AMERICAN FROZEN FOOD INSTITUTE

# 5th Annual Food Policy Impact

**Institute of Food Technologists**
**Washington DC Section and**
**Food Laws and Regulations Division**

# *Food Safety Modernization Act*
# Implementation and Industry Preparedness

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# Frozen Food Industry

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- National trade association representing all segments of the frozen food industry
- Advocates public policy interests before legislative and regulatory entities
- Serves as the voice of the industry before consumers, media, and policy makers, and promotes increased consumption of frozen foods
- Fosters industry development and growth through educational and research programs
- Members represent over 90% of the frozen food segment

# Agenda

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- Food Safety in our Facilities: Now and Future
- Key Elements of FSMA and Impact
- Benefits and Challenges of Preventive Controls for Human Food Rule
- Implementation Approaches and Industry Preparedness
- Culture of Food Safety
- Inspections and Records Access
- AFFI-FSMA Readiness Self-Assessment Tool

# Food Facilities Now

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- cGMPs (Title 21, CFR 110)
- Cover food industry personnel, plants and grounds; sanitary facilities, controls, and operations; equipment and utensils; warehousing, and distribution; and natural or unavoidable defect levels.
- Not tailored to individual facilities
- cGMPs do not require a facility to identify and prevent risks
- No documentation or record keeping necessitated
- FDA inspections observational in nature

# Facilities under FSMA

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- Reflect changes in food industry, rise in Ready-to-Eat foods, little preparation or cooking for food safety before consumption to eliminate hazards
- Science Based Preventive Controls throughout the food supply chain
- Includes Imports, Enhanced Inspection, Compliance, Outbreak response and Recalls
- Hazard Analysis Risk Based Preventive Controls (HARPC) (Section 103 which added section 418 to Federal FD&C act)- having the greatest impact on operation of food facilities
- HARPC requirements on operation of food facilities that manufacture, process, pack, or hold human food for consumption

# Key Elements of FSMA

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- **Preventive Controls:** Requires comprehensive, risk-based preventive controls across the food production chain.
- **Inspection and Compliance:** Specifies how often FDA should inspect food producers.
- **Imported Food Safety**: Requires importers to verify that their foreign suppliers have adequate preventive controls in place to ensure safety.
- **Response:** Provides mandatory recall authority for all food products.
- **Enhanced Partnerships:** Recognizes the importance of strengthening existing collaboration among all food safety agencies – U.S. federal, state, local, territorial, tribal and foreign.

# Food Industry Impact

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- Responsibilities
- Requirements
- Resources

# Responsibilities

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- Register your food facilities
- HARPC –Hazard Analysis and implementation of Risk based Preventive Controls
- Facility must identify known or reasonably foreseeable hazards that may be associated with the food handled at the facility.
- Determine hazards that require Preventive Controls to significantly minimize or prevent the hazard
- Implement Preventive Controls to provide assurance the food in the facility will not be adulterated or even misbranded for failure to label an allergen

# Requirements

- Preventive Controls for Human Food Rule
- Facility and Food specific- Food Safety Plan and Hazard Analysis
- Process Controls, Allergen Controls, Sanitation Controls, Supply Chain controls, Recall Plan
- Effective monitoring procedures and documentation
- Validation and Verification of Preventive Controls and Corrective action: Adequacy and Implementation
- Risk-based supply chain program-on site audits , review of supplier records, etc.
- Training requirements-Qualified individual and Qualified Auditor

# Resources

- Becoming compliant
  - Expertise to understand and implement HARPC (hiring and training Qualified Individuals)
  - Implementation
- Written food safety plan, hazard analysis, recall plan monitoring plan, document training, and supply chain program
- Continual  Verification, Monitoring and Re-analysis (deviations are expected to be corrected and re-validated)
- Entire food safety system reviewed every 3 years
- Facility investments: Role of management

# FSMA Approach: Value

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- Risk-based
- Requirements for manufacturers to identify and manage risk
  - ➢ Should allow various approaches to managing risk
    - Most current Food Safety Management systems in scope
  - ➢ Guidance(s) should provide examples and support to smaller operators
- FDA Investigator training
  - ➢ Evaluate risk, identified controls and their management versus a checklist
  - ➢ FDA escalation process

# FSMA Approach: Challenges

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- Ensuring sufficient information on hazards and performance of controls
  - Hazard analysis documentation
  - Validation
  - Record keeping
- Adapting to a new approach to inspection
- Ensuring guidance does not become regulation
- Status of some industry segments and smaller operators

# Inspections

- Changing nature of FDA inspections
- Intensive document review during FDA inspections
- Documentation allows FDA to determine how a facility's food safety plan is performing
- The agency need not rely on appearing at a facility on a particular day when it happens to be in violation of the FD&C Act

# FSMA Implementation

- FSMA implementation team established
  - Internal leads for key rules and components.
- Conduct detailed review of final rule requirements- Public meetings
  - Technical Assistance Network
- Face to face workshops to confirm roll out strategy and action plan
  - Identify needed modifications to internal program
  - Determine standardized approach for facilities
  - Determine requirements and communication strategy for stakeholders

# Industry Preparedness

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- Verify conformance of current HACCP and pre-requisite controls to final rule and other FSMA requirements
- Review / challenge validation of control measures
- Review robustness of documentation system
  - Hazard assessment
  - Preventative controls plan, including monitoring, verification and corrective actions
- Participation in trade association trainings, seminars, workshops, and other external discussions on FSMA

# Industry Preparedness

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- Strengthen programs for monitoring and response to new and emerging issues
- Update guidance to manufacturing plants on regulatory audits
- Roll out requirements to partners
  - Suppliers, co-manufacturers, foreign manufacturers
- AFFI Self-Assessment Tool

# "Culture of Food Safety"

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- FDA provided flexibility in the regulations in exchange for facilities developing a "culture of food safety"
- FDA wants to assess whether a company has a "culture of food safety" as a barometer of competence
- How can you demonstrate a "culture of food safety"?
  - Employees understand their responsibilities and why
  - You can explain your programs, the rationale behind decisions

- ***With flexibility comes responsibility***

# Educate and Regulate

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- FSMA implementation is occurring just as FDA culture is changing
- Facilitate industry implementation of modern preventive practices
  - Commodity and sector-specific guidance
  - Education, outreach and technical assistance
  - Regulatory incentives for compliance

# New FDA Strategies

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- FDA to develop inspection cadre specially trained in and devoted to food inspections
- Closer integration of field inspections and CFSAN/ headquarters experts (in real time)
- Distinct types of inspections by staff with different technical expertise
- Two-tiered inspections and centralized records review

# Systems-Based Approach

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- Historically, FDA has inspected food facilities for basic sanitation and to detect visible problems with the facility or the product produced
  - ➢ FDA has assessed compliance based on this "snapshot" of the facility's operations
- FSMA requires FDA to take a risk-based approach to facility inspections
  - ➢ Shift from reaction to prevention

# Systems-Based Approach

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- To implement FSMA's risk-based inspection mandate, FDA will focus on whether facilities are implementing the systems needed to make safe food
- The "systems-based" approach is aimed at preventing problems on a continuing basis, not just when the inspector is in the facility

# Increased Records Access

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- FSMA provides FDA with greatly expanded access to records during routine inspections
- This new authority facilitates the systems-based inspection approach
  - Let's FDA know how a company is operating when inspectors aren't present
  - FDA will know what happened not just today, but last week, last month, and last year!
- Records review will be a central component of FDA inspections
  - Inspections will become more like audits

# Records Access

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- Companies decisions will be become much more exposed to scrutiny by inspectors
  - Flexibility in FSMA proposed rules is double edged sword: with it comes responsibility

- **If it isn't documented, it didn't happen!**
  - **"You are what your records say you are"**

# FSMA Inspections

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**New FDA culture**

**+**

**New records access authority**

**+**

**New tools**

**=**

**New inspection paradigm**

**(Starting September 2016)**

# For More Information

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- **Web site: http://www.fda.gov/fsma**
- **Subscription feature available**
- **Send questions to FSMA@fda.hhs.gov**

# What to do now ?

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- Food Safety Preventive Controls Alliance
  - ➢ Training
  - ➢ Qualified Individual
- Review and prepare: FSMA regulations
- Know your rights
- Start preparing for FSMA inspections
  - ➢ Update your inspection manual
  - ➢ Recordkeeping training -apply good record keeping practices
  - ➢ Review audits for areas of improvement

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# Background of the Self-Assessment

## ➢ Objectives

- Assist food facilities in determining whether they comply with new FSMA proposed preventive control rules (Gap Analysis)
- Provide educational background and training information to assist in strengthening food safety programs and FSMA compliance
- Help provide justifications for Food Safety investments/ programs for corporate

# Background of the Self-Assessment

## How the Self-Assessment Tool was Developed

- Review of FSMA by AFFI subject matter experts
- Development of assessment questions (58), alternative answers, evaluation model to determine "level of readiness," & background materials on FSMA
- Development of a Readiness Assessment Report
- Detailed review by AFFI Counsel (Hogan Lovells US)
- Pilot testing by several AFFI members

# Review of the Sections of the Self-Assessment

## Sections (Facility-specific)

- Exclusions
- Food Safety Plan
  - Hazard Analysis
  - Process Preventive Controls
  - Allergen Preventive Controls
  - Sanitation Preventive Controls
  - Supply Chain Controls
- cGMPs
- Recall & Traceability
- Implementation and Documentation
  - Validation & Verification
  - Corrective Actions
  - Monitoring, Records & Recordkeeping
  - Training


## For Each Section

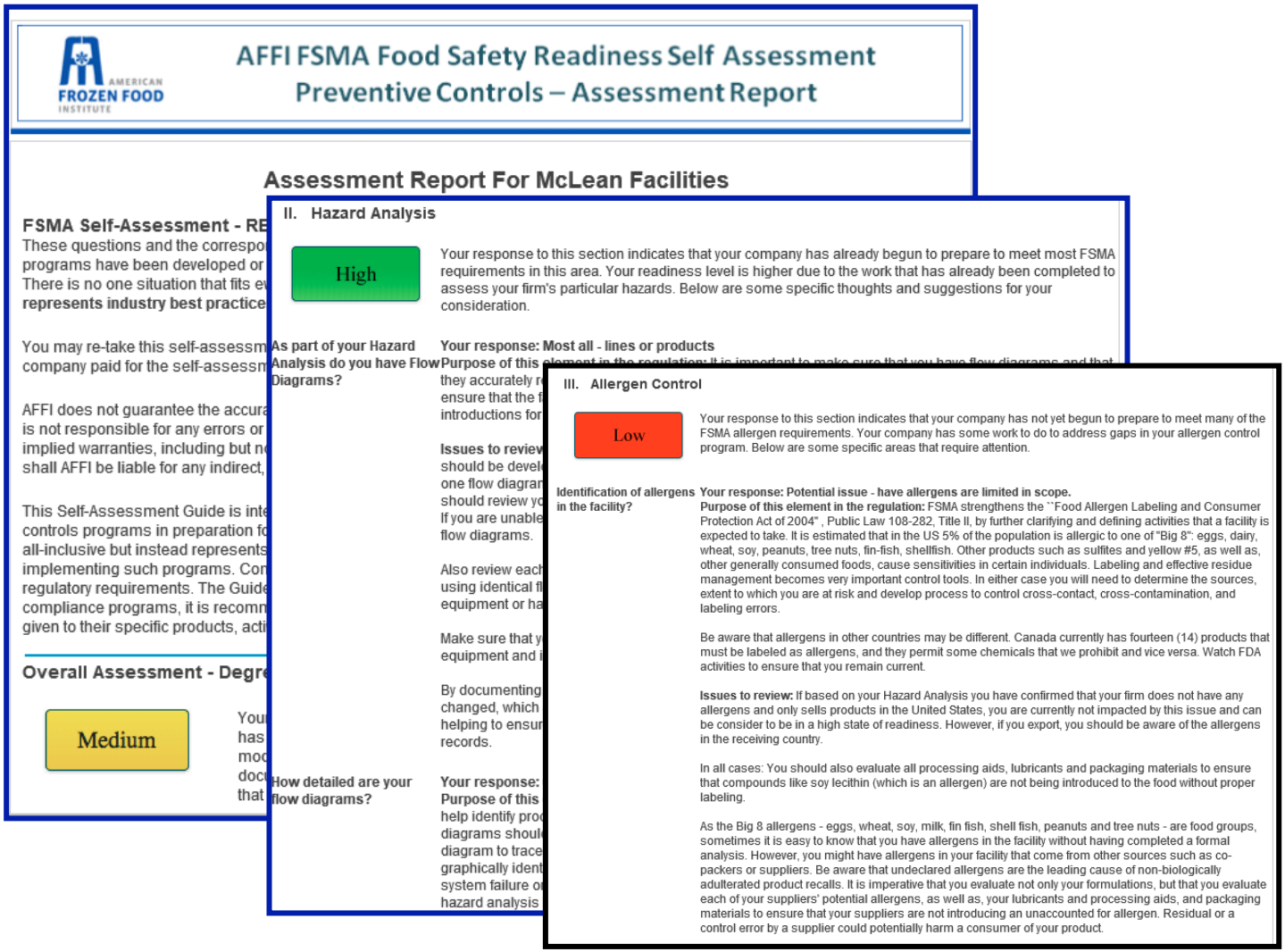
- Purpose of this element in the regulation
- Questions
- Issues to review

## Assessment based on the language of the statutes

# Overview and Live Demonstration of Self-Assessment Program

- **Taking the Self-Assessment**
  - Complete 58 questions, provide facility information
- **Immediate On-Line Assessment Report**
  - Indications of "levels of readiness" for each FSMA-related categories
  - Background and educational explanation for each of the questions
    - "Purpose of this element in the regulation"
    - "Issues to review"
- **Email Assessment Report to the User**
- **Retake As Many Times as Desired**
  - No need to be "perfect" – can do research and come back and finish!
  - New report generated each time – with an updated assessment

# On-line and Email Reports



AFFI FSMA Food Safety Readiness Self Assessment
Preventive Controls – Assessment Report

Assessment Report For McLean Facilities

FSMA Self-Assessment - RE
These questions and the correspo
programs have been developed or
There is no one situation that fits e
**represents industry best practice**

You may re-take this self-assessm
company paid for the self-assessm

AFFI does not guarantee the accura
is not responsible for any errors or
implied warranties, including but n
shall AFFI be liable for any indirect,

This Self-Assessment Guide is inte
controls programs in preparation fo
all-inclusive but instead represents
implementing such programs. Con
regulatory requirements. The Guide
compliance programs, it is recomm
given to their specific products, acti

Overall Assessment - Degr

Medium

You
has
moc
doc
that

II. Hazard Analysis

High

Your response to this section indicates that your company has already begun to prepare to meet most FSMA requirements in this area. Your readiness level is higher due to the work that has already been completed to assess your firm's particular hazards. Below are some specific thoughts and suggestions for your consideration.

**As part of your Hazard Analysis do you have Flow Diagrams?**

**Your response: Most all - lines or products**
**Purpose of this element in the regulation:** It is important to make sure that you have flow diagrams and that they accurately r
ensure that the f
introductions for

**Issues to review**
should be develo
one flow diagram
should review yo
If you are unable
flow diagrams.

Also review each
using identical fl
equipment or ha

Make sure that y
equipment and i

By documenting
changed, which
helping to ensur
records.

**How detailed are your flow diagrams?**

**Your response:**
**Purpose of this**
help identify proc
diagrams should
diagram to trace
graphically ident
system failure o
hazard analysis

III. Allergen Control

Low

Your response to this section indicates that your company has not yet begun to prepare to meet many of the FSMA allergen requirements. Your company has some work to do to address gaps in your allergen control program. Below are some specific areas that require attention.

**Identification of allergens in the facility?**

**Your response: Potential issue - have allergens are limited in scope.**
**Purpose of this element in the regulation:** FSMA strengthens the ``Food Allergen Labeling and Consumer Protection Act of 2004" , Public Law 108-282, Title II, by further clarifying and defining activities that a facility is expected to take. It is estimated that in the US 5% of the population is allergic to one of "Big 8": eggs, dairy, wheat, soy, peanuts, tree nuts, fin-fish, shellfish. Other products such as sulfites and yellow #5, as well as, other generally consumed foods, cause sensitivities in certain individuals. Labeling and effective residue management becomes very important control tools. In either case you will need to determine the sources, extent to which you are at risk and develop process to control cross-contact, cross-contamination, and labeling errors.

Be aware that allergens in other countries may be different. Canada currently has fourteen (14) products that must be labeled as allergens, and they permit some chemicals that we prohibit and vice versa. Watch FDA activities to ensure that you remain current.

**Issues to review:** If based on your Hazard Analysis you have confirmed that your firm does not have any allergens and only sells products in the United States, you are currently not impacted by this issue and can be consider to be in a high state of readiness. However, if you export, you should be aware of the allergens in the receiving country.

In all cases: You should also evaluate all processing aids, lubricants and packaging materials to ensure that compounds like soy lecithin (which is an allergen) are not being introduced to the food without proper labeling.

As the Big 8 allergens - eggs, wheat, soy, milk, fin fish, shell fish, peanuts and tree nuts - are food groups, sometimes it is easy to know that you have allergens in the facility without having completed a formal analysis. However, you might have allergens in your facility that come from other sources such as co-packers or suppliers. Be aware that undeclared allergens are the leading cause of non-biologically adulterated product recalls. It is imperative that you evaluate not only your formulations, but that you evaluate each of your suppliers' potential allergens, as well as, your lubricants and processing aids, and packaging materials to ensure that your suppliers are not introducing an unaccounted for allergen. Residual or a control error by a supplier could potentially harm a consumer of your product.

# Confidentiality & Legal Issues

## ➢ Confidentiality

- The Assessment Report is sent to the facility contact person
- AFFI does not have access to the individual reports (only statistical summaries of all assessments)

## ➢ Reduction in Possible Liability/ Discoverability

- General Counsel review
- “Readiness” vs. “Risk”
- Same “Issues to Review” for all Readiness Levels

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