Recapping the FSMA Race: The Finish Line or the Starting Blocks? What to Expect Now?

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2016: A Year in Review…Why Were We Racing So Fast?

- ❑ Y2K or Real Impact?
- ❑ Implementation Realities. . .
  - ✓ PCQI Training
  - ✓ HACCP vs Food Safety Plans
  - ✓ Understanding what a PC was
  - ✓ Realizing the Importance of Validations
    - ✓ ….And how they differ from Verifications….
- ❑ Appreciating the Sheer Volume of Additional Records Required

And Now I Need To Focus On 2017 ?!?!?!

2017: The Year of Implementation and Execution

- ❑ **Supply chain controls (domestic & FSVP)**
- ❑ **Sanitary Transportation**
- ❑ **FDA FSMA Inspections**

WHAT IS THE COMMON THEME BETWEEN 2016 and 2017?

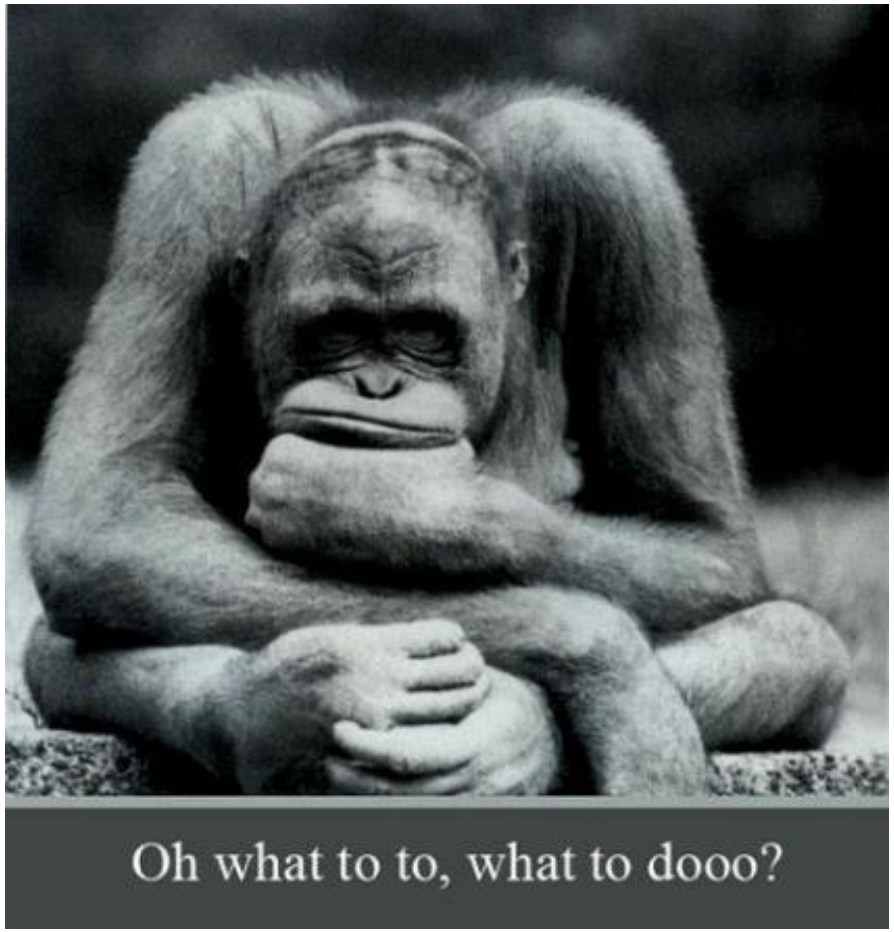
RECORDS & DOCUMENTATION

Status Update –What We Know

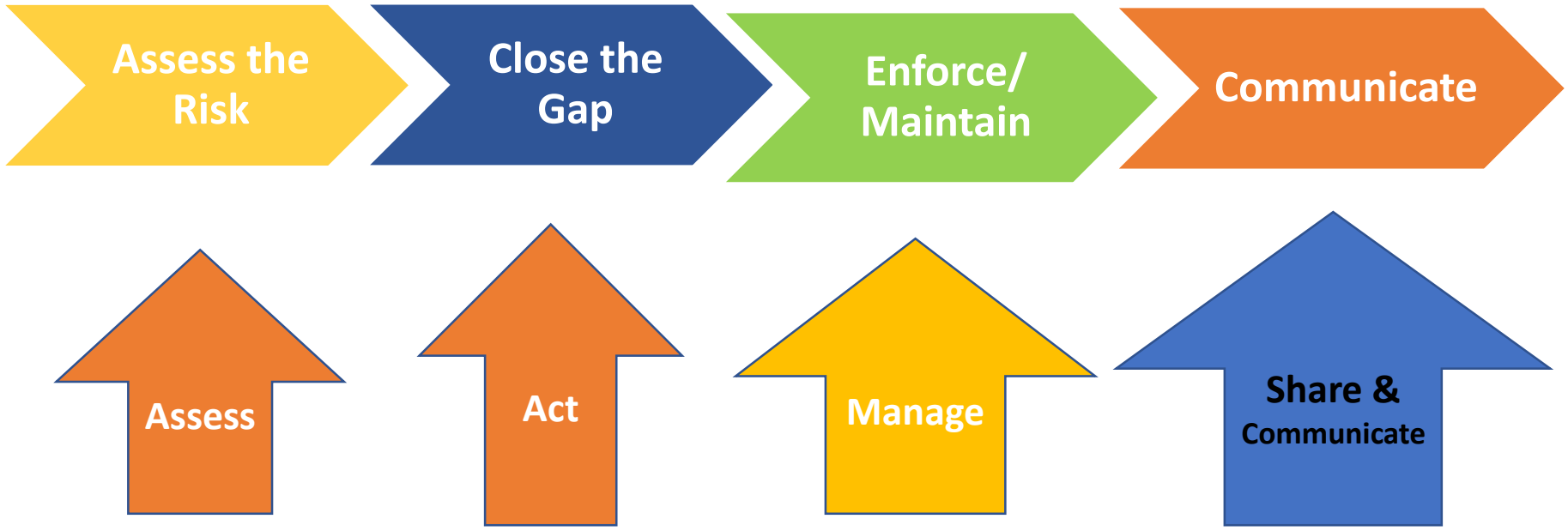
- Records Access Expanded Upon FSMA Signing and Upon Rule Compliance Dates
- Guidance Documents are Starting to Roll out
- Some Compliance Date Extensions
  - Customer assurances for hazards controlled downstream
- FDA “FSMA” Inspections Have Begun
- FDA Will Educate “Before AND While” they Regulate

We Must Be Audit Ready All the Time

The Year Ahead…2017



Have a Process to Assess, Manage, & Communicate Risk



Understand & Assess Your Supply Chain

- **Supply Chain Controls**

- **Supply Chain Risk Assessment**
- **Ongoing Risk Management**
- **Risk communication:**
  - **How are you communicating nRTE hazards?**
  - **Who is communicating?**
  - **You? Brokers? Distributors?**

Show Your Work--Hazard / Risk Assessments

Ingredient / Processing Step		Identify potential food safety hazards	Are any hazards requiring a Preventive Control?		Justify your decision for column 3			What Preventive Control measure(s) can be applied?	Is the PC applied at this step?	
			Yes	No	Severity	Likelihood	Justification & References*		Yes	No
Cooling Tower	B	Environmental pathogens such as *Salmonella*	x		High	Medium	*Salmonella* harbored in the environment could contaminate exposed product.	*Sanitation PC* - Zoning and Sanitation Procedures	x	
	C	Undeclared Allergen	x		High	High	Bakery 1 shares equipment with peanuts and tree nuts based on scheduling.	*Allergen PC* - Allergen Changeover	x	
	P	Foreign Material - Metal	x		High	High	Foreign material contamination from equipment possible, but not likely with preventative maintenance programs. Magnet downstream to remove magnetic foreign material.	*Process PC - CCP* - subsequent Metal Detection		x

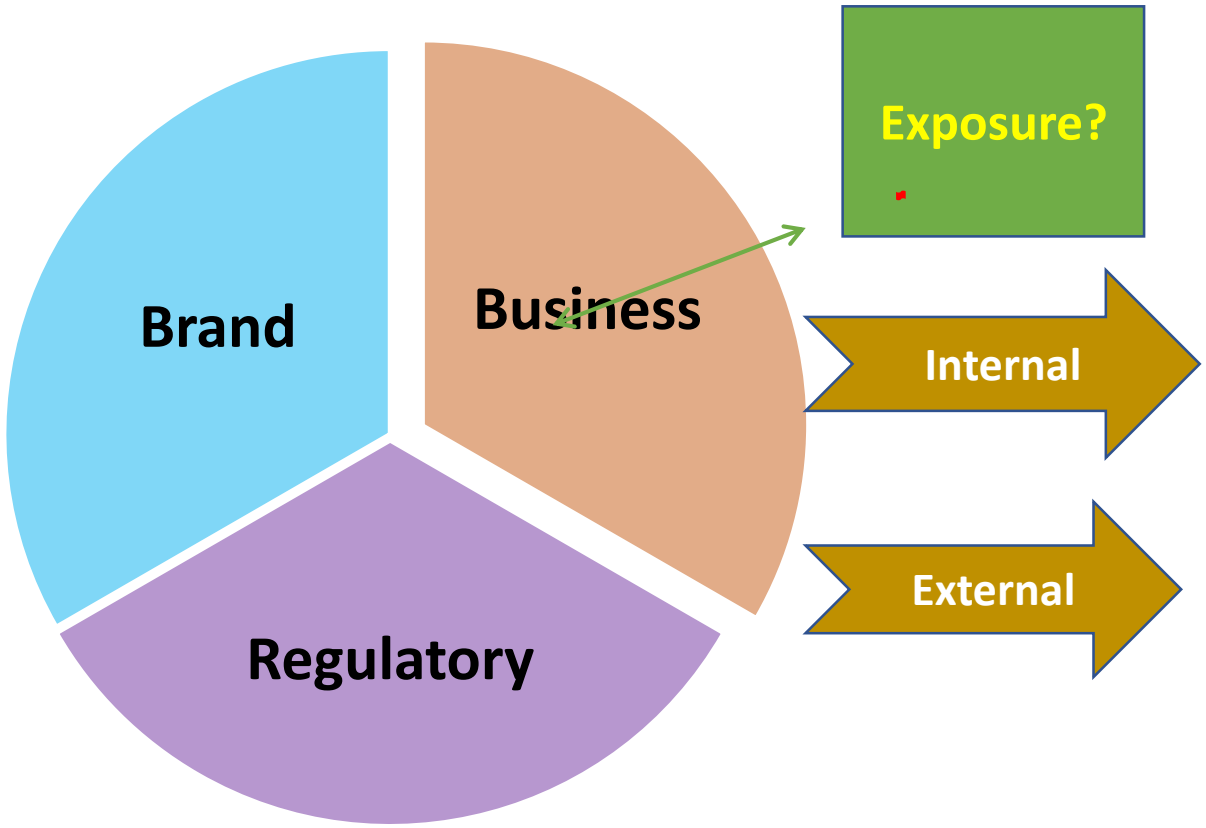
Show Your Work--Validations

- **<u>Validations:</u>** Documented Scientific and Technical evidence that the Preventive Control will effectively control the hazard.
  - Process PC's require:
    - ✓ Prior to Implementation **<u>OR</u>**
    - ✓ Within First 90 Days of Production **<u>OR</u>**
    - ✓ Reasonable Time with Written Justification
    - ✓ Performed **<u>OR</u>** Overseen by PCQI.

- **Science-based.**

- **Be sure its Apples to Apples!**
  - Same product, process, equipment.

Determine Your Exposure

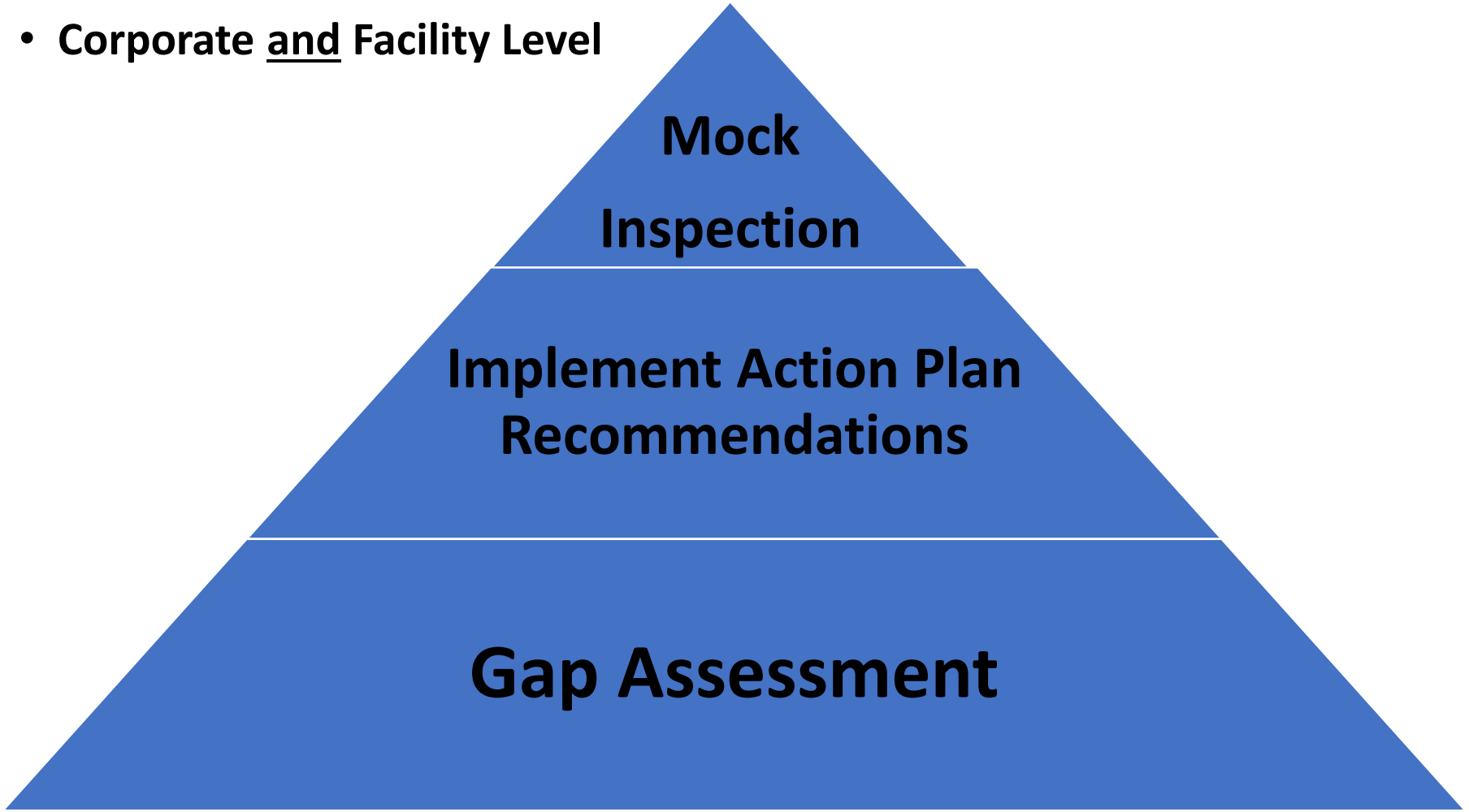


Kick The Tires--Do a Gap Assessment

- Third-Party Credibility
- Someone who knows how rules “intersect”
- FSMA…and beyond
  - Record retention, CAPA programs, EMP
- Recommendation in Form of an Action Plan
  - Risk-Based, Cost-Based
- Consider someone other than your CB
  - Different Lens
  - Think ERM
    - Business, Brand, & Legal/Regulatory Risks

Mock Regulatory Inspections

- **Corporate and Facility Level**



Consider Amping Up Your EMP Testing Programs

- **$55.5 Billion:** A 2015 study estimates the annual cost of medical treatment, lost productivity, and illness-related mortality due to microbiological food borne illness.
- **18%** of companies surveyed stated the recall cost was between $30 million and $99 million dollars.

5% said the financial impact was **> $100 million**.

❑ ***It's Cheaper to Test Before than Recall After!***

- Many EMP Programs have not been updated post FSMA.

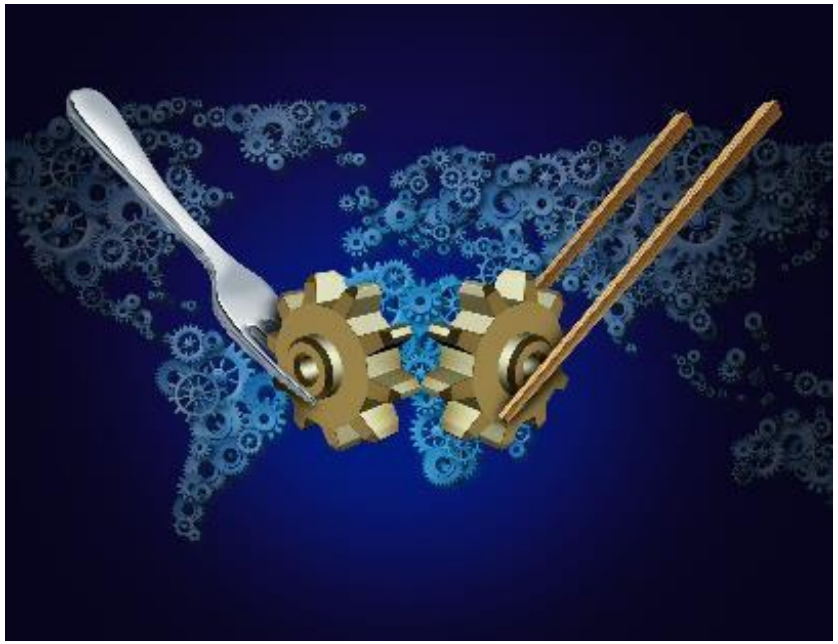
❑ ***RTE Post Process Prior to Packaging***

❑ ***Let your Data Guide You.***

Study by Robert Scharff, Associate Professor at The Ohio State University

Prepare for Upcoming FSMA Rules

FSVP, Sanitary Transportation, and More!



FSVP: What to Do?

- Intent – Imported foods must be produced in compliance with the preventive controls and produce safety rules, not be adulterated or mislabeled.
- Importers must develop, maintain, and follow a FSVP.
- **Definition of Importer** is different than before and its **Key**!

- Determine if the rule applies to you!
- If it does develop a plan if you need to.
- If it doesn't…identify if you use a broker / importer who it does apply to.
- Develop a monitoring / oversight plan.

IMPORTER:
Who is it?

- **An Importer is the U.S. Owner or Consignee of a food offered for import into the United States.**

- **If there is no U.S. Owner or Consignee, the Importer is the U.S. Agency or Representative of the Foreign Owner of Consignee at the time of entry, as confirmed in a signed statement of consent.**

FSVP: Compliance Dates

- **Importers that are themselves a manufacturer or processor subject to the Supply Chain Program provisions in the PC rules** compliance is the later of the applicable date in the below list **or** the date by which the importer is required to comply with the PC Supply Chain Program provisions.
- **FSVP importer whose foreign supplier is required to comply with the PC rule for human food**: Compliance dates range:
  - **First Up: "All Other" Businesses Suppliers**: **May 30, 2017.**
  - **Small Businesses** as defined in 21 CFR 117.3: **March 19, 2018.**
  - **Qualified Facilities** (including Very Small Businesses) as defined in 21 CFR 117.3: **March 18, 2019.**
  - **Long End:** Very Small Businesses under Produce Rule as defined in as defined in 21 CFR 112.3: **July 27, 2020**

Sanitary Transportation Rule:

Goal: To prevent practices during transportation that create food safety risks, such as failure to properly refrigerate food, inadequate cleaning of vehicles between loads, and failure to properly protect food.

- **Requirements** for vehicles and transportation equipment, transportation operations, records, training and waivers.

  Rules for:

  - Shippers
  - Carriers
  - Loaders
  - Receivers

- **Applies to motor or rail vehicles.**
- **Compliance Dates start one year after publication date of Rule**

Sanitary Transportation Rule

- **Effective Date 6/6/2016 - Compliance Dates 1 & 2 Years After Publication 4/6/2016**

Small Businesses—

- Businesses other than Motor Carriers who are not also Shippers and/or Receivers employing fewer than 500 persons **and**
- Motor Carriers having less than $27.5 million in annual receipts would have to comply two years after the publication of the final rule. **4/6/2018.**

Other Businesses—

A Business that is not small and is not otherwise excluded from coverage would have to comply one year after the publication of the final rule. **4/6/2017.**

Produce Safety Rule

- Agricultural Water
- Water Testing
- Biological Soil Amendments
  - Raw Manure & Composting
- Domestic and Wild Animals
- Training—Worker Health And Hygiene Standards
- Equipment, Tools, and Buildings

Produce Safety Compliance Dates

Business Size	Compliance Dates for Sprouts	Compliance Dates For All Other Covered Produce	Water Related Compliance Dates[1,2]	Compliance Date for Qualified Exemption Labeling Requirement [3]	Compliance Date for Retention of Records Supporting a Qualified Exemption
All other businesses (>$500K)	1/26/17	1/26/18	1/27/20	1/1/20	1/26/16
Small businesses (>$250K-500K)[4]	1/26/18	1/28/19	1/26/21		
Very small businesses (>$25K-250K)[5]	1/28/19	1/27/20	1/26/22		

Source: Produce Safety Alliance

Intentional Adulteration Rule

Applies to both domestic and foreign companies that are required to register with the FDA as food facilities.

- Covers large companies whose products reach many people > $10million.
- Exempting smaller companies; many other exemptions

Requirements:

- Food Defense Plan:
- Vulnerability Assessment:
  - Identify vulnerabilities and actionable process steps,
  - Mitigation strategies,
  - Procedures for food defense monitoring, corrective actions and verification.

- A **reanalysis is required** every three years or when certain criteria are met.

Compliance Dates

Very Small Businesses—a Business (including any subsidiaries and affiliates) averaging less than $10,000,000, adjusted for inflation, per year, during the three-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).

- These Businesses would have to comply with modified requirements within **five years** after the publication of the final rule.

Small Businesses—a Business employing fewer than 500 persons would have to comply **four years** after the publication of the final rule.

Other Businesses—a Business that is not small or very small and does not qualify for exemptions would have to comply **three years** after the publication of the final rule.

Final Rule Published May 27, 2016.


What to Expect

EXPECT: More Guidance To Issue

- **Read Them**
  - Not binding…
    - Wink wink..

- **Implement new learnings**
- **Anyone notice PCQI Parallelism ?**
- **Cite in References, Food Safety Plan when rely upon**

“Educate WHILE we Regulate” – not BEFORE

- **Recalling Based on Environmental Findings.**
- **Not Finished Product; Zone 1’s.**
- **Review EMP Programs, Documentation, What You Test for.**
- **What Pathogens Really are of Concern?**
- **What Does the Data Show?**

Now, more than ever… Industry is *likely* a step ahead in knowledge base.

“SWAB-A-THONS”

EXPECT: To Defend Through Documentation

- **EXPECT:**
- **Multi-Agency Investigations - Guilt Until Innocence?**

Criminal Liability Investigations Are Real

MORE!

Jensen Farms

Risks & Realities

The Risks

- FDA Is less trained than you are
  - They are training as they go
  - Audits @ a week; document heavy on food safety plans yet still on floor
- “May” is a very subjective standard (“may”… be injurious to health…”is standard in FD&C Act
- FDA has increased records access –this means copying too
- Stopping photos is getting increasingly difficult
- FDA is trying to solve past cold cases in CDC Pulsenet
  - About 1000 outstanding
  - Swabathons
  - Using WGS

New Regulatory Realities for FSQ/ Operational Success

Ensuring program Execution & Compliance everyday

Catching Issues Earlier before they become larger problems

Easy Access to Records for inquires, inspections & audits

Daily Visibility of Operational Trends to track & improve performance

Risks

Regulatory Non-compliance

Miss identifying trends

Delays, customer shortages

Waste, rework,

Customer returns

Customer & consumer complaints

Poor audits (3rd Party & Regulatory)

Recalls, scope larger than necessary

Poor Regulatory Relationship

Challenges

Managing / finding documentation in required timeframes

Missing documentation

Ensuring tasks completed; requirments met

Passive review of data collected

Incomplete records; lack of follow up

Responding to inquiries & audits

Identifying problem areas; root cause

No Closed Loop processes

Inability to trend

Data rich, information poor!


Useful Tips

Leverage Technology

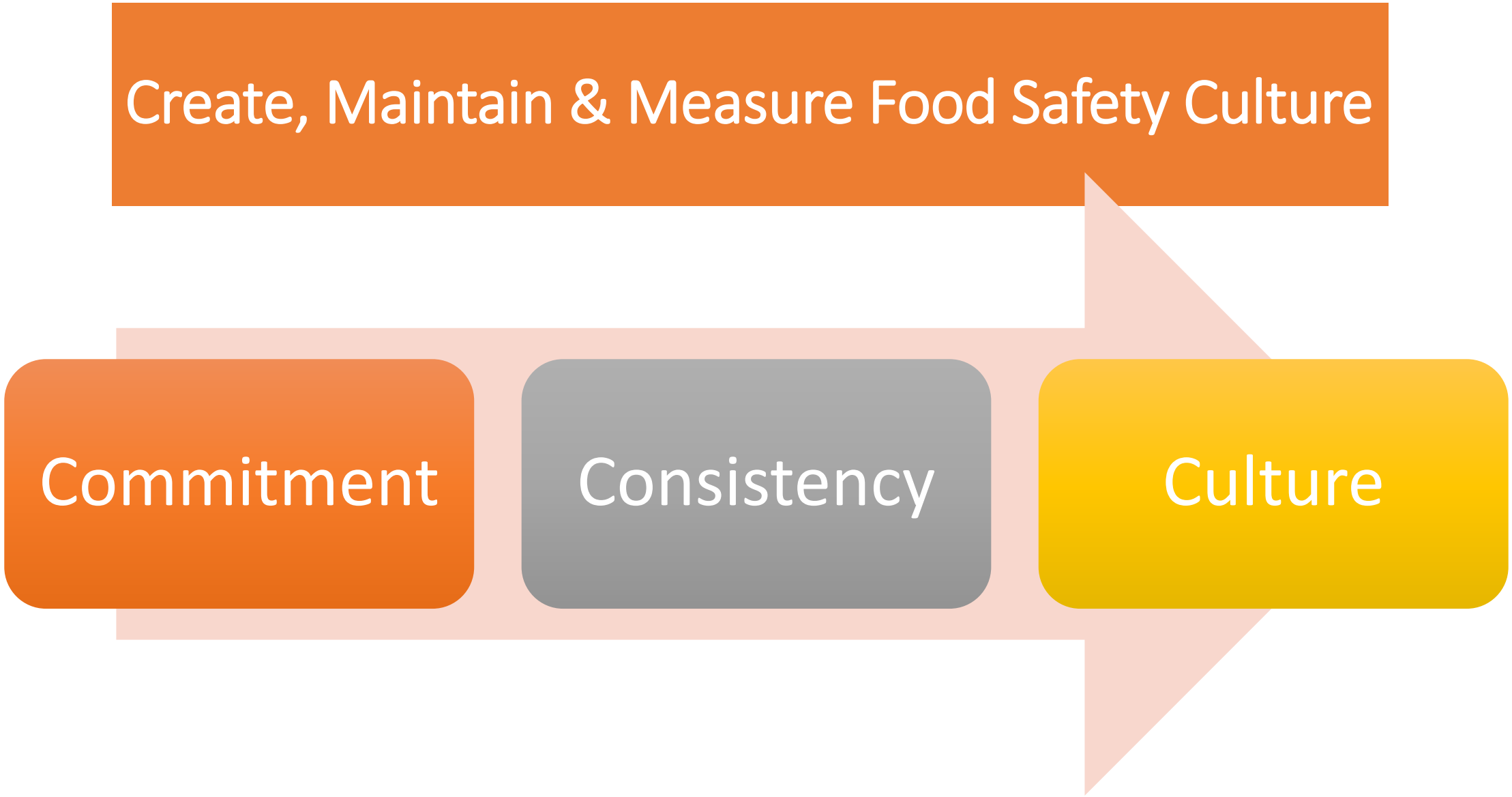
- Information and data analytics are your keys to successful prevention
  - Process controls
  - Supply chain controls
  - Testing results
  - Complaint Management
  - Product tracking
  - Recall Scope

- Let technology help you manage risk:
  - Unusual trends
  - Maintain required records for compliance
  - Enhances operational efficiency
  - Helps with CAPA process
  - Protects the brand, bottom line and consumer!

Have Your Policies In Order

- FDA inspection policy
  - Photo policy
  - Swabs
  - Signing 483's/NR's

Be Prepared


Create, Maintain & Measure Food Safety Culture
Commitment
Consistency
Culture

Parting Messages

How are the Leaders Do-ing It?

- Knowledge Sharing
- GFSI / Third-Party Certification
- Shaping Legislation
- Intensive Training / Education – Both Internal and External
- Supplier Summits; One-on-One's
- Supply Chain Risk Assessment & Management
- ***Leveraging Technology***
- Engaging the Consumer
- Labeling, Social Media, CRM Programs, etc.
- Testing—True Seek and Destroy Philosophy; Risk-Based
- ***Trending***

EXPECT: The Finish Line to Move!

Thank you!

Questions?

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