ASB BakingTech – March 3, 2020

FSMA Inspections – What to Expect and How to Prepare

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Agenda

- Recall key elements of the FDA's strategy and plans for implementing and enforcing FSMA requirements
- Discuss FDA inspections and results
- Discuss feedback from client's recent inspections and AIB Intl gap assessments
- What to consider when updating or developing your regulatory policies and procedures
- Developing mock audits

FDA's Goal for FSMA

- Reduce the risk of illness or injury attributed to food manufactured and distributed from facilities subject to FSMA
- Domestic
- Imported
- FDA's implementation mantra: "to educate before it regulates"

FSMA Implementation Strategy

- Phase 1 - Complete for all FSMA regulations
  - Setting new standards through regulations, guidance, and policy
- Phase 2- Ongoing
  - Addressing and planning implementation
  - Designing strategies to gain and maintain food industry compliance with the new rules
- Phase 3 - Ongoing (Starting IA regulation March 2020)
  - Monitoring implementation and evaluating success through the use of KPI's and metrics

FDA Inspections

- Inspections performed by:
  - FDA personnel
  - State personnel
  - Accredited third parties
  - Individual inspector
  - Large team of inspectors

Question

- When is an Inspection Required?

Answer

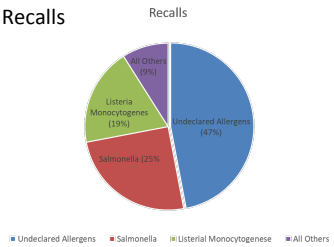
- Routine Basis
  - Increased frequencies
  - Frequency determined by risk
- For Cause
  - Lower threshold
  - Used to require “credible evidence”
  - Now only needs “reason to believe”

Intent of FDA Inspections

- Violation findings will be risk-based
- Targeted inspections
- More aggressive inspections
- Subject matter expert availability
- Form 483s

Focusing on Companies Considered High-Risk

- Reportable Food Registry
- Product Category Recalls
- Allergens



What Happens in an Inspection?

- Inspector has authority to
  - Inspect during normal business hours
  - Take samples
  - Take photos
- Inspector must present
  - Credentials
  - Form 482
- Facility provides
  - Designated, trained escorts
  - Overview of policies and GMPs

What Happens in an Inspection?

- More assertive and comprehensive
  - Prior to FSMA, FDA was insistent on accessing records
  - FDA is asserting "right" to take photographs and review records
  - Inspections becoming more detailed, emphasizing:
    - Basic sanitation
    - Allergen control
    - Personnel adherence to GMPs

Regulatory Expectations

- FSMA audits are more in-depth
  - Hazard analysis conclusions
  - Allergen controls
  - Environmental monitoring
  - Qualified individuals
  - Following your plan
- Includes all FSMA regulations
  - Preventive Controls
  - Sanitary Transportation Act
  - Foreign Supplier Verification Act
  - Intentional Adulteration Regulation

How Are They Doing it Now?

- Reviewing Regulatory Plans for Compliance
  - Food Safety Plans
  - Food Defense Plans
  - Foreign Supplier Verification Program
  - Sanitary Transport Regulation
- Interviewing personnel
- Observing monitoring, corrective actions, and verification activities
- Reviewing training records
- Swabathons

Inspection Results FY 18 and FY 19

Inspection Results

- Inspection results between 10/1/17 – 9/30/19
  - Number of food F483s issued FY 18= 2,583
  - Number of food F483s issued FY 19= 2,540
- Top six issues (45% of the 2,583 issued in FY 18)
- Top six issues (52% of the 2,540 issued in FY 19)
  1. Did not develop FSVP (278)
  2. Sanitation Monitoring (188)
- (FY 2018 results)

Inspection Results FY 18

3. Pest Control (183)
   - Use of pesticides
   - Exclusion of pests
4. Controls-production, packing, and holding (175)
   - Minimize microorganisms
   - Allergen cross-contact
   - Contamination of food
   - Deterioration of food

Inspection Results FY 18

5. Sanitary Operations-Plant Maintenance (167)
   - Good repair
   - Clean and sanitary conditions
6. Personnel (161)
   - Did not take a reasonable measure and precaution related to personnel practices.
7. Majority related to FSMA

Inspection Results FY 19

1. Did not develop FSVP (298)
2. Personnel (226)
3. Pest Control (222)
4. Sanitation Monitoring (195)
5. Sanitary Operations-Plant Maintenance (193)
6. HACCP plan implementation (182)
7. Majority FSMA related

Responding to Form 483

- Respond in writing within 15 business days
- Report all corrective actions taken
  - Include a timetable (if necessary)
- FDA reviews response
  - Follow-up actions may include:
    - Follow-up inspection
    - Warning letter
    - Registration suspension

Industry Feedback

- Inspections are longer
- Back to basics
- Focus on your plan
- Environmental monitoring program
- Allergen Controls
- Photos
- Training and qualified individuals
- Visits at 3 A.M.

Gap Assessment Results

- Qualified individuals
- Allergen Controls
- Not including EMA in the hazard analysis
- Not following the regulatory requirements
- Not verifying monitoring or corrective actions documents within seven working days
- Not prepared for FDA

Wholistic Approach

Preparedness

- Holistic approach to regulatory compliance
- Review and improve regulatory policy
- Back to basics on GMPs
- Training
- Develop, review, or improve internal inspections and audits
- Outside the organization review

Holistic Approach to Regulatory Compliance

- Develop list of current requirements
- Review FSMA and key regulations
- Obtain training to gain understanding
- Network
- Develop teams and action plans

Preparation for FDA Audits

- Well developed regulatory inspection procedure
  - Designated trained individuals (all shifts)
  - Questions to ask
  - Interviewing employees
  - Photo requests
  - Samples and swabbing requests
  - Document submission
  - Control information
  - Be aware of Forms 482,483,484

Back to Basics

- Food safety culture
- Sanitation
- GMPs
- General maintenance
- Attention to detail

Training

- Four levels of training
- Documentation
- Interviews
- Corrective actions

Internal Inspections and Audits

- Review and update
- Train
- Complete detailed inspections

Developing Mock Audit Program

Conducted by someone that will not be recognized

- Designated trained employees
- Representative on all shifts
- Only provide what is asked for
- Do not volunteer or add information that is not requested
- Ask the right questions to FDA

Developing Mock Audit Program

Conducted by someone that will not be recognized

- Challenge personnel
  - Photo requests or challenges
  - Sample and swabbing procedures
  - Interview "qualified individuals"
  - Witness activities
    - Are all written procedures followed?
    - GMPs followed?
    - Information controlled?

Outside the Organization Review

- 3rd Party inspections and audits
- Gap assessments
- FDA information
- Consultants

Resources

- www.FDA.gov
- Notifications
- www.aibinternational.com
- Additional courses
- FDA Preparedness Assessments
- Industry publications
- Food Safety Magazine
- Quality Assurance Magazine

Key Takeaways

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