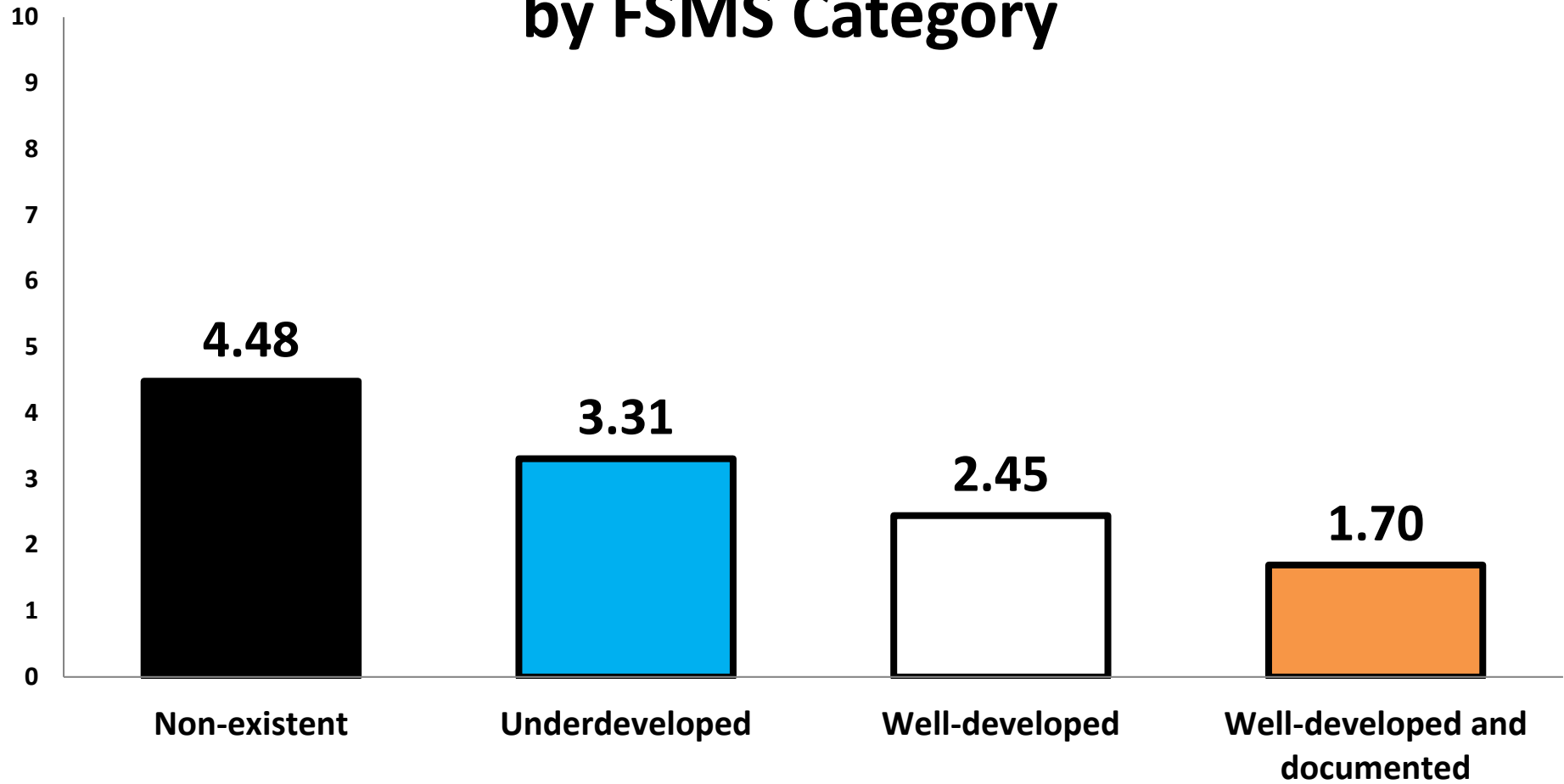
## Fast Food Restaurants





# Fast Food Restaurants

## Average Number Primary 10 Data Items Out-of-Compliance by FSMS Category

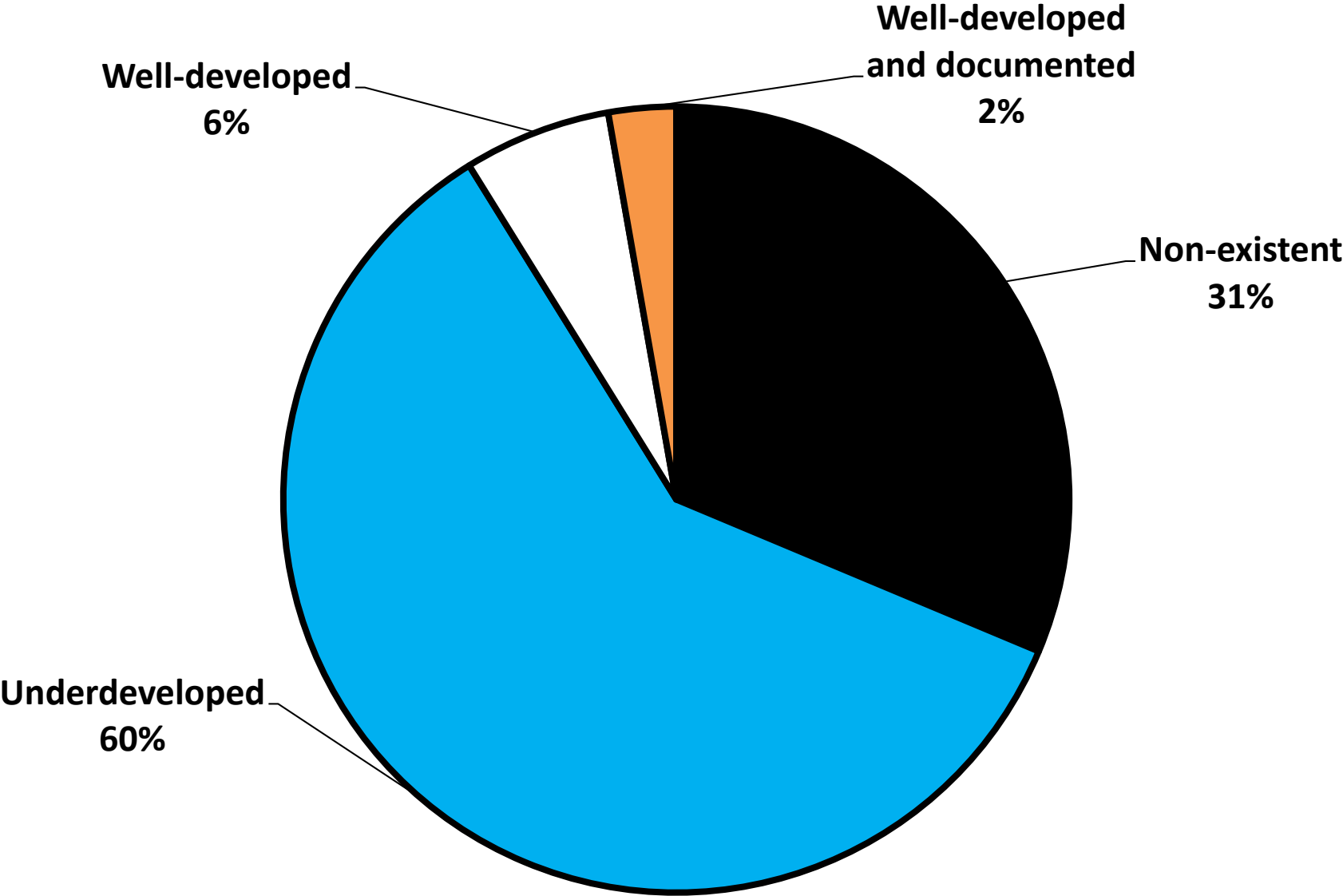






# FSMS Results

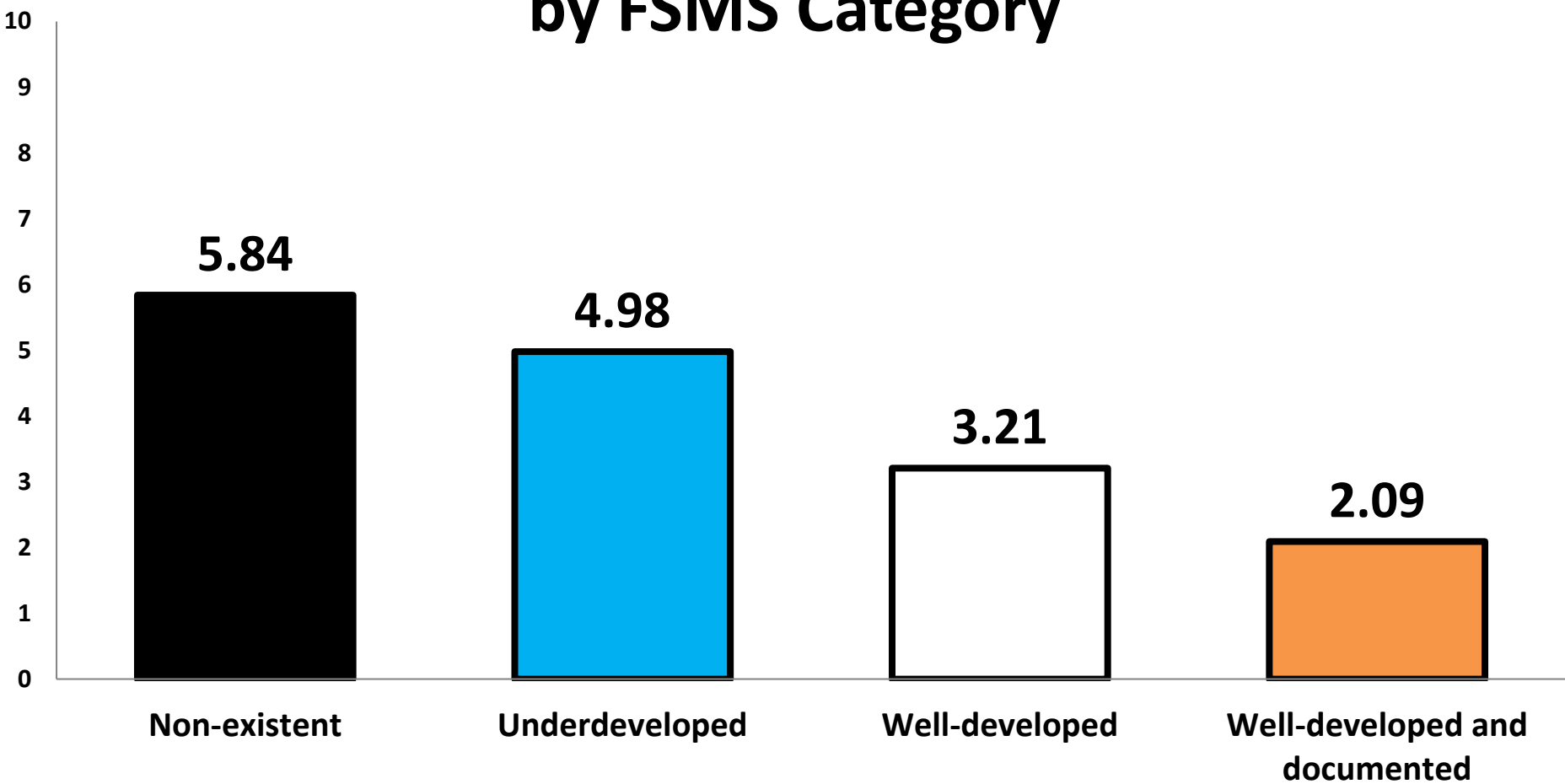
## Full Service Restaurants





# Full Service Restaurants

## Average Number Primary 10 Data Items Out-of-Compliance by FSMS Category



# **2020 CFP Issue** **Form FSMS Committee**

**Purpose: To provide recommendations for promoting universal development & implementation of documented, HACCP principles-based FSMSs by industry**



# Supporting the Collaborative's Work

- **Retail Association Collaboration**  
FOA to be posted in Feb 2020;  
Awards by May – June
- **Any regulatory association can apply**
- **Up to 5, 2-year awards, \$750K max per award**
  - **\$1.5M TOTAL CAP FUNDING**
  - **Can reevaluate need/ objectives when the NRFT strategic plan is completed**
  - **Subawards allowed**





## New Era of Smarter Food Safety Pillar #4

### Food Safety Culture



“The goal of the food safety professional should be to create a food safety culture, not a food safety program.” – Frank Yiannas, *Food Safety Culture: Creating a Behavior-Based Food Safety Management System*

# Food Safety = Behavior

“You can have the best documented standards in the world, but if they’re not consistently put into practice by people, they’re useless.” – Frank Yiannas, 2009

# We Need Your Help!



**ORA Think » Plan » Act**  
*Strategic Planning Initiative*



## Strategic Planning Timeline



<http://bit.ly/ORAStrategicPlan>



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**U.S. FOOD & DRUG**  
ADMINISTRATION