Food and Beverage Industry: Preparing for FSMA

Agenda

- FDA's implementation plans
- Inspections today
  - FDA's new culture
- How inspections will change even more under FSMA
  - Changes to the statute/regulations
  - FDA current thinking/plans
  - Consequences of noncompliance
- What to do to prepare

FDA's FSMA Implementation Plan

- FSMA implementation as a continuum
- Phase 1: Set standards
  - Develop regulations, guidance, protocols for new administrative enforcement tools
- Phase 2: Implement standards
  - Design strategies to implement standards
  - Fully develop and implement the standards
- Phase 3: Monitor, evaluate, refresh
- Stakeholder engagement throughout the process

Phase I: Standard Setting

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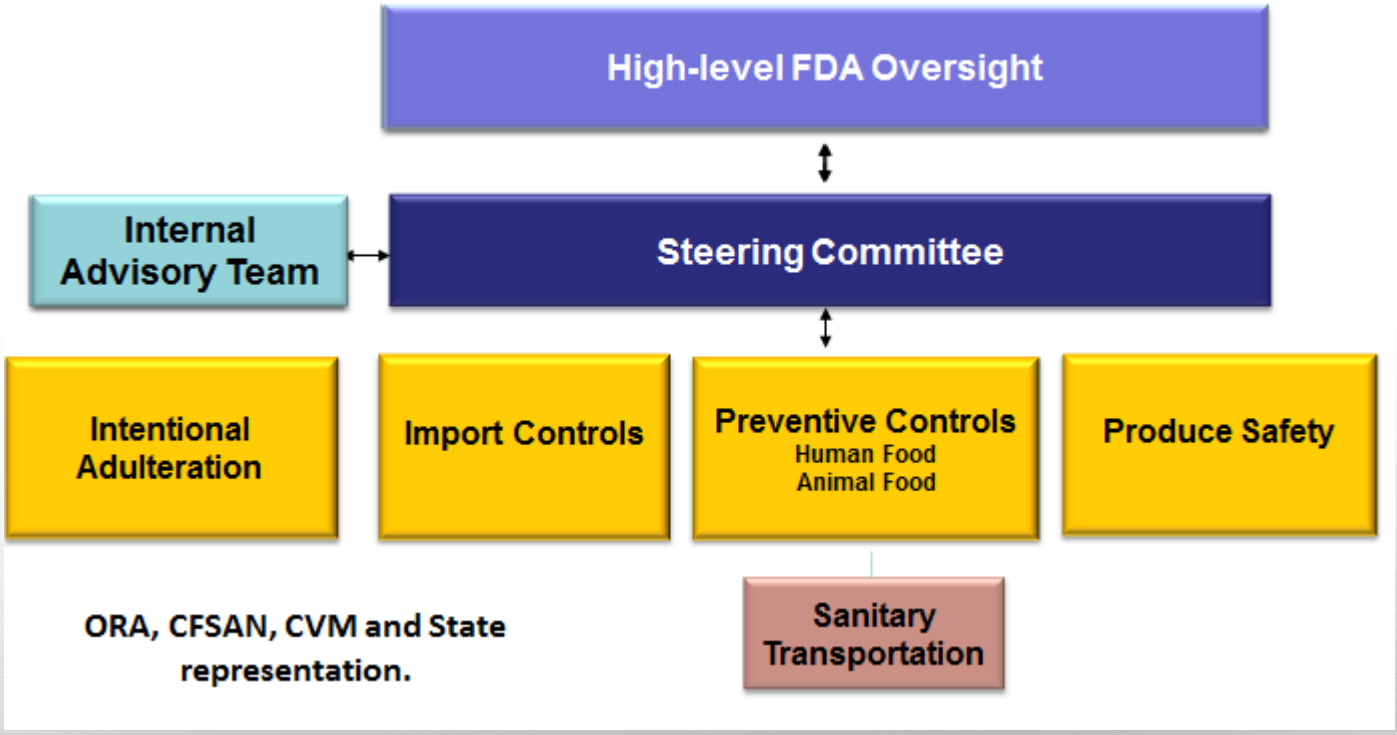
Regulation	Proposal	Final (consent decree)
Preventive Controls (Human Food)*	Jan 16, 2013	Aug 30, 2015
Preventive Controls (Animal Food)*	Oct 29, 2013	Aug 30, 2015
Produce Safety*	Jan 16, 2013	Oct 31, 2015
Foreign Supplier Verification Program*	Jul 29, 2013	Oct 31, 2015
Third Party Accreditation	Jul 29, 2013	Oct 31, 2015
Sanitary Transport	Feb 5, 2014	Mar 31, 2016
Intentional Adulteration	Dec 24, 2013	May 31, 2016

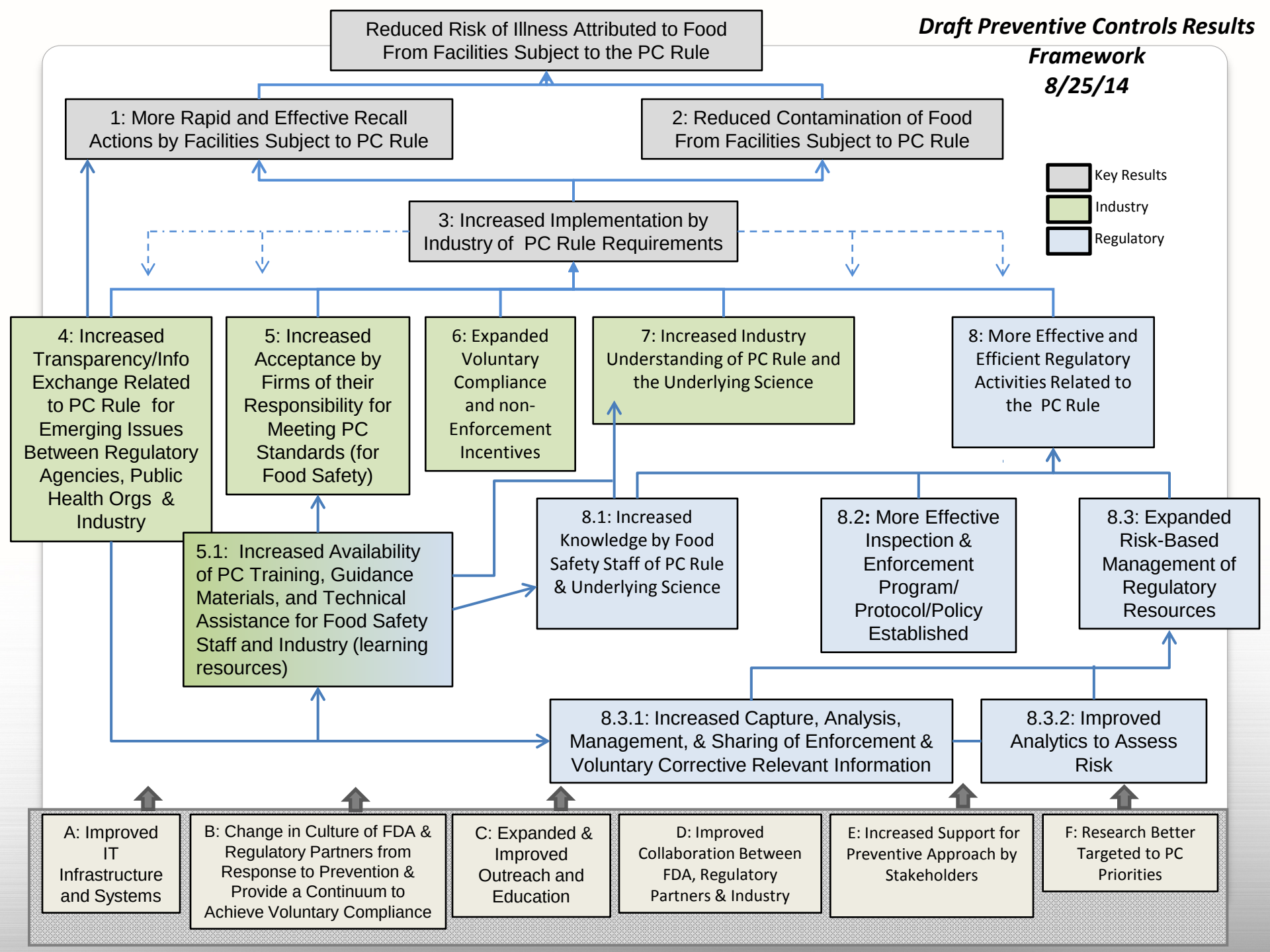
**Supplemental proposals published September 2014*

Transition to Phase 2: Implementation

- Teams continue rulemaking, guidance and other policy work until completed
- Concurrently, workgroups:
  - Implement the final rules, programs established through guidance and other policy
  - Design specific strategies, capacity building, training and operation plans needed to implement FSMA
- Steering Committee oversees 5 workgroups:
  - Preventive Controls in Food and Feed Facilities, Produce Safety Standards, Import Oversight, Intentional Adulteration, and Training

Operations and Policy Working Together




Draft Preventive Controls Results Framework
8/25/14
Reduced Risk of Illness Attributed to Food From Facilities Subject to the PC Rule
1: More Rapid and Effective Recall Actions by Facilities Subject to PC Rule
2: Reduced Contamination of Food From Facilities Subject to PC Rule
Key Results
Industry
Regulatory
3: Increased Implementation by Industry of PC Rule Requirements
4: Increased Transparency/Info Exchange Related to PC Rule for Emerging Issues Between Regulatory Agencies, Public Health Orgs & Industry
5: Increased Acceptance by Firms of their Responsibility for Meeting PC Standards (for Food Safety)
6: Expanded Voluntary Compliance and non-Enforcement Incentives
7: Increased Industry Understanding of PC Rule and the Underlying Science
8: More Effective and Efficient Regulatory Activities Related to the PC Rule
5.1: Increased Availability of PC Training, Guidance Materials, and Technical Assistance for Food Safety Staff and Industry (learning resources)
8.1: Increased Knowledge by Food Safety Staff of PC Rule & Underlying Science
8.2: More Effective Inspection & Enforcement Program/ Protocol/Policy Established
8.3: Expanded Risk-Based Management of Regulatory Resources
8.3.1: Increased Capture, Analysis, Management, & Sharing of Enforcement & Voluntary Corrective Relevant Information
8.3.2: Improved Analytics to Assess Risk
A: Improved IT Infrastructure and Systems
B: Change in Culture of FDA & Regulatory Partners from Response to Prevention & Provide a Continuum to Achieve Voluntary Compliance
C: Expanded & Improved Outreach and Education
D: Improved Collaboration Between FDA, Regulatory Partners & Industry
E: Increased Support for Preventive Approach by Stakeholders
F: Research Better Targeted to PC Priorities

New FDA Culture

- FSMA implementation is occurring just as FDA culture is changing
- FDA is rapidly becoming:
  - More inspection-oriented
  - More enforcement-minded

Educate Before and While We Regulate

- Facilitate industry implementation of modern, preventive practices through:
  - Commodity and sector-specific guidance
  - Education, outreach and technical assistance
  - Regulatory incentives for compliance

New FDA Strategies

- 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

FDA is More Inspection-Oriented

- FDA is:
  - Conducting more domestic inspections (with the states)
  - More strategic about selecting inspection sites
  - Posting some 483s on website
  - Expanding definition of “high risk”
  - Testing more, especially environmental testing
  - Increasing oversight of imports, especially ingredients, and conducting foreign on-site inspections
  - Much more forceful in demanding access to records regardless of current legal authority

Enforcement is on the Rise

- FDA is more critical and more inclined to identify/find issues
- Increase in Warning Letters for food adulteration based on food inspections/GMPs
- Increase in court injunctions
- Heightened use of Import Alerts
- New authorities for mandatory recalls and suspension of registration are now in play
- Expanded use of *Park Doctrine* on the horizon

What Does This Mean?

- FDA's expectations are changing
- Inspections are changing
- Testing has increased
- Imported ingredients will face particular scrutiny
- Crackdowns will increase in frequency

Food companies need to

1) **Know their rights**
2) **Adapt to these changes and be prepared!**

Know Your Rights

- The FFDCA and implementing regulations specifically address the records that FDA legally is entitled receive during an inspection
  - When a general inspection, FDA currently has very limited access to records
  - Once Bioterrorism is invoked, records access is almost unlimited
    - FDA must provide written notice that the inspection is under the Bioterrorism statute
- FDA can ask (and frequently demands) it has the right to records when no such authority exists
- Companies should know their rights and then make informed decisions on whether they will voluntarily release additional information

What does this mean for your next inspection?

- Inspections have already changed:
  - FDA is energized and persistent and will note all possible violations as inspectional observations
  - FDA will demand access to records the agency lacks the legal authority to access
  - FDA will try hard to take photographs even without express legal authority
  - Inspections involve comprehensive environmental sampling ("swab-a-thon")

Note: Some states have additional legal authorities (e.g., records access), so know your local rules

Inspectional Observations

- 483 Inspectional Observations
  - A few years ago, investigators would note minor observations orally but would not record them
  - Today, minor observations are included in the Form 483
  - Unusual for a company to escape an inspection without receiving a 483
- FDA policy announced in August 2009 gives industry 15 business days to provide a response
- **Absolutely essential** to respond, in writing, to every 483 observation within the 15 period

Implications of FSMA for Inspections

New FDA culture

+

New records access authority

+

New tools

=

New inspection paradigm

(Starting September 2016)

FSMA: Systems-Based Approach

- 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

- 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

“Culture of Food Safety”

- 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*

Increased Records Access Authority

- 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 an IRS audit

Implications of Records Access

- 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"**

What to Do NOW:

- 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


NEW FSMA FOOD SAFETY
READINESS SELF-ASSESSMENT PROGRAM
Online self-assessment tool assists frozen food facilities determine whether they comply with new FSMA preventive control rules.

Objectives/ Background of the Self-Assessment

➢ Objectives of the AFFI FSMA Self-Assessment

- 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 QA/FS investments/ programs for corporate

➢ How Self-Assessment Developed

- Review of FSMA by AFFI subject matter experts
- Development of assessment questions (46), 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)
- Pilot testing by several AFFI members

Brief Review of the 11 Sections of the Self-Assessment

➢ Sections of the Self-Assessment (separate for each facility)

- Exclusions
- Hazard Analysis
- Allergen Control
- Sanitation
- Recall
- cGMPs
- Supplier Verification
- Corrective Actions
- Validation & Verification
- Monitoring, Records & Recordkeeping
- Training

➢ For Each Section

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

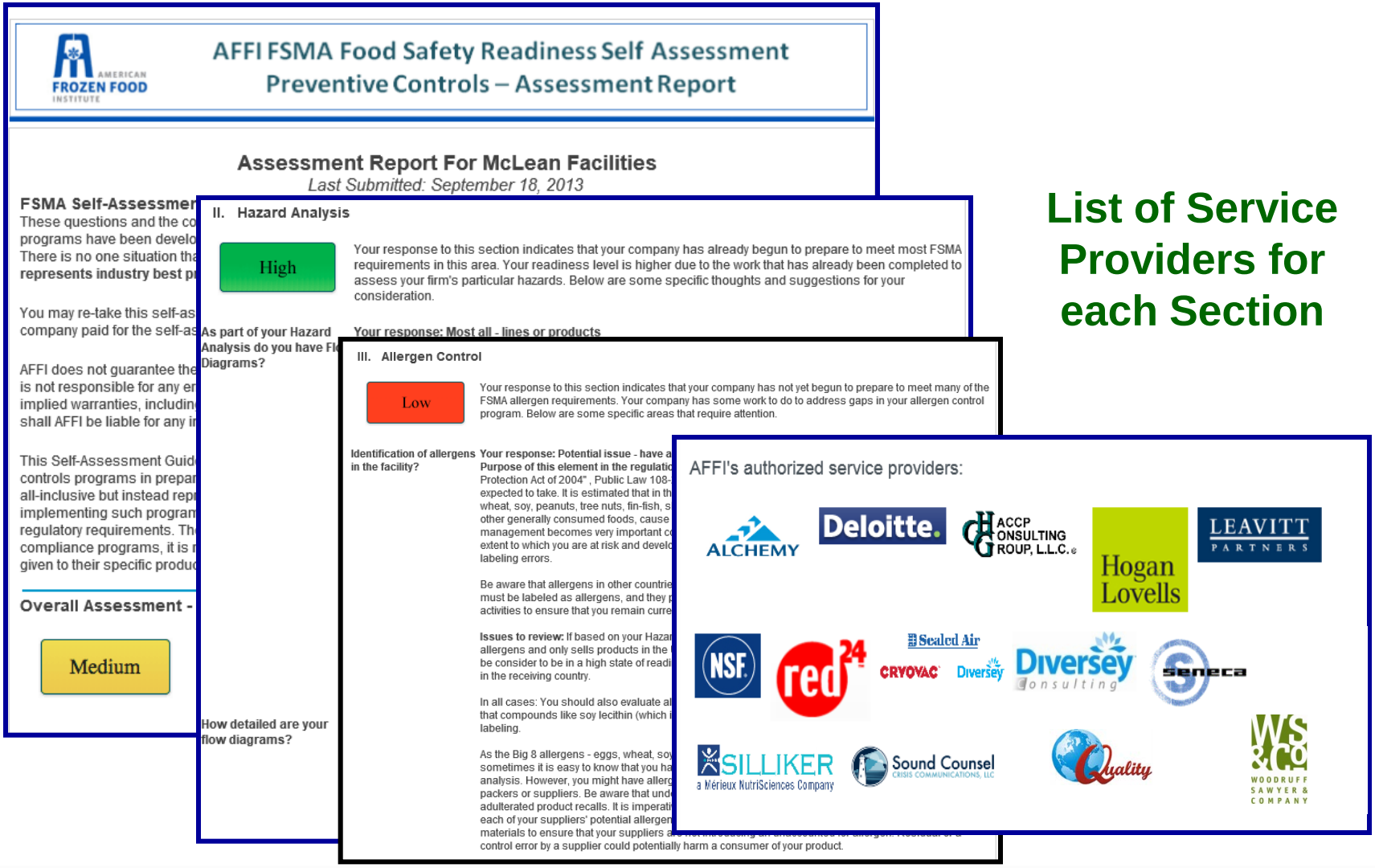
➢ Will be Revised, if Required, based upon Final Regs

- Assessment based upon the language of the statutes

Overview and Live Demonstration of Self-Assessment Program

- **Taking the Self-Assessment**
  - Filling out 46 questions, enter brief facility information
- **Immediate On-Line Assessment Report**
  - Indications of "levels of readiness" for each of 10 FSMA-related categories
  - Educational explanations for each of the 46 questions
    - "Purpose of this element in the regulation"
    - "Issues to review"
- **Email Report to the User**
- **Retake As Many Times as Desired**
  - Not need to be "perfect" – can do research and come back and finish!
  - New report sent for each time – with updated assessment

On-Line Report, eMail Report, Service Providers



List of Service Providers for each Section

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

Questions?

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