FSMA

ConAgra Foods

An Industry Perspective

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MCAFDO – February 24, 2016

ConAgra Foods Overview

ConAgra Foods started in 1919 as Nebraska Consolidated Mills.

In 1971, it was renamed ConAgra, Inc. and the company became ConAgra Foods in 2000.

ConAgra Foods (NYSE: CAG) is a Fortune 500 company with more than 20,000 employees worldwide. 15.8 billion in net sales for fiscal year 2015.

The company's world headquarters is moving to Chicago, Ill. in summer 2016.

Other key locations include: Omaha, Neb., Naperville, Ill. and Kennewick, Wash.

Our Brands


Hebrew National
Orville Redenbacher's
Healthy Choice
Banquet
RO*TEL
Reddi wip
Hunt's
Crunch 'n Munch
Marie Callender's
Blue Bonnet
Snack Pack
Slim Jim
Chef Boyardee
ACT II
Jiffy Pop
DAVID
Fleischmann's
Dennison's
PAM
Rosarita
BERTOLLI
GULDEN'S
ANDY CAPP'S
P.F. CHANG'S
Parkay
Del Monte
egg beaters
LambWeston
SEEING POSSIBILITIES IN POTATOES
WOLF BRAND CHILI
LA CHOY
RANCH STYLE
Orville Redenbacher's
POPPYCOCK
Wesson
PURE & 100% NATURAL
Gebhardt
Kangaroo
We bake really good stuff.
Peter Pan
AYLMER
Move Over BUTTER
Hunt's MANWICH
JM SWANK
All Natural ALEXIA
Libby's
Odom's TENNESSEE PRIDE Real Country Sausage
fiddle faddle
spicetec FLAVORS & SEASONINGS
VH
H·K ANDERSON
VanCamp's
CLAIM JUMPER
SWISS MISS
KID CUISINE

FSMA

aims to ensure the food supply is safe by shifting the focus from responding to contamination to preventing it.

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Interpreting the new regulations is a task in itself!

Understanding FSMA:
New Responsibility for the Food Industry

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Specific Provisions

§102: Registration of Facilities

§103: Hazard Analysis & Risk-Based Preventive Controls

§106: Protection Against Intentional Adulteration

§108: Food Defense

§204: Enhancing Traceability

FSMA impacts daily operations in all FDA registered facilities, domestic and foreign

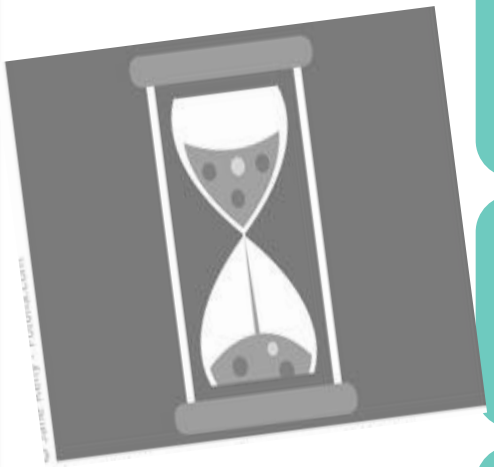
- Food Safety Systems
- Supply Chain Management
- Records Access and Maintenance
- Food Defense Plan
- Traceability

HOW DID CONAGRA INTERPRET THE NEW LAWS?

WE DIDN'T DO IT ALONE!!!

- GMA (Grocery Manufacturer's Association)
- GMA was the vehicle to submit comments for many companies about the proposed laws in the early stages
- ConAgra FSMA SME's were on GMA working groups
- GMA & the Working Groups work directly with the FDA
- GMA legal team helped interpret the law with help from the working groups and conversations with the FDA

New Deadlines for FSMA Final Rule



Final:	• Preventive Controls for Human Food • Preventive Controls for Animal Food
Final:	• Produce Safety • Foreign Supplier Verification Program • Accreditation of Third-Party Auditors
Mar/Apr 2016:	• Sanitary Food Transportation
May 2016:	• Intentional Adulteration • Food Defense

Main Elements of FSMA

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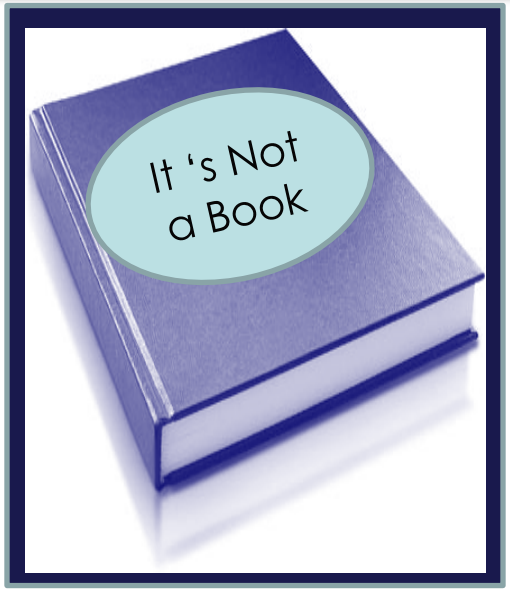
Food Safety Plan



§103: Hazard Analysis & Risk-Based Preventive Controls

Written food safety plan must include:

- Hazard Analysis
- Preventive controls
- Supplier Program
- Recall Plan
- Monitoring the Implementation of the Preventive Controls
- Corrective Action Procedures
- Verification Procedures

- **Qualified individual** (s) to prepare and implement food safety plan. This means documented training!

Food Safety Program

Written Plan

Documentation

Hazard Analysis

- Biological
- Chemical
- Physical
- Radiological
- Pesticides
- Allergens
- Unapproved Food or Color Additives
- Natural Toxin
- Unintentional Hazard
- Intentional Hazard

Preventive Controls

- Including those in GMPs & CCPs
- Sanitation
- Sanitary Design
- Hygiene Training
- Allergen Control
- Pest Management

Supplier Program

Recall Plan

Food Defense

Verification

- Preventive controls are adequate to control hazard
- Validation
- Monitoring
- Corrective actions
- Reanalysis
- Testing
- Environmental Monitoring

Corrective & Preventive Actions

- Take action to reduce likelihood of hazard recurrence
- Evaluate affected food
- Prevent affected food from entering commerce
- Document efficacy

Prepared and implemented by Qualified Individual

Hazard Analysis Risk Based Preventive Controls Requirements

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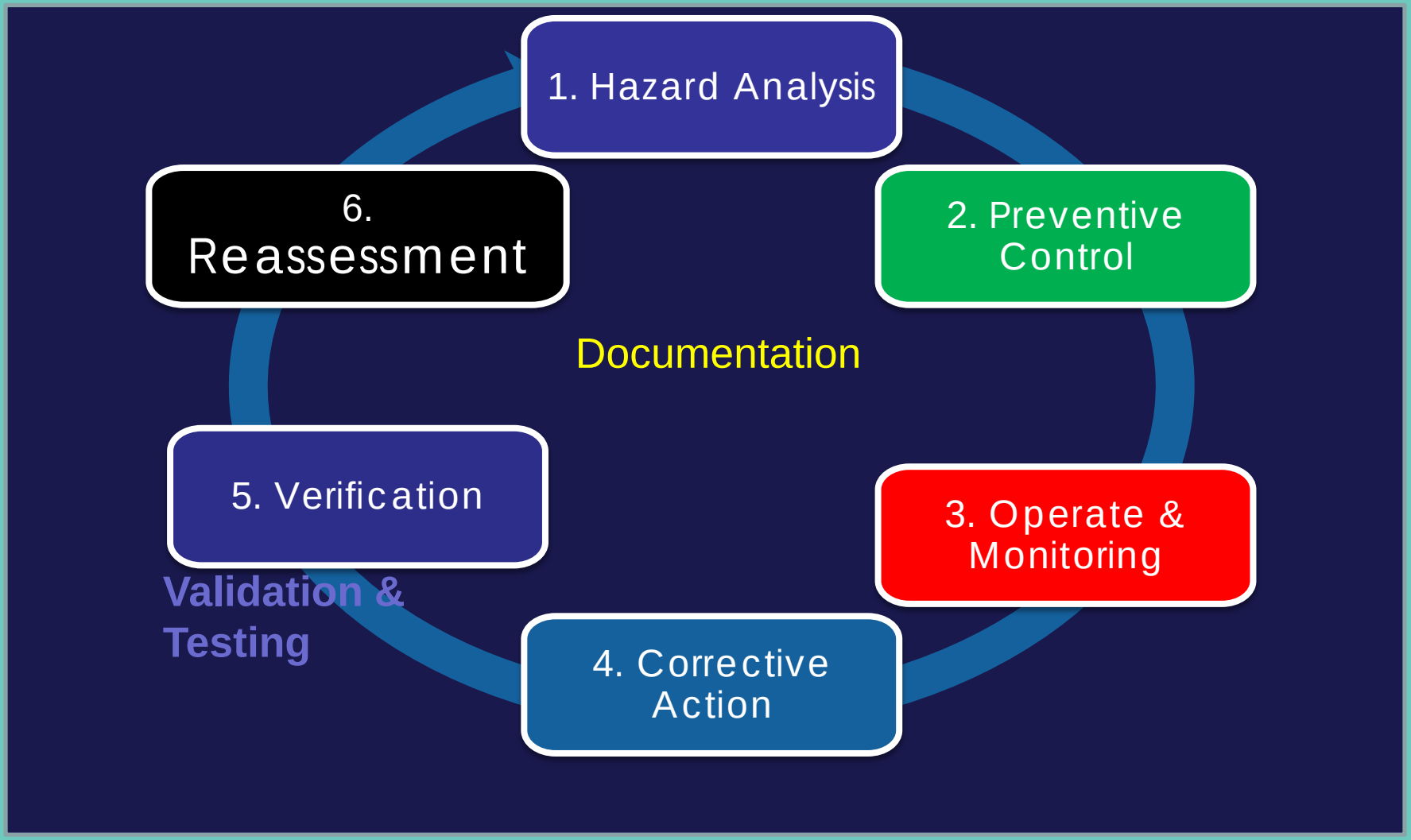

Hazard Analysis

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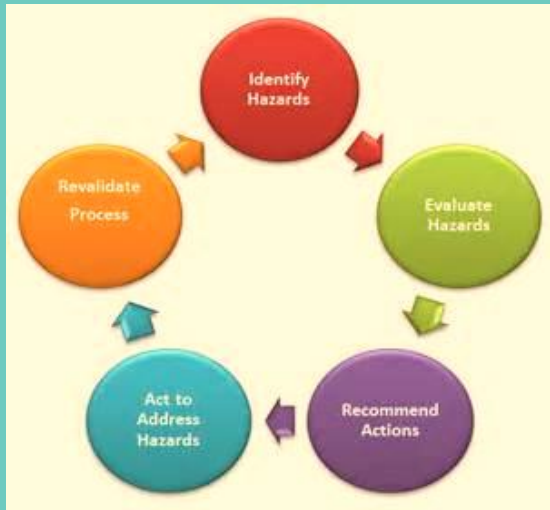
Hazard Analysis must include:

Hazard identification biological, chemical (radiological), physical, naturally occurring, unintentional and intentional hazards

- Assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.
- Hazard evaluation must consider the following :
  - Formulation
  - Condition, function and design of the facility and equipment
  - Raw material and ingredients
  - Transportation practices
  - Manufacturing/ processing procedures
  - Packaging and labeling activities
  - Storage and distribution
  - Intended or reasonably foreseeable use
  - Sanitation (including employee hygiene)
  - Any other relevant factors



Preventive Controls

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Preventive Controls

Must be written

Preventive controls must include: Procedures, Processes and practices .

Preventive controls as appropriate to food and facility:

- Controls at critical controls Points (CCPs) if there are any CCPs
- Controls, other than those at CCPs that are also appropriate for food safety

Preventive Controls Required:

- Process control
- Food allergen controls
- Sanitation controls
- Supplier controls

Monitoring

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To provide assurance that the outcomes shall be achieved.

Establish and implement written procedures for monitoring sanitation controls

- Would include frequency of monitoring activities
  - FSMA does not specify monitoring frequency, but states that monitoring must be performed at adequate frequency to ensure that the PCs are being performed consistently.

Monitoring activities shall be

- Documented
- Subject to verification activities, including records review by a qualified individual within a week after the records are created

Management of Preventive Controls

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HARPC What you should know

We all agree that not all controls should be managed the same way (slide scale concept)

Level of oversight for various preventive controls is flexible based on the nature of the control

Examples provided in the preamble include:

- Not all monitoring activities generate records
- Not all corrections required records
- Not all preventive controls requires validations
- Not all corrective actions require verification

Difference Between Correction, Corrective Action and Preventive Action

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Correction

- Action to eliminate a detected nonconformity
- Fix the symptom(s) of an existing problem

Corrective Action

- Action to eliminate the cause(s) of a detected nonconformity and hazard
- Fix the cause(s) of an existing problem to stop its recurrence

Root Cause Analysis

Preventive Action

- Action to eliminate **the cause (s) of** a Potential nonconformity or hazard
- Fix the cause(s) of a potential problem to stop its occurrence

Verification

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Confirmation the controls implemented are being followed

Must verify that-

- The preventive controls are adequate to control the hazards identified
- [They are] conducting monitoring
- [They are]making appropriate decisions about corrective actions
- The preventive controls are effective and SMOP (Significantly Minimize or Prevent) the occurrence of identified hazards, including the use of environmental programs and other appropriate means.
- There is documented, periodic reanalysis of the procedures to ensure that the procedures are still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats

Recordkeeping

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Facilities must establish and maintain records documenting:

- monitoring of preventive control
- Instances when corrective action where implemented
- verification activities
  - review, reanalysis
  - calibration
  - environmental test

Instances of nonconformance material to food safety

Efficacy of preventive controls and corrective action

Testing - Environment

- Verification activity
- Evaluate when
  - RTE food is exposed to the environment prior to packaging
  - Food does not receive a treatment that would significantly minimize the pathogen.
- Procedures need to
  - identify the location and sites
  - timing and frequency
  - Actions required

Testing - Product

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- Consider: ingredient testing, in process testing, and finished products
- Procedures required to specify sampling, tests conducted and corrective actions
- Corrective action procedures required to address the presence of an EP or appropriate indicator organism
- Key to understand what suppliers and external manufacturers are doing

Supplier Verification

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Requirements for Supplier Program for raw materials and ingredients:

- Applies to both foreign and domestic facilities

Receiving facility must have a written supplier program that includes:

- Hazard analysis and risk evaluation
- Supplier's procedures, processes and practices related to the safety
- Supplier 's compliance with FDA food safety regulations (i.e. FDA inspection, import alert)
- Supplier's food safety performance history
- Storage and transportation
- Must understand (in writing) who is controlling risk

Recall Plan

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Written recall plan must include:

- Procedures that describe steps to be taken, and assigned responsibility for taking those steps to perform the following actions:
- Directly notify the consignees of the food being recalled, including how to return or dispose of the affected food
- Notify the public about any hazard
- Procedures to conduct effectiveness checks to verify that the recall is carried out
- Procedures for appropriate disposition of recalled food
- Recall plans must be “tested” by those who perform the functions

New Food Import Controls

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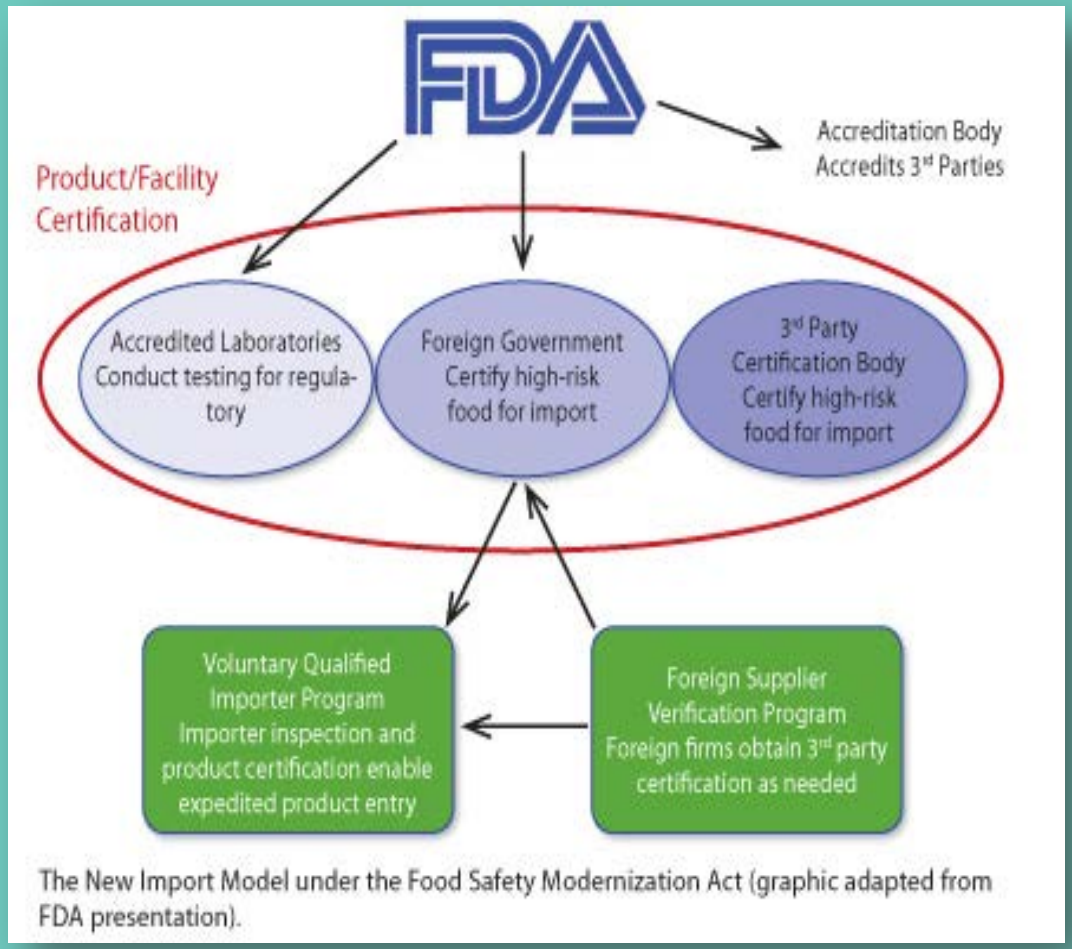
Specific Provisions

- **§ 201:** Imports: Inspection Risk Factors
- **§ 301:** Foreign Supplier Verification Program
- **§ 302:** Voluntary Qualified Importer Program
- **§ 303:** Requirement for Import Certification
- **§ 304:** Prior Notice of Imported Food Shipments
- **§ 307:** Accreditation of 3rd Party Auditors



The New Import Model under the Food Safety Modernization Act (graphic adapted from FDA presentation).

FSMA's Import Tool Kit

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New authorities, mandates work together to create integrated import safety system

- Foreign supplier verification programs (sec. 301)
- Voluntary qualified importer program (sec. 302)
- Mandatory certification (sec. 303)
- Enhancements to prior notice (sec. 304)
- Building capacity of foreign governments (sec. 305)
- Improved enforcement authorities (sec. 306)
- Accreditation of third-party auditors (sec. 307)
- Foreign offices (sec. 308)

Foreign Supplier Verification Program

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Foreign suppliers must produce food in manner consistent with FDA regulation

Should assure that food is not adulterated or misbranded

Consideration of supplier risks

Approach to SAHCODHA hazards

(Serious Adverse Health Consequence or Death to Humans or Animals)

Confidentiality of audit reports

Approve supplier

Foreign Supplier Verification Program

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Where do we have concerns?

- Importer of Record Owns Understanding Risk
- We own making sure they are doing what they are supposed to do!
- Many brokers do not understand Food Safety
- Even if we are not the importer of record- this can still mean a lot of work!

Training

It can feel overwhelming....

Plants
Co-Manufacturers
Suppliers

- PCQI training – lots of plant & corporate folks…
- 100's & 100's to be trained on SOP changes at the plant & corporate level

Let's Boil This Down

Where Should Plants Start-

- If on HACCP- start by making a list of any pre-requisite programs in the Hazard Analysis
- If on HARPC- already have this list

Take these procedures and make sure these elements are included

- How are you documenting?
- Verification (and Validation where necessary)
- Corrective Actions
- Monitoring

What are some of things we are doing to prepare our plants?

- HACCP to HARPC training and deployments
- Executive Summaries
- Audit Template Revisions - start asking questions now
- Rolling FSMA Interpretations into Policies and Procedures Updates
- Bi-monthly calls
  - Procedure Reviews
  - Best Practice Sharing
  - Q and A from plant personnel

Corporate Managed Programs

Even if corporate owns a “function”, such as supplier approval, the plant personnel need to understand it and be able to speak to it.

You don’t have to be the SME but you need basic knowledge.

Example of best practice-
Executive Summaries

Two Tiered Inspections

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FDA is evaluating an inspection process in which centralized functions of a major food company will be inspected separately from that of a plant.

- FDA requested partners in a pilot of the tiered inspection program
- FDA will use this experience to refine the FSMA inspection process and provide facilities with guidance
- FDA has identified 30 inspectors who are specialists in FSMA Preventive Controls
- Inspectors will each inspect at least 10 facilities for Preventive Control compliance beginning in September 2016


Questions?
Thanks