



Representing the Makers of the World's Favorite Food, Beverage and Consumer Products



Implications of the Food Safety Modernization Act – February 2015 Update

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www.gmaonline.org

Agenda

- ❖ Introduction and Overview
- ❖ Key Takeaways
- ❖ Key Points from Supplemental Proposed Rules
 - Preventive Controls for Human Food
 - Preventive Controls for Animal Food
 - Foreign Supplier Verification Program
 - Produce Safety
- ❖ Question and Answer Session



Introduction

- ❖ FDA first issued proposed rules to implement the FDA Food Safety Modernization Act (FSMA) in 2013
- ❖ FDA released four supplemental notices of proposed rulemaking on September 19, 2014
 - Comments on the revised provisions were due December 15, 2014
- ❖ FDA is under court order to issue final rules by
 - August 30, 2015 (Preventive Controls)
 - October 31, 2015 (FSVP and 3PAC)
 - October 31, 2016 (Intentional Adulteration)



Scope of the Supplemental Proposals

- ❖ FDA has not issued complete re-proposals of the rules proposed in 2013
- ❖ Only those issues contained in the supplemental proposals are open for comment
 - FDA will not accept comment on issues raised in the original proposals but not specifically addressed in the supplemental proposals
- ❖ FDA will continue to review comments submitted to the original proposed rules
 - These and issues raised by the supplementals will be addressed in the final rules

Key Takeaways

1. FDA is directly responsive to many requests from the food industry
2. The revised regulations are more flexible and more risk-based, and tailored
3. What you see is likely what you will get
4. Many major issues have been resolved, but others won't be until the final rule
 - E.g., consumer complaints & Part 11 Compliance



Preventive Controls



Overview of Key Provisions

- ❖ Hazard Analysis
 - RLTO has been replaced with “significant hazard”
 - Evaluate “severity” and “probability”
 - Consider economically motivated adulteration
- ❖ Management of Controls
 - FDA agrees that not all controls should be managed the same way (“Sliding scale” concept)
 - Repeated use of the phrase “as appropriate to the nature of the preventive control”
- ❖ Testing
 - FDA proposes specific regulatory language for both product testing and environmental monitoring
 - FDA suggests RTE products appropriate candidates for product testing
 - No reference to Zone 1 testing

Overview of Key Provisions Continued...

- ❖ Supplier Verification
 - Very detailed requirements, but limited to circumstances where the supplier is controlling any significant hazards
 - Supplier risks taken into account
 - Hybrid approach for onsite audits
 - Confidentiality of audit reports
 - Consistent with FSVP
- ❖ Human Food By-Products Diverted to Animal Feed
 - Subject to human food requirements up to point of diversion, then GMPs for holding and distribution
- ❖ Animal Food GMPs
 - Revised to be more tailored to diverse animal food facilities

Overview of Key Provisions Continued...

- ❖ Small business definition
 - \$1 million total annual sales of human food
 - \$2.5 million total annual sales of animal food
 - Would be qualified facilities subject to modified requirements
- ❖ Revised definitions for “farms,” “packing,” and “holding”



Hazard Analysis

- ❖ FDA proposes to remove the term “reasonably likely to occur” and replace it with “significant hazard”:
 - A “known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of the hazard analysis, establish controls to significantly minimize or prevent the hazard in a food component to manage those controls . . . As appropriate to the food, the facility, and the nature of the control.”
- Facilities would evaluate “significant hazards” by assessing “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 preventative controls. (our emphasis)”

Implementation of Preventive Controls

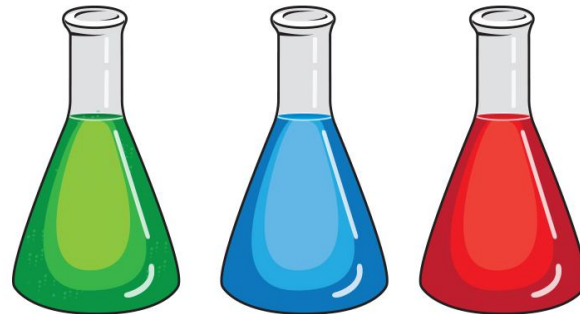
- ❖ Preventive controls would be implemented to significantly minimize or prevent (SMOP) significant hazards
- ❖ The regulations would explicitly provide that:
 - Preventive controls include controls other than those at critical control points (CCPs)
 - Parameters (max/min values) only needed for process controls

Management of Preventive Controls

- ❖ Level of oversight for the various preventive controls (referred to as “management components”) is flexible based on the nature of the control
- ❖ Examples provided in the preamble include:
 - Not all monitoring activities generate records;
 - Not all corrections require records;
 - Not all preventive controls require validation; and
 - Not all corrective actions require verification

Product Testing

- ❖ FDA proposes to require product testing as a verification activity (“as appropriate”)
- ❖ “Product testing” would encompass ingredient testing, in-process testing, and finished product testing
- ❖ Facility corrective action procedures would be required to address the presence of an environmental pathogen or appropriate indicator organism in a ready-to-eat (RTE) product tested through product testing



Environmental Monitoring

- ❖ As part of the hazard evaluation, FDA proposes to require an evaluation of environmental pathogens whenever a RTE food is exposed to the environment prior to packaging and the food does not receive subsequent lethality treatment
- ❖ FDA proposes to require environmental monitoring as a verification activity if contamination of a RTE food with an environmental pathogen is a significant hazard
- ❖ Environmental monitoring procedures would need to:
 - Identify the locations and sites for routine environmental monitoring;
 - The timing and frequency of monitoring; and
 - Address the presence of an environmental pathogen or appropriate indicate organism detected through environmental monitoring

Supplier Verification - Scope

- ❖ FDA proposes to require a “supplier program” for raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt
 - If you or your customer control the hazards, no SP
- ❖ “Suppliers” are establishments that manufacture or process food, raise animals, or harvest food that is provided to a receiving facility without further processing
- ❖ “Receiving facilities” manufacture or process raw materials or ingredients that they receive from suppliers



Supplier Verification – Scope continued...

- ❖ Facilities that pack or hold food without manufacturing are not suppliers
- ❖ Facilities would not be required to establish a supplier program for food they only pack or distribute
- ❖ Receiving facilities would be required to establish supplier verification activities if they receive material from a distribution center and they identify a significant hazard in the material that is controlled by the supplier to the distribution facility

Supplier Verification – Scope continued...

- ❖ If a facility receives an ingredient from a supplier, but the hazard is controlled by the supplier's supplier, the receiving facility would conduct supplier verification activities that would include verifying that the supplier has conducted appropriate verification that its supplier has controlled the hazard
 - For example, the receiving facility could review the supplier's food safety records for its supplier program

Verification Activities continued...

- ❖ FDA provides flexibility for facilities to determine the appropriate verification activities based on:
 - (1) the severity of the hazard;
 - (2) where the preventive controls for those hazards are applied;
 - (3) the supplier's food safety practices;
 - (4) the supplier's compliance with FDA food safety regulations;
 - (5) the supplier's food safety performance history; and
 - (6) any other factors, such as storage and transportation

Verification Activities continued...

❖ SAHCODHA Hazards

- Initial onsite audit and annually thereafter
- *unless* the facility documents its determination that other verification activities and/or less frequent audits provide adequate assurance

❖ Special suppliers

- Facilities could conduct alternative verification activities for materials received from
 - qualified facilities
 - a farm not subject to requirements under the produce safety rule



Verification Activities- Approved Suppliers

- ❖ FDA proposes to require verification activities, as well as documentation, to ensure materials are received only from approved suppliers
 - No “list” required
 - When necessary and appropriate, materials could be received on a temporary basis from unapproved suppliers whose materials the receiving facility subjects to adequate verification activities before acceptance for use

Documentation of Supplier Verification

- ❖ FDA proposes minimum requirements for:
 - Records documenting an audit;
 - But not the underlying audit report
 - Records of sampling and testing;
 - Records documenting review of the supplier's relevant food safety records; and
 - Documentation of alternative verification activities for suppliers that are qualified facilities or farms not subject to the produce rule
- ❖ FDA explains that it would expect many of the records to be accessible during facility inspections because they would be in electronic form



Supplier Programs and Deemed Compliance with FSVP

- ❖ Deemed compliance with FSVP
 - If an importer is required to establish and implement a risk-based supplier program under the preventive controls regulations (for either human or animal food), and the importer is in compliance with those requirements
 - If an importer's customer is required to establish and implement a risk-based supplier program under the preventive controls regulations (for either human or animal food), and the importer annually obtains written assurance that its customer is in compliance with those requirements

Economically Motivated Adulteration (EMA)

- ❖ FDA proposes to require the hazard identification to consider hazards that may be intentionally introduced for purposes of economic gain
 - Focus is on adulterants that are reasonably likely to cause illness or injury in the absence of their control
 - Not focused on adulterants that solely affect quality and value
- ❖ FDA suggests it is practicable to determine whether EMA is reasonably foreseeable by focusing on circumstances where there has been a pattern of adulteration in the past

“Farm Definition”

- ❖ FDA proposes to revise the definition of “farm”
 - A farm would no longer be required to register as a food processor merely because it packs or holds raw agricultural commodities (RACs) grown on another farm not under the same ownership
 - A farm could manufacture or process RACs by drying or dehydrating to create a distinct commodity, and package and label the commodity, as long as there is no additional processing
 - Would be exemption from PC, but not GMPs (but could satisfy requirement through compliance with produce safety rules)



“Farm Definition” continued...

- ❖ FDA clarifies that an establishment devoted to growing crops, raising animals, or both, can remain within the “farm” definition if it packages RACs grown or raised on a farm to prepare them for storage and transport, without additional manufacturing or processing
 - Packaging activities would continue to qualify as manufacturing or processing
 - Packaging a RAC would not transform the RAC into a processed food
- ❖ Farms that manufacture or process products such as dried, cut apples **would be** a farm mixed-type facility subject to registration and preventive control requirements

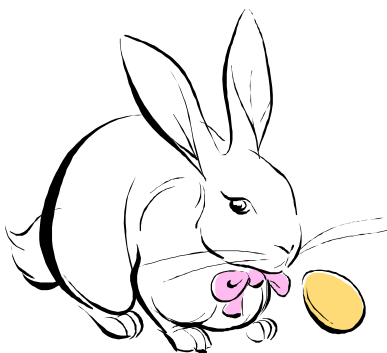


Very Small Business

- ❖ FDA proposes to define a “very small business” as a business that has less than \$1 million in total annual sales of human food
- ❖ A company’s status as a “very small business” impacts the compliance date for those facilities and the exemption for qualified facilities
- ❖ The proposed revision would essentially make “very small business” and “qualified facility” synonymous

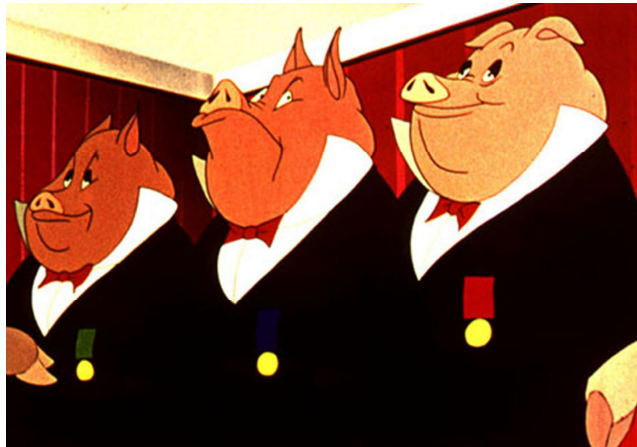


Preventive Controls for Animal Food



Overview

- ❖ The preventive control requirements for animal food are essentially the same as those for human food
- ❖ FDA responded to industry concerns regarding human food by-product diverted to animal food



Diversion of By-Products

- ❖ FDA proposed that human food processors already complying with human food safety requirements would not need to implement additional preventive controls or GMPs when supplying a by-product for animal food
 - Exception: Proposed GMPs to prevent physical and chemical contamination when holding and distributing the by-product would require compliance with Preventive Controls for Animal Food rule
- ❖ This exemption would **not** apply:
 - When contamination or adulteration has occurred that is material to food safety; or
 - To human food by-products derived from animal products such as meat and/or poultry
 - To by-products that are further processed (i.e., citrus pellets)

Diversion of By-Products continued...

- ❖ New GMP requirements for holding and distributing human food by-products would include:
 - Containers used to hold animal food before distribution must be designed, cleaned, and maintained to prevent contamination;
 - Animal food held for distribution must be held in such a way to prevent contamination;
 - Labeling identifying the by-product by the common or usual name must be affixed to or accompany the animal food; and
 - Shipping containers and bulk vehicles used to distribute animal food must be inspected prior to use

Foreign Supplier Verification Program (FSVP)



Overview of FSVP Proposal

- ❖ Closely tracks supplier verification program in supplemental proposed rule for preventive controls
 - Consideration of supplier risks
 - Approach to SAHCODHA hazards
 - Confidentiality of Audit Reports
 - Approved supplier list
 - Deemed compliance

Purpose of Supplier Verification

- ❖ FDA proposes that the purpose of an importer's supplier verification activities should be to provide assurances that the foreign **supplier** produces food in a manner consistent with FDA regulations
 - Should assure that food is not adulterated
 - Should assure food is not misbranded regarding allergen labeling
- ❖ FDA proposes to adopt this purpose instead of ensuring that identified hazards are adequately controlled

Hazard Analysis

- ❖ FDA proposes to require importers to conduct a written hazards analysis for each imported food to determine whether there are any significant hazards
 - Would evaluate both known and reasonable foreseeable hazards
 - Would consider hazards that may be intentionally introduced for purposes of economic gain
 - Would evaluate environmental pathogens whenever ready-to-eat food is exposed to environment before packaging without any additional treatment
- ❖ If there are no significant hazards, no supplier verification required

Hazard verification continued . . .

- ❖ Importers could comply by reviewing and assessing a hazards analysis conducted by the foreign supplier
- Importers would not be required to determine or conduct any foreign supplier verification activities if either
 - The importer determines there are no significant hazards in the food; or
 - The importer's or its customer's preventive controls are adequate to significantly minimize or prevent all significant hazards
 - But if **customer** controls the significant hazards, the importer must annually obtain from the customer written assurance that it has established and is following procedures that will significantly minimize or prevent the hazard

Supplier Risk Evaluation

- ❖ Many industry stakeholders commented that industry common practice involves:
 - Basing supplier verification activities on assessment of information about risks presented by supplier
 - Basing supplier verification activities on risks presented by the particular food
- ❖ In response, FDA agrees and proposes two significant changes to original proposed rule:
 - Delete the requirements on “compliance status”
 - Add a new requirements for “risk evaluation”

Supplier Risk Evaluation continued . . .

- ❖ Under the new “risk evaluation” provision, importers would consider (in addition to the hazards analysis):
 - The entity that will be applying controls for the hazards
 - E.g., the foreign supplier, the foreign supplier’s raw material, or ingredient suppliers
 - Applicable FDA food safety regulations and information regarding foreign supplier’s compliance;
 - Including, specifically, whether the foreign supplier is the subject of an FDA warning letter or import alert
 - Foreign supplier’s food safety performance history; and
 - Including food testing results, audit results, and supplier’s record of correcting problems
 - Other factors as appropriate and necessary, such as storage and transportation practices

Appropriate Verification Activities continued . . .

- ❖ Potential verification activities would include:
 - Onsite auditing;
 - Sampling and testing food;
 - Reviewing the foreign supplier's food safety records; or
 - Additional risk-based verification activities
- ❖ Onsite auditing would need to be conducted by a qualified auditor
 - Could include foreign government employee
- ❖ Sampling and testing could be conducted by either the importer or the foreign supplier

Appropriate Verification Activities continued . . .

❖ SAHCODHA Hazards

- Importer must conduct or obtain documentation of an onsite audit of foreign supplier
 - Must take place before initially importing the food and at least annually thereafter
- May use another supplier verification activity and/or less frequent auditing if importer specifically determines they would adequately address identified risks

Appropriate Verification Activities continued . . .

- ❖ FDA does not believe uncertainty about SAHCODHA standard would make it difficult for importers to comply with provision
 - Directs importers to Reportable Food Registry Questions and Answers document and weekly Enforcement Reports
 - FDA may issue further guidance to clarify what food hazards are SAHCODHA hazards
- ❖ FDA intends to provide guidance on circumstances, including both food and supplier risks, under which onsite auditing of foreign suppliers and/or other supplier verification approaches are appropriate

Appropriate Verification Activities continued . . .

- ❖ Instead of onsite audit, FDA proposes to allow importers to rely on results of an inspection of the foreign supplier by FDA or food safety authority of a country whose food safety system FDA has recognized as comparable
 - Inspection must have been within 1 year of the date that onsite audit would have been required
 - Importer would need to document inspection results relied upon

Approved Supplier List

- ❖ FDA proposes to require importers to establish and follow procedures to ensure they import foods only from approved suppliers
 - May import from unapproved suppliers when necessary and appropriate, on a temporary basis
- ❖ Importers would be required to document the use of these procedures
 - May address approval of suppliers, approval or rejection of particular shipment of foods, and documentation of receipt from approved suppliers
- ❖ Importers would not have to maintain a list of foreign suppliers

Records and Documentation

- ❖ The supplemental proposed rule contains numerous documentation requirements
 - Hazard analysis and risk evaluation
 - Written procedures for supplier verification activities
 - Written procedures and use of procedures for ensuring importers only import food from approved suppliers
 - Verification activity and frequency for supplier and food
 - Implementation of verification activities

Records and Documentation - Audits

- ❖ FDA proposes not to require FDA access to audit reports of suppliers
- ❖ Instead, FDA will accept:
 - Documentation regarding audit procedures;
 - The dates audit was conducted;
 - Conclusions of audit;
 - Any corrective actions taken in response to deficiencies identified during audit; and
 - Documentation that audit was conducted by qualified auditor

Records and Documentation - Testing

- ❖ Sampling and testing documentation would need to include:
 - Identification of the food tested
 - The number of samples tested;
 - The test(s) conducted, including analytical methods used;
 - The date(s) on which the test(s) were conducted;
 - The results of the testing;
 - Any corrective actions taken in response to detection of hazards;
and
 - Information identifying the laboratory conducting the testing

Records and Documentation – Safety Records

- ❖ FDA proposes to require documentation of each review of foreign supplier safety records
- ❖ Documentation would need to include:
 - Date(s) of review;
 - Any corrective actions taken in response to significant deficiencies identified during the review; and
 - Documentation that the review was conducted by a qualified official

Record Retention

- ❖ Importers would need to maintain for at least 2 years after the records were created or obtained:
 - Written assurances from their customers that they are in compliance with the supplier program requirements of the preventive controls regulations;
 - Certain verification activities;
 - Investigations and corrective actions;
 - FSVP reassessments; and
 - Documentation of supplier verification activities that importers conduct

Very Small Importer/Supplier

- ❖ FDA proposes to increase annual sales ceiling used in proposed definition of “very small importer” and “very small foreign supplier”
 - Increase from \$500,000 to \$1 million
- ❖ FDA is still considering comments concerning whether the regulations should include any similar modified provisions for very small importers and suppliers



Produce Safety



Overview of Produce Safety Proposal

- ❖ In response to extensive comments on the original proposed rule, FDA made “significant changes” in its thinking on certain provisions
- ❖ The provisions in the re-proposal address:
 - (1) the scope of the proposed rule, including which farms are covered;
 - (2) new provisions regarding the withdrawal and reinstatement of a qualified exemption; and
 - (3) revisions to specific produce safety standards for agricultural water, biological soil amendments, and domesticated wild animals

Scope of Rule

- ❖ Original proposed rule would apply to only farms and farm mixed-type facilities with an average annual monetary value of all food sold during the previous three-year period of more than \$25,000
 - The supplemental proposal would apply the \$25,000 limit to sales of produce rather than all sales of food
- ❖ FDA also proposed to revise the definition of “farm” such that packing or holding others’ RAC produce on a covered farm would be subject to produce safety standards



Changes to Standards for Hazards

- ❖ FDA proposes changes related to three of six specific hazards in the proposed rule:
 - Agricultural water. FDA proposes to:
 - (1) incorporate additional flexibility for meeting the microbial quality standard for water used for growing produce;
 - (2) amend the provisions regarding the frequency of testing agricultural water; and
 - (3) provide that a farm may meet the requirements for testing using the farm's own test results or data collected by a third party



Changes to Standards for Hazards continued...

- Biological Soil Amendments. FDA proposes to:
 - (1) remove the proposed 9-month minimum application interval for use of raw manure; and
 - (2) remove the 45-day minimum application interval for use of a biological soil amendment of animal origin that is treated by a composting process and minimizes potential for contact with produce
- Domesticated Wild Animals. FDA proposes to:
 - Explicitly state that the regulation does not authorize or require covered farms to take actions that would constitute the “taking” of threatened or endangered species in violation of the Endangered Species Act

What we still don't know or have...

- ❖ Reproposed rules on
 - Third Party Auditing
 - Intentional Adulteration (Food Defense)
- ❖ Voluntary Qualified Import Program
 - Not until FSVP finalized
- ❖ Mandatory Import Certification



Voluntary Qualified Importer Program

Section (302)

- ❖ FDA to establish, in consultation with DHS, a VQIP to expedite movement of food through the import process
- ❖ Eligibility: an importer must be importing food from a facility that has been **certified by an accredited third-party auditor** under FSMA accreditation procedures (TBD)
- ❖ An importer wishing to participate must submit a notice and application to FDA at the time and in the manner to be established by FDA

Import Certification

- ❖ **In determining whether to require such certification, FDA shall consider such factors as**
 - Known safety risks of the food
 - Known safety risks of the country, territory, or region of origin of the food
 - A finding by FDA that the food safety programs, systems, and standards in the country, territory, or region of origin are inadequate
 - Certification would assist FDA in making an admissibility determination



REGISTRATION

FEEs

❖ Food facilities and importers are subject to new fees, including one for each domestic facility or importer that undergoes a re-inspection because of a material non-compliance identified during an initial inspection.

❖ FDA Fee category rates for 2012

- Hourly rate, no foreign travel **\$225**
- Hourly rate, foreign travel is required **\$335**
- FR Notice Aug 1, 2011: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-01/pdf/2011-19331.pdf> Currency exchange Nov 4, 2013

Food Safety Plan

Written Plan
(includes procedures)

Ongoing Documentation
(keep at least 2 years)

Hazard Analysis

- Biological
- Chemical
- Physical

• Intentionally introduced hazards

Preventive Controls*

*Includes all preventive controls that may be appropriate, including those in cGMPs and CCPs, if any:

- Sanitation
- Hygiene training
- Environmental monitoring
- Allergen control
- Recall plan
- cGMPs
- Supplier verification
- Other controls

Monitoring

- Monitor and document effectiveness of preventive controls

Material Non-conformance

Corrective Actions

- Take action to reduce likelihood of recurrence
- Evaluate affected food for safety
- Prevent affected food from entering commerce if necessary
- Document efficacy

Verification

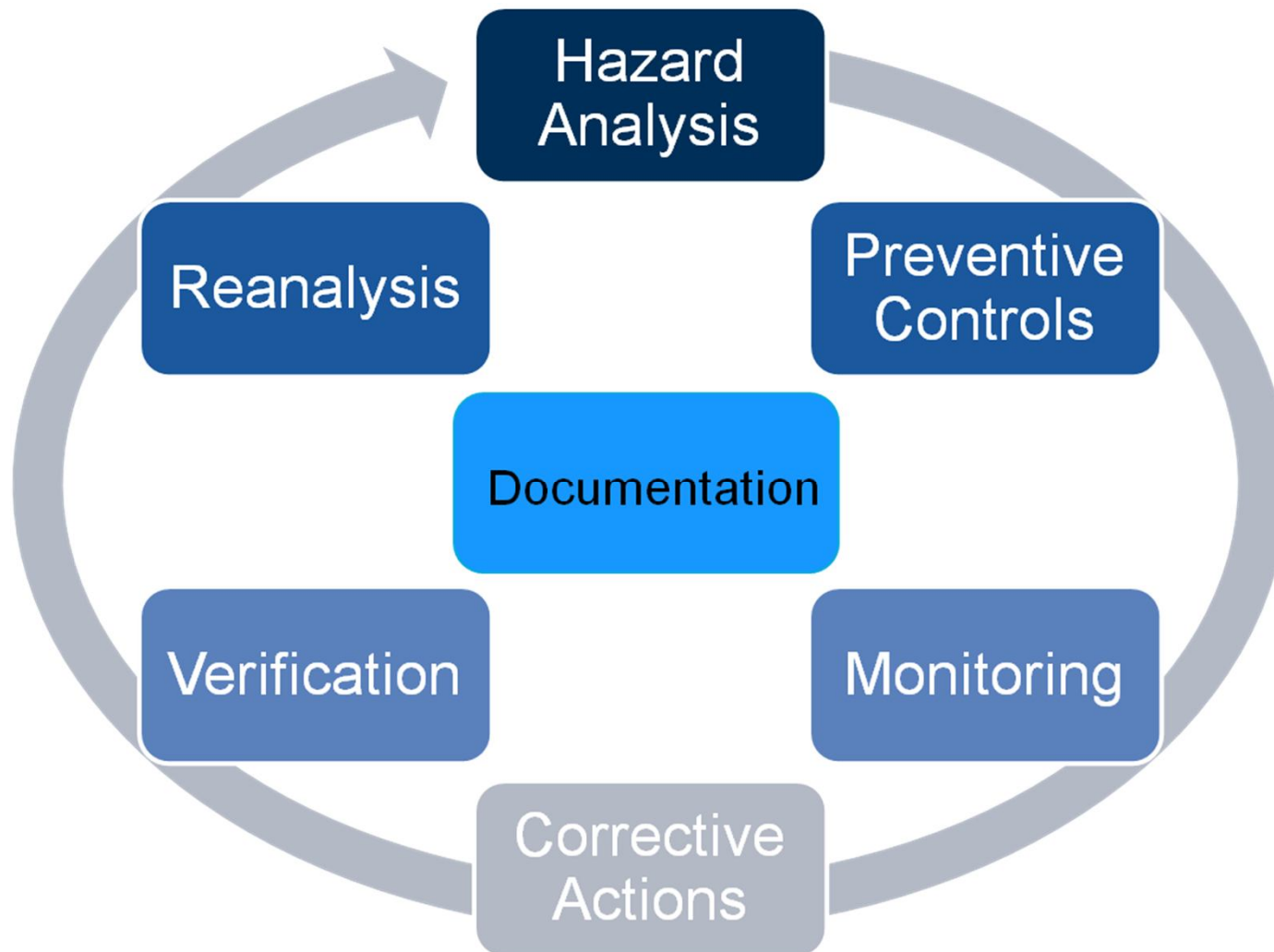
- Preventive controls are adequate to control hazards
- Monitoring
- Appropriate decisions about corrective actions
- Addressing hazards (including environmental and product testing programs and other appropriate means)
- Periodic reanalysis

Intentional Adulteration
(Food Defense)

GMA

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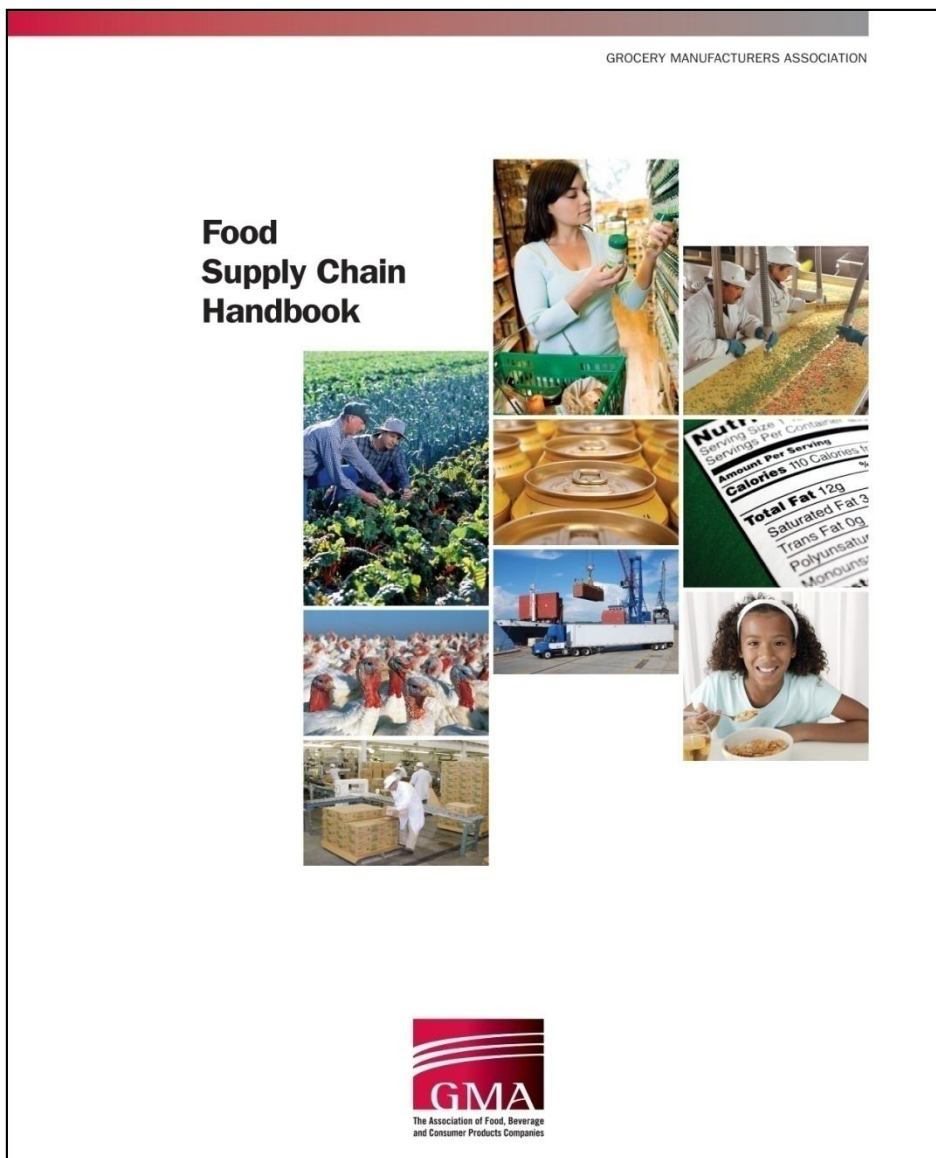
FSMA Food Safety Planning Process





Available in:

- English
- Japanese
- Spanish
- Mandarin
- French
- Russian



http://www.gmaonline.org/file-manager/About/JP_SupplyChainHandbook.pdf



THE 2015 GMA SCIENCE FORUM

CONNECTING SOUND SCIENCE AND RESPONSIBLE SOLUTIONS

SAVE THE DATE:
2015 GMA Science Forum
Gaylord National Resort & Conference
Center
National Harbor, MD
April 12-15, 2015

Keep an eye on www.gmaonline.org/events for updated registration and agenda information.

FSMA IMPLEMENTATION STRATEGY



CHALLENGES AHEAD

Mid-Continental Association of Food & Drug Officials
2015 Educational Conference
Presented by
Lenora Howard, Ph.D., MPH

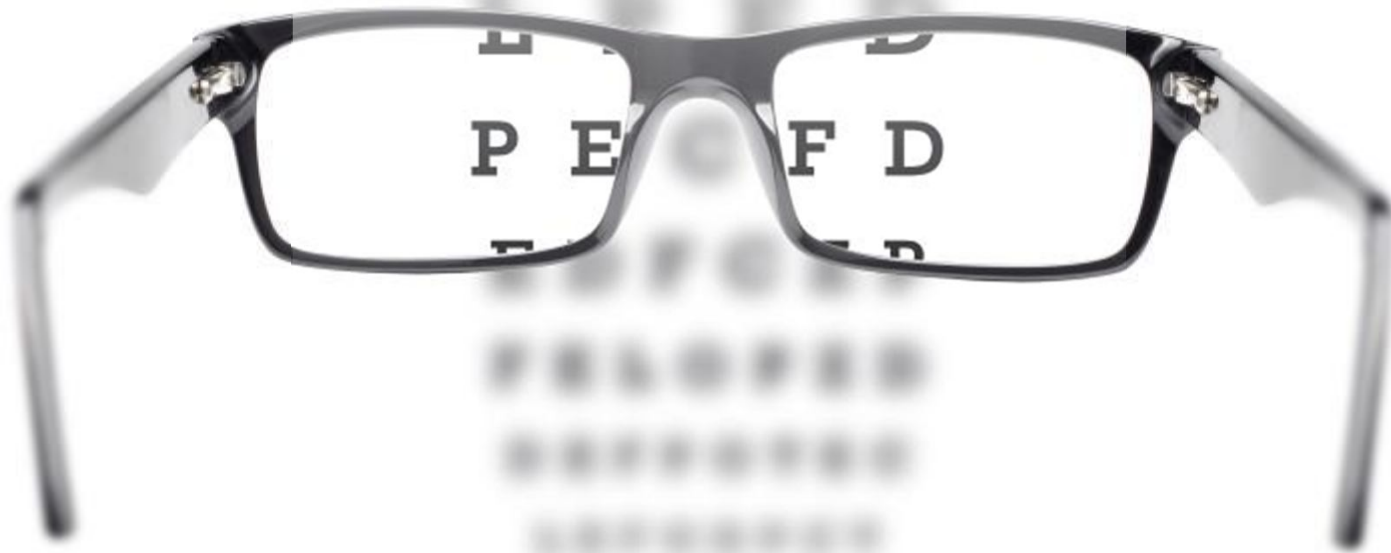


Agenda

- FSMA Purpose & Focus
- Food Industry Responsibilities
- FSMA Implementation Steps
- Constraints
- Impacts

FSMA

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



FSMA FOCUS

Alter approach to focus on **prevention** rather than response

Shift **accountability** onto food processing companies

Evaluates hazards and requires written plan of action to **prevent** food contamination

Expands **oversight** of imports

New Responsibility for the Food Industry

Specific Provisions

§101: Inspection of Records

§102: Registration of Facilities

§103: Hazard Analysis & Risk-Based Preventive Controls

§106: Protection Against Intentional Adulteration

§108: Food Defense

§204: Enhancing Traceability

FSMA will refine daily operations in all FDA registered facilities

- **Food Safety Systems**
- **Supply Chain Management**
- **Maintenance and Control**
- **Food Defense**
- **Traceability**
- **Sanitary Transportation**

IMPLEMENTATION STEPS



FSMA IMPLEMENTATION CORPORATE TEAM

Quality
Leaders

Regulatory

Human
Resources /
Education
and
Training

Legal

Food Safety
Administration
Policy &
Procedures

Food
Safety
Audits

Food
Protection
(Microbiology,
Toxicology,
Thermal-
Processing,
Allergens)

Supplier
Quality

Food
Defense



FSMA IMPLEMENTATION FACILITY TEAM

Operation /
Production
Manager

Sanitation
Manager

Shipping &
Receiving
Manager

Plant
Manager

HACCP
Coordinator

Food
Defense
Coordinator

Quality
Manager



Steps to Compliance: Improving Food Safety Culture

Corporate

Understanding FSMA
Laws & Regulations:
Preparing Objectives

Gap Assessment
Corporate Level

Strategy to Close
Gaps

Implementation
Strategy

Facility

Gap Assessment at
Facility Level

Strategy to Close
Gaps

Implementation at
Facility Level

Maintenance and
Continual
Improvement

Implementing Regulation Requirements

FSMA Proposed Rules

Review and understand FSMA and its implementing regulation requirements :

- Preventive Controls for Human Food
- Preventive Controls for Animal Food
- Produce Safety
- Foreign Supplier Verification Program
- Accreditation of Third-Party Auditors
- Sanitary Food Transportation
- Food Defense
- Intentional Adulteration

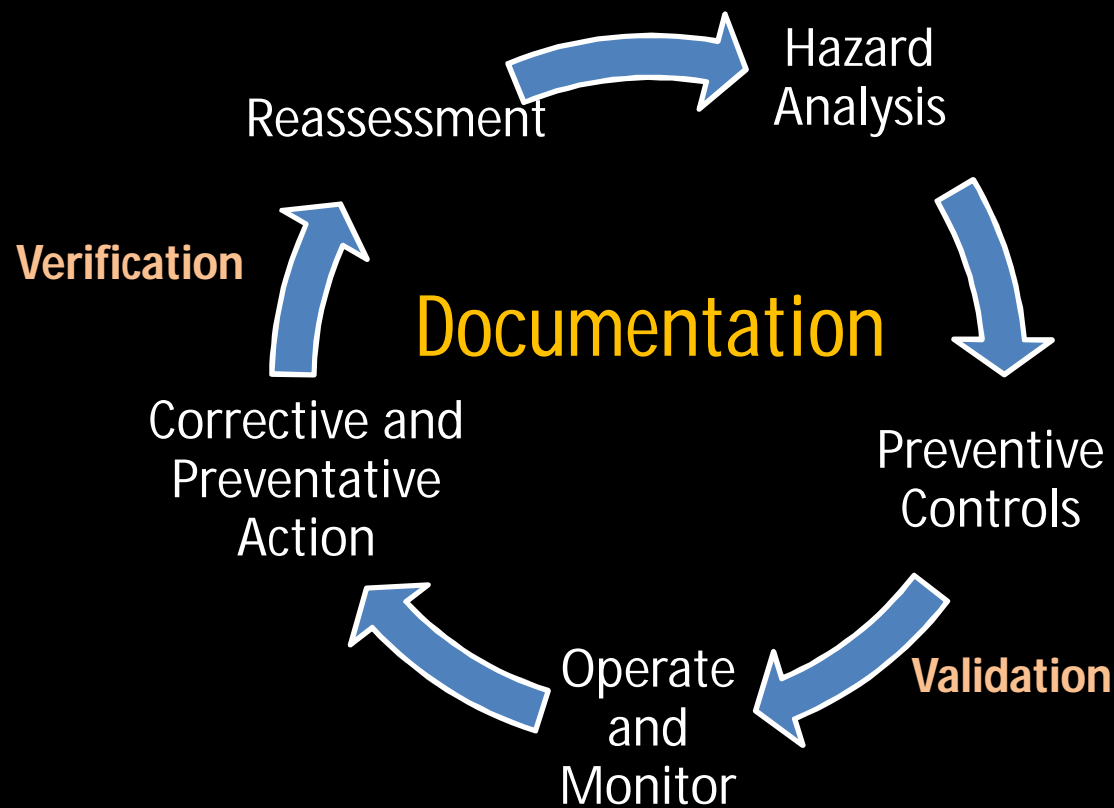


Modernization Act

Gap Assessments

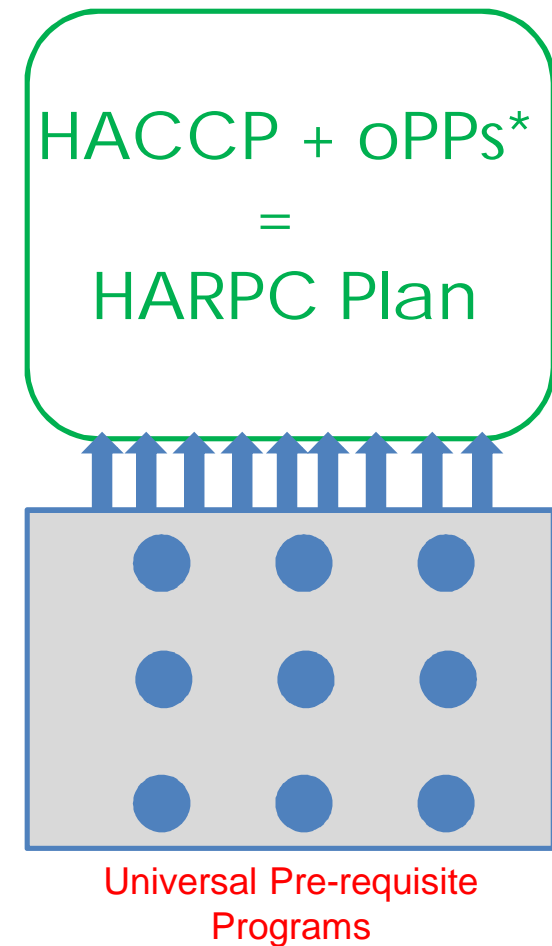
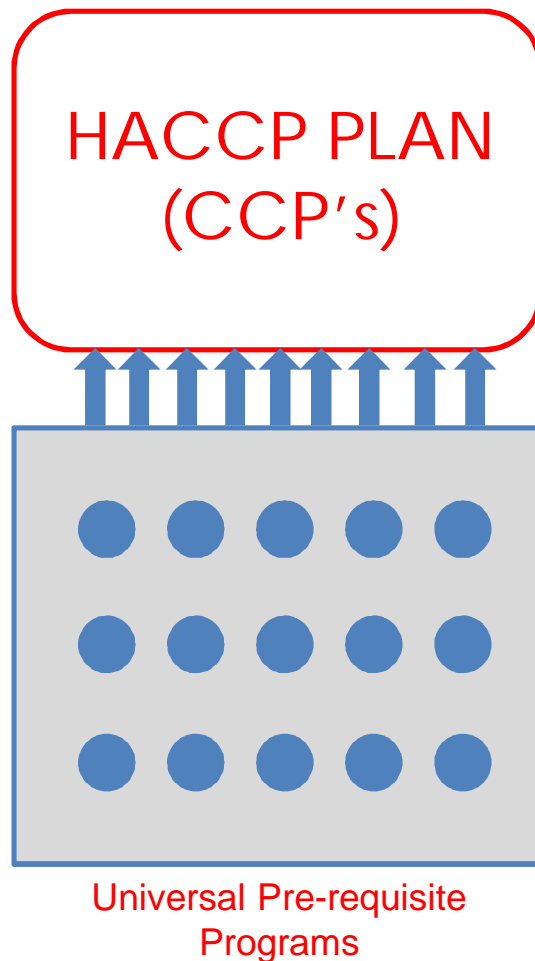
Detailed gap assessments to identify system and process steps that need enhancement and/or development

Food Safety System Process for Preventive Controls



Gap Assessments

HARPC is similar to HACCP in principles but markedly different from HACCP in other aspects



*Operational Pre-requisite Programs

Documents

Support Documents: Utilize scientific, risk-based approaches to enhance food safety system

Documentation: Acquire, improve, organize and store data available for hazard analysis, preventive controls, risk assessments, validations and food defense.

Recordkeeping

Records can be dangerous!!!!

- Too Few Vs Too Many
- FSMA requires 2 years
- 24 hours to retrieve



Resources

- **Identify resource needs**
 - **personnel (headcount)**
 - **financial (estimate cost)**
 - **Documentation changes**
 - **New equipment**
 - **Validation materials**
 - **Training**
 - **Supplier and 3rd Party audits**
 - **Support documents (research paper are not free)**
 - **Import fees (VQIP)**
- **Obtain commitment from senior management**

Communication Strategy

Develop a collaborative communication approach among corporate management, corporate support expertise, facility management and stakeholders

Communication objectives (What do we want to accomplish?)

Analyze and segment target audiences (Who do we want to reach?)

Develop and pretest message concepts (What do we want to say?)

Select communication channels (Where do we want to say it?)

Select , create and pretest messages (How do we want to say it?)

Develop promotion plan (How do we get it used?)

Implement communication strategies and conduct evaluations (Getting it out there)

Conduct outcome and impact evaluation (How well did we do?)

TRAINING

- Training plans to ensure that facility management has an enhanced knowledge of how to implement all requirements.
- Develop training for appropriate individuals and facilities.
- Training frequency should be include in all procedures.
- Training plans should include outcomes, assessments & evaluations

IMPLEMENTATION CONSTRAINTS

- **Timing - one year after the final rules are passed to comply with regulations.**
- **Expertise to support facilities**
- **Multi-phase effective dates established by FDA (implementing regulations and guidance)**
- **Resources required - both financial and human**
- **Workload on leaders and core team members**

MCAFO Annual Meeting 2015

Preventive Controls

Animal Feeds

Michele M. Evans, Ph.D.

Executive Director of Food Safety and Quality
Diamond Pet Foods



PC Animal Feed – Implications Overview

- **Final Rule Compliance:**
 - Big company vs. small company
 - Industry culture change
- **Training and Education Strategy:**
 - Trade organization: PFI
 - Preventive Controls Alliance
- **Supply Chain:**
 - Supplier/Customer strategy
- **Profession Affiliations**
- **Regulatory Agencies**

PC Animal Feed – Implications

- **Final Rule Compliance:**
 - Big Company vs. Small Company
 - Industry Culture Change
 - animal feed vs. pet food



PC Animal Feed – Implications

- **Training and Education Strategy**
 - **Trade Organization: Pet Food Institute (PFI)**
 - **Regulatory Affairs Committee (RAC)**
 - **Product Safety Subcommittee (PS2)**
 - **Microbiological Technical Advisory Group (MTAG)**
 - **Food Safety Preventive Controls Alliance (FSPCA)**



Food Safety Preventive Controls Alliance

FSPCA Steering Committee

Federal and
State Food
Inspection
Officials

Academic
Researchers
and Educators

US Food
Industry
Trade
Association
Reps

Training Materials, Course, Models, Protocol

Editorial
Subcommittee

Continuation
Subcommittee

Working
Groups

Certificates and Records

Association of Food and
Drug Officials

International Food
Protection Training
Institute

Food Safety Preventive Controls Alliance

FSPCA Audience(s)

Sector

- FDA regulated food industry
 - Target – small and medium-sized firms
 - Large and multinational firms engaged
- FDA field investigators
- State inspectors
- Food safety trainers

Experience

- Brand new to some
- A shift in thinking for others

Food Safety Preventive Controls Alliance

Summary

- FSPCA has a draft curriculum on Preventive Controls for Human Foods
- FSPCA's diverse representation is an asset in developing a curriculum for a diverse workforce
- The draft FSPCA curriculum **cannot** be finished until AFTER the final rule is published.
- Understanding audience needs and differing viewpoints is essential to develop robust training material

For Updates Visit the FSPCA Website

<http://www.iit.edu/ifsh/alliance/index.shtml>



The screenshot shows the homepage of the Food Safety Preventive Controls Alliance (FSPCA). At the top, there is a black header with the Illinois Institute of Technology (IIT) logo and name on the left, and a search bar with 'Quick Links' and 'Search Content' on the right. Below the header is a banner featuring the IFSH logo (Institute for Food Safety and Health) on the left, a collage of food images in the center, and the FSPCA logo (Food Safety Preventive Controls Alliance) on the right. The main content area is divided into a left sidebar and a main body. The sidebar contains links to 'IFSH Home', 'FSPCA Home', 'The Alliance', 'Upcoming Events', 'Committees', 'FAQ', and 'Resources', along with a 'SIGN UP FOR IIT IFSH NEWS' button. The main body has a 'FSPCA Home' link, a 'Welcome to FSPCA Online' section with a paragraph about the alliance's mission, a 'NEWS' section with a link to 'New! Hazard Analysis and Preventive Controls for Human Food - Draft Training Curriculum Outline', a 'FSPCA Webinars' section with dates for August 26, 2014 and May 12, 2014, a 'FSPCA Committees, Subcommittees and Working Groups' section with links to 'Executive Committee' and 'Meeting summaries', and a 'FSPCA Committees' section. On the right side of the main body, there is a 'FSMA' section with a 'Supplemental Rules' subsection, which includes text about redline versions of proposed supplemental rules and links to 'Proposed Supplemental Rule for Preventive Controls for Human Food' and 'Proposed Supplemental Rule for Preventive Controls for Animal Food'. At the bottom right, there is a 'FSPCA' logo with the text 'FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE' below it.

ILLINOIS INSTITUTE OF TECHNOLOGY

Quick Links:

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

IFSH Home

FSPCA Home

The Alliance

Upcoming Events

Committees

FAQ

Resources

SIGN UP FOR IIT IFSH NEWS

FSPCA Home

Welcome to FSPCA Online

The Food Safety Preventive Controls Alliance (FSPCA) is a broad-based public private alliance consisting of key industry, academic and government stakeholders whose mission is to support safe food production by developing a nationwide core curriculum, training and outreach programs to assist companies producing human and animal food in complying with the preventive controls regulations that will be part of the Food Safety Modernization Act (FSMA).

NEWS

New! Hazard Analysis and Preventive Controls for Human Food - Draft Training Curriculum Outline

Click here to [download the PDF](#)

FSPCA Webinars

To listen the webinars, and view the accompanying slides click on the links below.

August 26, 2014

May 12, 2014

FSPCA Committees, Subcommittees and Working Groups

Executive Committee

The Executive Committee met February 2, 2015. [Meeting summaries.](#)

Standing Committee

FSMA

Supplemental Rules

Redline versions of the codified text of the four recently released proposed supplemental rules are now available. The redline versions allow you to see how the proposed codified text has been modified from the original proposal.

[Proposed Supplemental Rule for Preventive Controls for Human Food](#)

[Proposed Supplemental Rule for Preventive Controls for Animal Food](#)

Translations of the fact sheets of the four proposed supplemental rules are now available.

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

PC Animal Feed – Implications

- Supply Chain – supplier/customer strategy
 - Communicate efforts
 - New expectations
 - Discuss ramifications (cut orders, delays)



PC Animal Feed – Implications

- **Supply Chain – supplier/customer strategy**
 - **Collaborative Efforts example:**
 - Education, research
 - Fats and Proteins Research Foundation (FPRF)



National Renderers Association

NRA

PC Animal Feed – Implications

- **Profession Affiliations**

- **International Assoc. Food Protection (IAFP)**

- **Members of Professional Development Groups (PDG's)**

- » **Applied Lab Methods**
 - » **HACCP & Food Safety Systems**
 - » **Micro Modeling & Risk Assessment**
 - » **Sanitary Equip. & Facility Design**
 - » **Low Water Activity Foods**



- **Co-Chair and presenter of 2015 Annual Mtg Symposium on Pathogen Control Processes for Pet Food Manufacturing**

- **3A Sanitary Standards Inc.**

- **Invited speaker Annual Mtg and Education Conference “Pet Food Processing – New Attention to Hygienic Design – The Journey of Legacy Equipment to Hygienic Design”**



3-A Sanitary Standards, Inc.

PC Animal Feed – Implications

- Regulatory Agencies

- Communicate (visits, meetings)

- Diamond initiated

- PFI coordinated

- FDA public meetings



U.S. Food and Drug Administration
Protecting and Promoting Your Health

- Adversarial to Amicable

- Regulatory / Industry Groups

- Heartland Food Safety Roundtable

- AFDO/MCAFDO



Association of Food and Drug Officials

"Promoting Public Health, Fostering Uniformity, and Establishing Partnerships"

Q&A

