GFSI-Compliant Prerequisite Program/Preventive Controls Matrix

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Agenda

- **Food Safety Overview**
    - Why Food Safety Improvement is a Priority
    - Government Response to Need for Improvement
    - Food Industry Response to Need for Improvement
- **Progressive Change in Food Safety Plan Structure**
- **Some Key GFSI-Compliant Food Safety Plan Attributes**
    - Very strong, cross-functional Food Safety Team (FST) to oversee the Plan
    - Risk-based HACCP plan with PAS220-compliant Prerequisite Programs (PRP)
    - Thorough, science-based, risk assessment and hazard analysis program
    - FSMA-mandated Preventive Controls (PC) defined, implemented and verified to significantly minimize or prevent hazards from occurring
- **GFSI-Compliant PRP/PC Matrix for FST Oversight of the Food Safety Plan**

Food Safety Overview

- ## **Why Food Safety is a Priority:**
  - Current Global Business Climate
    - We are more dependent on imported food products in our global supply chains (~20% of the US food supply is imported)
    - Businesses face catastrophic consequences from media-hyped adverse events
    - Food safety systems today are not preventing food-borne illness and death

  - High Profile Recalls
    - Fresh Spinach in 2006; Melamine in 2007; PCA in 2009; Daniele Salami and Basic HVP in 2010, etc.

  - Actual and Perceived Threats to Consumer Health
    - Regulatory framework and inspection systems could not secure the food supply chain
    - Food illness is a significant burden per CDC data
      - About 48 million (1 in 6 Americans) get sick each year
      - 128,000 are hospitalized
   - About 3,000 die

Food Safety Overview

Government Response: FDA Reportable Food Registry (RFR)

RFR Established by FDA in September 2009 to track patterns of food adulteration

- Requires food facilities to file a report through an FDA electronic portal within 24 hours of determining it is a reportable food.

- A reportable food exists when there is reasonable probability that exposure to that food will cause serious or adverse health consequences or death to humans or animals.

- FDA Reportable Food Registry (RFR)
  1st Annual Report Results
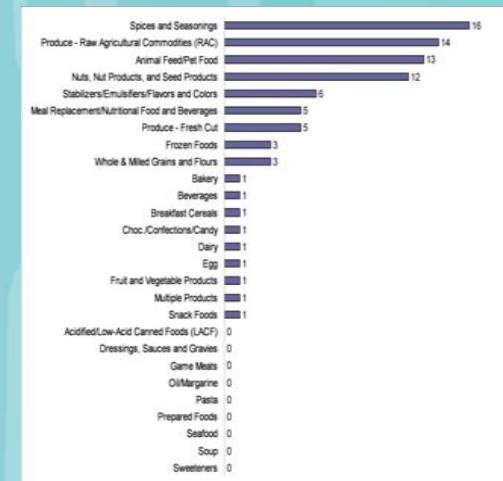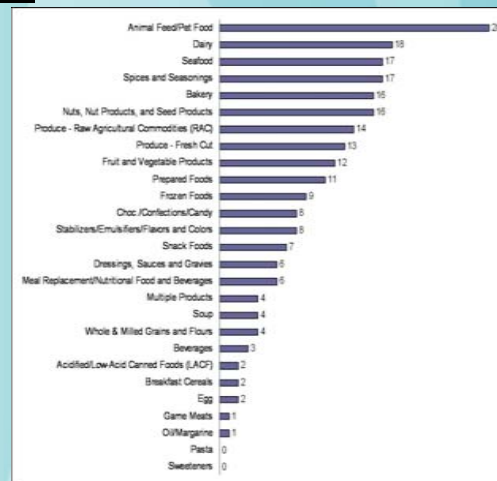
- Passed Food Safety Modernization Act (FSMA)
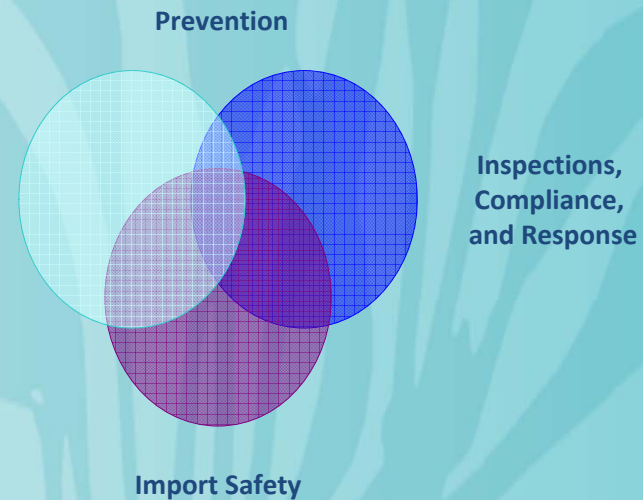
Food Safety Overview

Government Response: Food Safety Modernization Act (FSMA)

FSMA Signed into law on January 4, 2011

- Shifts the focus of the food safety system and the key players in it from responding to contamination issues to preventing them.
- Involves creation of a new risk-based food safety system
- Includes new system of import oversight
- Emphasizes farm-to-table responsibility
- Requires the FDA to institute more than 40 actions including 12 rulemakings, 10 guidance documents and numerous other papers, projects and tasks over the next 18 months
- Emphasizes partnerships between:

    - FDA
    - Food Industry
    - Academia

Prevention

Enhanced Partnerships

Inspections, Compliance, and Response

Import Safety

Food Safety Overview
Government Response: __FSMA - Effective Now__

- Mandatory Recall Authority Given to the FDA
- Bi-annual Registration of all Food Facilities Doing Business in the US
- Mandated Inspections of Both Domestic and Foreign Food Facilities
- Mandated Fees for Re-Inspecting Companies Failing Their Inspections and Not Complying with Recall Orders (October 2011)
- Administrative Detention Rules - FDA has Authority to Detain any Food it has Reason to Believe is Adulterated or Misbranded (May 2011)
- Prior Notice of Imported Foods Regulation - FDA must have prior notice of country where product was refused entry (May 2011)
- Establishment, Maintenance and Availability of Records - FDA Can Now **Require** Records Related to Hazard Analysis, Preventive Controls, Corrective Actions and Product Monitoring and Testing on any product being run during that time period (IFR on February 28, 2012)

Food Safety Overview

Government Response: <u>FSMA - Effective in Next 6 Months</u>

- Final Rule for Hazard Analysis and Preventive Controls Plan That Must be Performed and Documented at all Registered Facilities
- FDA to Report to Congress the results of Their Traceability Pilot Projects (Major IFT Project)
- Final Rule for Implementation of Voluntary Qualified Importer Program - enables qualified companies to expedite product through import process
- Final Rule for the Requirements for the Import Certificate Program for High Risk Imported Food Products

Food Safety Overview
Government Response: <u>FSMA – Effective in Next 12 Months</u>

- ## Foreign Supplier Verification Program Must Be Implemented
    - Every US Importer will be required to Have a Foreign Supplier Verification Plan in Place
        - Risk Based Hazard Analysis Performed
        - Preventative Control Plans Defined and Implemented
        - Annual Onsite Inspections Required
        - Lot by Lot Certification

- ## Laboratory Accreditation Program Must Be Implemented
    - All Tests Performed for Regulatory Purposes Must Be Done By Accredited Lab
    - Independent Private, Foreign and Government Labs to Be Accredited
    - All Regulation-Required Test Results Must be Submitted Directly to the FDA

- ## Third Party Auditor Accreditation Program Must Be Implemented
    - FDA to Create System for Recognition of Accreditation Bodies to Accredit Third Party Auditors to Certify Foreign Facilities as Producing to US Regulatory Standards

Food Safety Overview
Food Industry Response: Defined & Implemented Proactive, Risk-Based Food Safety Management Systems

- Moved away from Quality and Sanitation system to their own Food Safety audit schemes managed by them or contracted to a third party

- Much more focus on their vendors integrating Supply Chain Management into their risk-based Food Safety programs

- Increased Auditing to the Requirements of the FDA/USDA Guidance Documents pertaining to Food Security and Defense Plans for Food Facilities

- Moved to a much more intense focus on Hazard Analysis Critical Control Point (HACCP) Plans and how they were being managed and defined

Food Safety Overview

Food Industry Response: <u>Mandatory Certification to GFSI-Approved Food Safety Management Systems</u>

Wixon Response:

Food Safety System Certification 22000

- Wixon is certified to the Food Safety System Certification 22000 (FSSC 22000) food safety management system.

- *FSSC 22000* is a globally recognized food safety management standard approved by the Global Food Safety Initiative (GFSI).

- *FSSC 22000* is a combination of the ISO 22000 & PAS 220 (ISO 22002) standards
  - ISO 22000 details the food safety management system requirements
  - PAS 220 details the requirements for all prerequisite programs

- *FSSC 22000* is a food safety management system (FSMS) that is rooted in HACCP-based hazard analysis & risk assessment

Progressive Change in Food Safety Plan Structure

- From cGMP's ➩ Prerequisite Programs (PRP)
- HACCP + PRP ➩ GFSI certification to approved food safety management standards (SQF, BRC, FSSC22000, IFS, etc.)
- **GFSI ➩ FSMA-mandated, proactive Food Safety Plans based on Hazard Analysis and risk-based, scientifically valid Preventive Controls**

Prerequisite Program Definition

- Essential component of an establishment's operations that are intended to keep low-risk potential hazards from becoming serious enough to adversely impact the safety of foods being produced

- Provide basic environmental and operating conditions necessary for production of safe, wholesome food.

- Should be well-documented as written standard operating procedures (SOP's)

- Should be revised, reviewed and audited against by the FST periodically

- Typically are general in nature covering multiple lines/areas

- Unlike HACCP programs, deviations from them may not be serious

Examples:

cGMP, Environmental Monitoring, Allergen Control, Pest Control, Preventive Maintenance, Traffic Flow, Facility Security Plan, Chemical Control, Glass & Brittle Plastic Control, Metal Detection, Vendor Management, Waste Management, Sanitation and Cleaning, Employee Training Programs, Product Testing & Approval, Change Management, Water Quality, Calibration, Records, Specification Control, Customer Complaint Program, CAPA Program, Employee Services, Local Environment Control, Inventory Shelf-life Management, Landscaping Program and many others.

Hazard Analysis Definition & FSMA Requirements

The owner, operator or agent in charge of a facility and/or the FST **must**:

- identify and evaluate known or reasonably foreseeable hazards that could affect food manufactured, processed, packed, or held by the facility
  - Including biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition hazards, parasites, allergens, and unapproved food and color additives
  - hazards that occur naturally, or may be unintentionally introduced
  - hazards that may be intentionally introduced, including by acts of terrorism
- identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards.
- prepare a written plan describing the procedures used by the facility to comply with the FSMA requirements. This Preventive Control Plan (PCP) **must**:
  - include a written analysis of the hazards identified
  - include a written analysis of the preventive controls used to significantly minimize or prevent the identified hazards from occurring

Preventive Controls Definition & FSMA Requirements

- Are scientifically valid, risk-based practices that facilities use to address hazards that their products might be exposed to

- Will typically be much more specific than PRP and are targeted at controlling specific hazards identified in the PCP

- All facilities will not have the same hazards or preventive controls. Each plan should be tailored to fit the facility and the risks associated with that facility's food.

- The owner, operator, or agent in charge of a facility and/or the FST shall identify and implement preventive controls, including at the defined critical control points, to provide assurances that all hazards identified in the hazard analysis will be significantly minimized or prevented

- The owner, operator, or agent in charge of a facility and/or the FST shall monitor the effectiveness of the implemented preventive controls to provide assurances that the anticipated outcomes have been achieved.

- FDA's intention is that all covered facilities would need to develop a plan;

Verification - FSMA Requirements

- The owner, operator, or agent in charge of a facility and/or the FST shall **verify** that the preventive controls implemented are adequate to control the hazards identified in the Preventive Control Plan (PCP)

- The owner, operator, or agent and/or the FST is conducting **monitoring** in accordance with the requirements defined in the PCP

- The owner, operator, or agent and/or the FST is **making appropriate decisions** about corrective actions taken under the PCP

- The preventive controls implemented under PCP are effectively and significantly minimizing or preventing the occurrence of identified hazards, as **verified** through the use of environmental and product testing programs and other appropriate means

- Documented, periodic **reanalysis** of the PCP to ensure that it is still relevant to the raw materials, conditions and processes in the facility, including any new or emerging threats

Recordkeeping - FSMA Requirements

The owner, operator, or agent in charge of a facility and/or the FST shall maintain, for not less than 2 years, **records** documenting the:

- monitoring of the preventive controls,
- instances of nonconformance material to food safety
- the results of testing and other appropriate means of verification
- instances when corrective actions were implemented
- the efficacy of preventive controls and corrective actions

Preventive Control Plan – FSMA Requirements

The owner, operator, or agent in charge of a facility and/or the FST shall prepare a written plan that documents and describes:

- the procedures used by the facility to comply with the specific requirements of the Hazard Analysis and Preventive Control requirements section including:
  - analyzing the hazards
  - identifying the preventive controls adopted to significantly minimize or prevent those hazards
- This written plan, together with the other documentation that was discussed, shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request (i.e. FDA inspectors)

GFSI-Compliant Prerequisite Program/Preventive Controls Matrix

- A great tool to use to summarize your FSMA-mandated Food Safety Plan for your Food Safety Team, employees for training purposes and of course for your internal, external and 3rd party auditors

- You can combine your new or previously defined PRP programs with your soon to be defined Preventive Controls (PC) into one easy to read (and share) document

- At the same time, you can cross-reference your PC and PRP to the individual requirements of the GFSI-compliant PAS220 PRP Standards

Questions?

Thank you