

**MCAFDO 2018**

**Workplanning**  
**#morethanjustaboutthelist**

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# Background

- Evolution of state contracts
  - 19K contract inspections
- Partnership Inspections
  - Inspection data for resources
- OIG Reports
  - 2000 and 2011



# Contributing Factors

- Frequency mandates
  - State vs. FDA
- Inventory
  - Valid
  - Numbers
  - Aligned?
- Contract requirements
  - Training
- IT Issues
  - eSAF, data exchanged, secure access

# FDA Field Activities



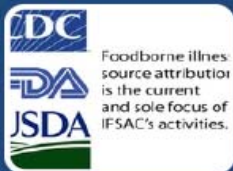
## Inspections

- Domestic
- International



## Sampling

- Product
- Environmental Sample
- FDA Laboratory Analysis



## Unplanned

- Consumer Complaints
- Referrals from state and other federal agencies
- Foodborne Outbreaks



## Miscellaneous Activities

- New Hire Training
- Programmatic Training



# FDA Field Activities

- FSMA Inspection Resources
  - Mandated to inspect domestic high-risk facilities not less often than once every three years
  - Mandated to inspect domestic non-high risk facilities not less than once every five years
- New FSMA Rules: Preventive Controls – Human and Animal (CGMP), FSVP, Sprout Inspections
- Center assignments
  - Emerging issues
  - Compliance follow-up
  - Congressional requests



# FSMA HR and NHR firms

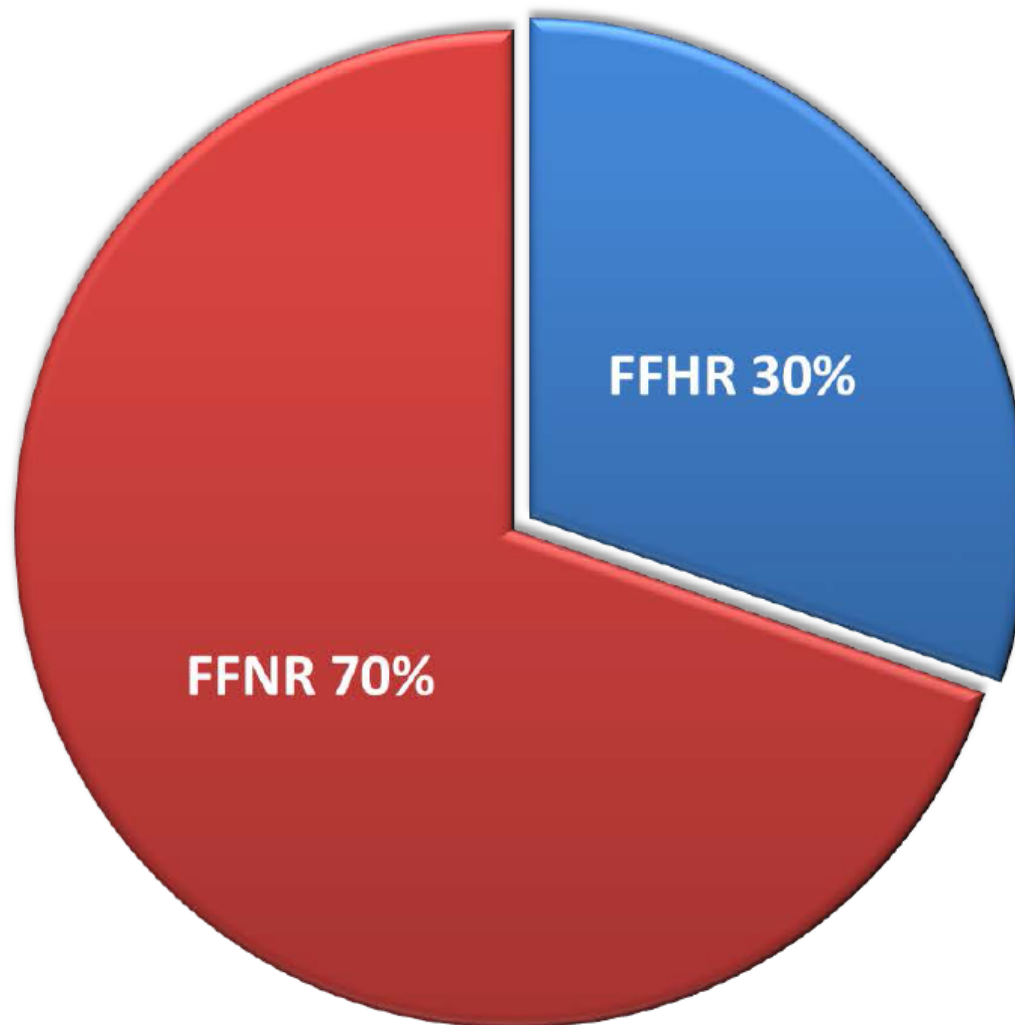
- High Risk Firms
  - OAI inspection, Outbreak, Class I recall or Class 3 Sample Analysis in last 5 years
  - Manufacturers of acidified, LACF and other human food products
  - Inspected every 3 years
  - HR firms with a cover by date in the current fiscal year are considered Performance Goals (PGs)
- Non-High Risk Firms
  - FSMA related codes not included on the HR list
  - Inspected every 5 years
  - New cycle FY18

# FDA Registered Firms (Domestic) by Facility Risk Category



*n = 78,304*

■ FFHR ■ FFNR

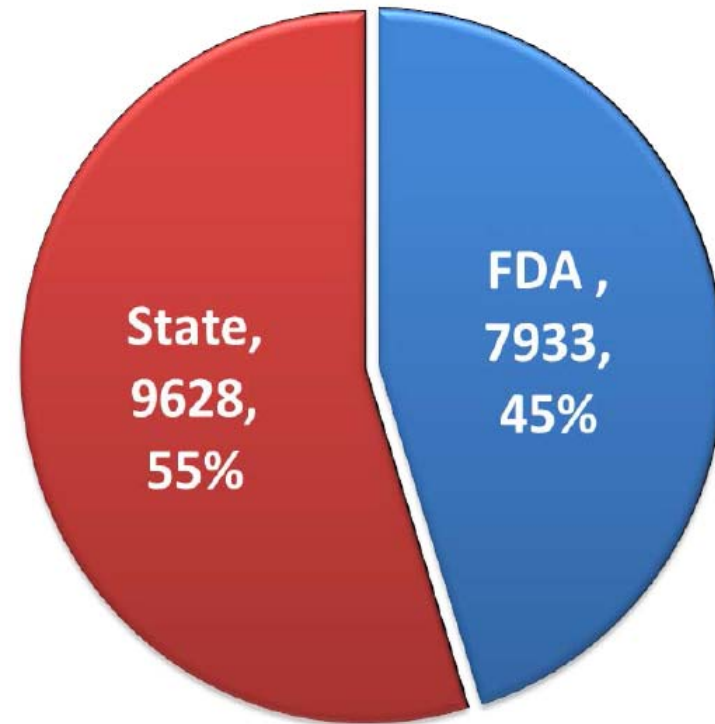


# FSMA Inspection Resources



*Are we allocating resources –  
FDA and state - to meet  
inspection frequency  
mandate?*

Establishment Inspections



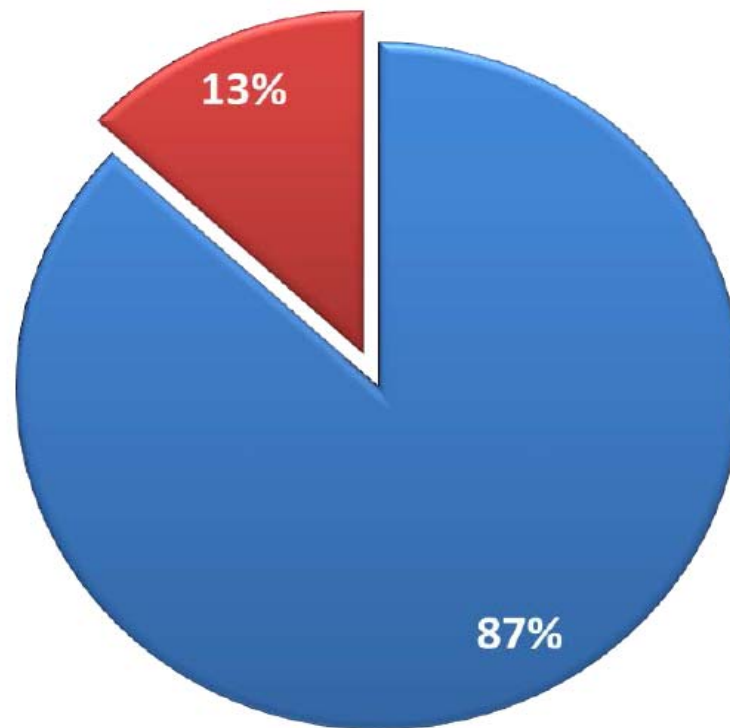
Data Source: [FY2018 ORA – Field Activities Budget](#) –  
FY16 Actuals, Unique Counts



# FY 2017 FSMA Inspection Frequency Mandates



FY2017 FSMA Inspection Frequency Mandates



■ FDA ■ State



# How Do We Get To The “List”

- High Risk/Non-High Risk with cover by dates for that fiscal year
- Compliance Issues
- Certifications/Audits
- Complaint Follow Ups
- Recall Follow ups



# How Do We Get To The “List”

- What’s Missing
  - Inventories
- Who Regulates What
  - What can go on a contract
- Special Assignments
  - Ready to Eat, Ice Cream
- Sampling

## And then...

- Coordinate an inspection schedule
- Prioritize when inspections will be done
- Cover by Dates
- Discuss visits/Out of Businesses (OOB)
- Firm inventories
- Audit schedule
- Regulatory authority



## And then...

- eSAF
- Contact info
- Key contract deliverables
- Training
- Samples
- Corrective action plans
- Collaborative efforts



# Moving Forward

- Work Planning is an evolving process
  - FSMA, ER/RRT, recalls, priorities, emerging issues
- States and FDA are working collaboratively to improve the process
- Project
  - Data Exchange
- Identify areas for expansion



# Moving Forward

- Avoid duplicating inspectional work between agencies
  - Can States accept FDA inspections as part of their inspection numbers?
  - Can FDA take action based on state work?
  - Can States take action based on FDA work?

