FDA’s FSMA:
Is Your Organization Prepared?

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Food Safety News

- 2013: Hepatitis A from frozen organic berries, 62 sick in 10 states.


- 2008: Chinese Tainted (Melamine) Milk: 290,000 infants sickened and 6 deaths.
FDA Culture is Changing

- **More inspection-oriented**
  - More domestic inspections (with the states)
  - More testing, both environmental and finished product
  - Increasing oversight of imports (e.g. ingredients) and conducting foreign on-site inspections

- **More enforcement-minded**
  - Increase in Warning Letters for food adulteration based on food inspections/GMPs
  - Increase in court injunctions
  - Heightened use of Import Alerts
<table>
<thead>
<tr>
<th>Center Name</th>
<th>483’s issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food</td>
<td>2386 (47%)</td>
</tr>
<tr>
<td>Devices</td>
<td>1099</td>
</tr>
<tr>
<td>Drugs</td>
<td>690</td>
</tr>
<tr>
<td>Veterinary medicine</td>
<td>328</td>
</tr>
<tr>
<td>Bioresearch monitoring</td>
<td>273</td>
</tr>
<tr>
<td>Biologics</td>
<td>191</td>
</tr>
<tr>
<td>Human tissue for transplantation</td>
<td>121</td>
</tr>
<tr>
<td>Parts 1240 and 1250</td>
<td>91</td>
</tr>
<tr>
<td>Radiological Health</td>
<td>32</td>
</tr>
<tr>
<td><strong>Total 483’s in the system</strong></td>
<td><strong>5050</strong></td>
</tr>
</tbody>
</table>
### FY13 FDA: Number of 483s issued in the system

*10/1/2012 to 9/30/2013*

Top 6 frequencies represent **56%** of total 483’s in Food category

Top 3 frequencies are: Pest Control, Sanitation, Hand-washing (35%)

<table>
<thead>
<tr>
<th>Ref No</th>
<th>Frequency</th>
<th>Short Descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 CFR 110.35(c)</td>
<td>318</td>
<td>Lack of effective pest exclusion</td>
</tr>
<tr>
<td>21 CFR 123.11(b)</td>
<td>300</td>
<td>Sanitation monitoring [maintenance of hand washing, hand sanitizing, and toilet facilities] [protection of food, food packaging material, and food contact surfaces from adulteration]</td>
</tr>
<tr>
<td>21 CFR 110.20(b)(7)</td>
<td>224</td>
<td>Screening [failure to provide adequate screening or other protection devices against pests]</td>
</tr>
<tr>
<td>21 CFR 123.6(b)</td>
<td>177</td>
<td>HACCP plan implementation [did not implement the monitoring [recordkeeping] [verification] procedures as listed in HACCP plan]</td>
</tr>
<tr>
<td>21 CFR 123.6(c)(1)</td>
<td>171</td>
<td>Food safety hazards [HACCP plan does not list the food safety hazards that are reasonably likely to occur]</td>
</tr>
<tr>
<td>21 CFR 110.20(b)(4)</td>
<td>160</td>
<td>Floors, walls and ceilings [the plant is not constructed to allow to be adequately cleaned and kept clean]</td>
</tr>
</tbody>
</table>
FSMA Background

- The Food Safety Modernization Act (FSMA) was signed into law on Jan 4, 2011
- Emphasis on moving from **REACTIVE** to **PREVENTIVE** food safety
- In effect now:
  - Mandatory recall
  - Suspension of registration
  - Administrative detention
  - Expanded records access during emergency
  - Re-inspection Fees - FY14 (Effective Oct 1, 2013):
    - Domestic Facilities $237/man hour, Foreign Facilities $302/man hour
- Affects all US and international food manufacturers that import ingredients or products to the USA
### FSMA Timeline

<table>
<thead>
<tr>
<th>Proposed Rules</th>
<th>Deadline for Publication of Proposed Rules</th>
<th>Deadline for Close of Comment Period</th>
<th>Deadline for Publication of Final Rule</th>
</tr>
</thead>
</table>
FSMA Food Safety Plan

Written Plan (includes procedures)

- Hazard Analysis
  - Biological
  - Chemical
  - Physical
  - Radiological
  - Natural Toxins
  - Pesticides
  - Drug Residues
  - Decomposition
  - Parasites
  - Allergens
  - Unapproved food or color additives
  - Natural hazards
  - Unintentional hazards
  - 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 Hazards (Food Defense)
FDA Current Definition of High Risk Food

1. Identify known safety risks of Food
   - Food commodity category associated with outbreaks, Class I Recalls?

   **Yes**
   - Facility manufactures food commodity category associated with outbreaks AND class I recalls within previous 5 fiscal years.
   - OR
   - Facility manufactures food commodity category associated with outbreaks OR class I recalls and NOT inspected within 5 years.

   **Yes**
   - High-Risk

   **No**

   **Yes**
   - Compliance History
     - Inspection classifications within previous 5 fiscal years
       - OAI or
       - VAI (≥3)

   **No**
   - Non-High-Risk

**Non-High-Risk**
Prevention Control for Human Foods

- Registered facilities must have a food safety plan
  - Hazard Analysis
  - Preventive Controls
  - Monitoring
  - Corrective Actions
  - Verification
  - Reanalysis
  - Recordkeeping
  - Make records available to FDA
  - Limited exemptions
Prevention Control for Human Foods

- FDA has tried to align proposal with HACCP
- Preamble traces origins of HACCP
- Repeated references to other government HACCP programs
- Many references to Codex
- Use of HACCP Principles and Terminology
  - Hazard “reasonably like to occur”
  - Use of parameters (like “critical limits”)
  - Preventive controls may be at critical control points
Emphasis on Validation and Corrective Actions

- FDA expects high level of scientific justification for the plan. They would include collecting and evaluating scientific and technical information.
- Food allergen controls, sanitation controls, and the recall plan would not need to be validated.
- FDA expects written corrective action procedures.
- Corrective actions would need to be documented and subject to verification and records review.
- Key areas where inspectors are likely to focus attention.
High emphasis on recordkeeping/FDA access

- New record creation requirements
- Specific requirements for the content of those records
- Keep records on-site at least 6 months
- Always keep food safety plan on-site
- Make records available promptly
- Facility profiles
- Remote access
- Electronic records
A Record is Anything that “Records” Thoughts
Allergen Control under Preventive Control for Human Foods

- Whenever the law mentions adulteration, it also cites misbranding under “403(w)” (i.e., misbranding due to undeclared allergens).

- Undeclared allergens are the #2 reason for Reportable Food Registry reports. Over 30% of RFR reports are due to undeclared allergens. Also a leading cause of Class 1 food recalls.

- Labeling mix-ups and cross-contact during manufacturing that result in undeclared allergens are the most common GMP issues that results in food allergen recalls.

- **Cross-Contact:**
  - FDA should clarify the definition of cross-contact and not impose a zero-tolerance standard for allergens. Industry opposes FDA requirement for facilities to have dedicated lines/equipment for products that contain food allergens.
Exemptions for Small and very small businesses

• Small – less than 500 employees across the entire company
• Very small – either $250,000, $500,000, or $1,000,000 in annual sales of food
• Extended time for compliance for both
• Very small businesses subject to modified requirements
• Small and very small businesses performing certain low-risk on-farm activities would be exempt
Preventive Control for Human Foods - RECAP

- Hazard Analysis
- Preventive Controls
- Validation
- Monitoring
- Verification
- Corrective Actions
- Reanalysis
- Recordkeeping
Foreign Supplier Verification Program (FSVP)

- Importers would be responsible for ensuring the food they bring into the US meets FDA safety standards. Importer is a US owner, or a US Consignee, or a US Agent
- The requirements provide flexibility based on the risk of the food, which include:
  - Compliance status review of foods and suppliers
  - Hazard analysis
  - Supplier verification activities and corrective actions if needed
  - Periodic reassessment of the FSVP every 3 years or sooner
  - Importer identification at entry (provide DUNS number to CBP when filing for entry of food)
  - Record keeping (English)
Option 2:

Diagram 2

Proposed Standard FSVP Requirements

- Perform food/supplier compliance status review
- Conduct hazard analysis (not required for microbiological hazards in produce)
- Maintain written list of foreign suppliers

Are there hazards that are reasonably likely to occur?

Yes

For hazards controlled by importer or by its customer:
  - Document importer or customer is controlling hazard

For other hazards:
  - Conduct verification from among:
    - Onsite auditing
    - Sampling and testing
    - Review of foreign supplier food safety records
    - Other appropriate procedure

Conduct investigative & corrective actions (as needed)

Reassess FSVP

Ensure importer identification at entry

Maintain records

No

Conduct investigative & corrective actions (as needed)

Reassess FSVP

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Maintain records
Accreditation of Third Party Auditors

**FDA**
FDA would recognize accreditation bodies based on certain criteria such as competency and impartiality.

**Accreditation Bodies (AB)**
Accreditation bodies would in turn accredit qualified third-party auditors.

**3rd Party Auditors or Certification Bodies (CB)**
Third-party auditors/certification bodies would audit and issue certifications for foreign facilities and foods.

**Foreign Facility**
Foreign facilities may choose to be audited by an accredited auditor/certification body.

AB would last 5 years, must maintain records for 5 years

CB would last 4 years. Certification would last 12 months. FDA would retain authority to directly withdraw accreditation for cause.

Auditors would be required to report to FDA immediately any Class I and Class II findings.

Regulatory audit reports would need to be sent to FDA routinely within 45 days after audit (e.g. GFSI audits)

Laboratory results taken during an accredited audit would be automatically sent to FDA by the accredited laboratories.
Accreditation of Third Party Auditors – Issues

• 3rd Party Certification: a ‘surrogate’ FDA inspection program
• No system in place to globally manage audit and lab information with industry and government
• Inability to handle the volume of information of direct reporting with the low criteria of Class II type of recalls for auditors to report
• Reduced incentive for consultative audits would potentially undermine improvement of food safety systems that industry is driving through GFSI
Preventive Controls for Animal Feeds

• For the FIRST TIME!
• Facilities that Divert Human Food or Waste
• Similar to cGMPs for human food
• Address:
  • Hygienic personnel practices and training
  • Facility operations, maintenance, and sanitation
  • Equipment and utensil design, use, & maintenance
  • Processes and controls
  • Warehousing and distribution
• Do not address allergen cross-contact
Preventive Controls for Animal Feeds

• Prepare and implement a written food safety plan which would include:
  • A hazard analysis of known or reasonably foreseeable hazards for each type of animal food
    • Human handlers
    • Consuming animal species
  • Preventive controls to significantly minimize or prevent hazards that are reasonably likely to occur
    • Including nutrient imbalance controls and a recall plan
  • Monitoring Programs
Preventive Controls for Animal Feeds

- Corrective action procedures
  - Correct problems and minimize reoccurrence
  - Evaluate the animal food for safety
  - Prevent affected animal food from entering commerce
  - If ineffective, the facility must reevaluate the food safety plan
- Verification activities, including validation of preventive controls and plan reanalysis
  - Note that product and environmental testing are not proposed requirements, but are expected to be part of a final rule
- Recordkeeping
Sanitary Transport of Foods and Feeds

- Applies to shippers, carriers and receivers of ground and rail transportation
- Exemption: Transportation solely of shelf-stable food that is completely enclosed by a container
- Requirements for Shippers –
  - Maintained sanitary condition
  - Provide access to a hand washing facility for food not completely enclosed by a container during loading operations
  - Maintain Records (e.g. temperature control requirements)
  - Keep records for 12 months
Sanitary Transport of Foods and Feeds

• Requirements for Carriers:
  • Visually inspect the vehicle for cleanliness before loading
  • For bulk vehicles, identify the three previous cargoes transported and the most recent cleaning
  • Develop written procedures that:
    • Specify practices for cleaning, sanitizing (if necessary), and inspecting vehicles
    • Describe how they will comply with the temperature control monitoring requirements
• Document training:
  • Provides an awareness of potential food safety problems that may occur during food transportation
  • Covers basic sanitary transportation practices to address those potential problems
Sanitary Transport for Foods and Feeds

- Requirements for the Receivers:
  - Provide access to a hand washing facility for food not completely enclosed by a container during loading operations
  - Offsite storage of records is permitted 6 months, provided the records can be retrieved within 24 hours of an official request

- FDA is working with USDA, DOT, and the states to determine the logistics of enforcement
Intentional Adulteration

• Each facility not eligible for an exemption must have a food defense plan (FDP). FDP must include:
  • A vulnerability assessment
  • Identification of actionable process steps, if any
  • Monitoring
  • Corrective actions
  • Verification
  • Records in support of the FDP
  • Training of supervisory and operational personnel as necessary
Intentional Adulteration

• The vulnerability assessment:
  • Must be performed by qualified individuals
  • Be risk-based
  • Evaluate existing mitigation strategies
  • Identify significant vulnerabilities, if any
  • Include documented rationale for conclusions
Intentional Adulteration - Exemption

- Proposed exemptions:
  - All food storage activities except liquid storage
  - Packing, re-packing, or labeling activities (immediate food container remains intact)
  - Activities subject to the produce rule
  - Animal food facilities
  - Certain alcoholic beverage facilities
  - Qualified facilities (i.e., very small businesses with less than $10 million in annual sales)
  - But must provide, upon request, documentation relied on to demonstrate very small business status
  - Would have 3 years to meet this proposed requirement
Next Steps

• Educate your company on FSMA proposed rules
• Perform gap analysis within the organization
• Determine resources and constraints
• Keep current through trade organizations
• To the Plants: Be Inspection Ready!