FDA FSMA Update

Northwest Food Safety and Sanitation Workshop

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U.S. Food & Drug Administration | FDA
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FDA Food Safety Modernization Act

• Update of FSMA programs timelines
• Summary of FSMA program assignments and training requirements
• Types of GMP/Preventive Control Inspections
• Observations and corrective actions
• Looking Forward

Food Safety Modernization Act (FSMA)

• Intended to build a food safety system for the future that makes modern, science- and risk-based preventive controls the norm across all sectors of the food system.
• FSMA’s success depends on bringing about high rates of compliance.
• FDA is committed to educating before and while we regulate.
• FDA will engage and communicate to international community that is consistent with domestic efforts.
### Compliance Dates 2018

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 2018</td>
<td>Sprouts: Small businesses</td>
</tr>
<tr>
<td>January 2018</td>
<td>VQIP applications</td>
</tr>
<tr>
<td>April 2018</td>
<td>Sanitary Transportation: Large and small business</td>
</tr>
<tr>
<td>Sept/Oct 2018</td>
<td>Preventive Controls: Human Food – All, Animal Food – Large, Qualified Facilities</td>
</tr>
</tbody>
</table>

### FY2019 FDA Assignments

<table>
<thead>
<tr>
<th>FSMA</th>
<th>Date of Issuance</th>
<th>Planned Number of Inspections</th>
</tr>
</thead>
<tbody>
<tr>
<td>Produce - sprouts</td>
<td>Will issue November 2018</td>
<td>Domestic: MIE small and very small firms</td>
</tr>
<tr>
<td>Sanitary Transportation</td>
<td>Issued October 2018</td>
<td></td>
</tr>
<tr>
<td>Foreign Supplier Verification Program</td>
<td>Issued October 2018</td>
<td>HF Imports: 1000, AF Imports: 25</td>
</tr>
<tr>
<td>Intentional Adulteration</td>
<td>No assignment issues</td>
<td>Quick checks will start on October 1, 2019</td>
</tr>
<tr>
<td></td>
<td></td>
<td>None at this time</td>
</tr>
</tbody>
</table>

### FY2019 FDA Assignments

<table>
<thead>
<tr>
<th>FSMA</th>
<th>Date of Issuance</th>
<th>Planned Number of Inspections</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preventive Controls in Animal Food</td>
<td>Issued October 2018</td>
<td>Domestic: 250</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Domestic: all other</td>
</tr>
<tr>
<td>Preventive Controls in Human Food</td>
<td>Issued October 2018</td>
<td>Domestic: 500, foreign: 150</td>
</tr>
<tr>
<td>GMP/Full Scope PC</td>
<td></td>
<td>All businesses subject to PC other than assigned</td>
</tr>
<tr>
<td>GMP/Limited Scope PC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GMP/Modified requirement – Qualified Facility</td>
<td></td>
<td>All businesses that have self-attested</td>
</tr>
<tr>
<td>Other Center directed assignments</td>
<td>Issued throughout year(s)</td>
<td>Inspections, Sample Collections (Product or Environmental)</td>
</tr>
</tbody>
</table>

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Produce

FY'19 Sprout Assignment to issue soon

- Sprout assignment issued September 2017 to conduct inspections of large sprout growers.
- Inspection Target: 90 small and very small businesses
  - Very small business subject to rule in January 2019
- Required Training: Pre-requisites and FD225 Sprout inspections for regulators
- Routine inspections under the PSR will not begin until the spring of 2019 to give both farmers and state regulators more guidance, training, technical assistance, and planning and ensure that they have the tools they need.
- FDA continues to work with States on On-Farm Readiness Reviews and educational outreach efforts with farmers.

Foreign Supplier Verification Program

FY'19 Assignment issued: October 15, 2018

- Inspection Target:
  - 1000 Human Food and 25 Animal Food Importers
- Required training
  - FSVP regulators training
    - Total trained to date 300
    - Expected trained in FY19 - 150
- VQIP
  - Applications went online October 1, 2018 and remain open until May 11, 2019
  - Application review starting in January 2019.
  - Challenges:
    - Dependent on Third Party Accreditation Bodies to accredit Certification Bodies
  - More education is needed with the importer community on new requirements.

Sanitary Transportation of Human and Animal Food

FY'19 Assignment issued: October 1, 2018

- Inspection Target
  - 38 large; 108 small businesses
  - Will attempt to link with other programs in FY20
- Required training:
  - Two internal presentations to FDA Staff provided to introduce HAF Investigators to the requirements of 21 CFR 1, Subpart O in preparation for upcoming inspections.
  - Online webinar
  - Online course, four part training module for carriers available on FDA’s webpage.
  - Sanitary Transportation Carriers Training Module (FDA’s Public webpage)
Intentional Adulteration
Assignments will issue in FY’20 +
• Two Level Inspectional Approach
  • Quick Check
  • Comprehensive
• Required training
  • Quick check: Webinar based
  • Comprehensive: IA regulators course

Training and Assistance to Industry
• Webinars
• Online courses
• FSMA Technical Assistance Network (TAN)

Preventive Controls for Animal Food
FY’19 Assignment issued: October 15, 2018
• Full PC requirements were delayed until FY19
• Inspection Target
  • 150 GMP/Full Scope PC – large facilities
  • 250 GMP
• Required Training
  • Pre-requisites
  • CGMP/Preventive Controls for Animal Food Regulators Course

Preventive Controls for Human Food
FY’19 PCHF Assignment issued: October 18, 2018
• Applies to both foreign and domestic food facilities
• Inspection target
  • FDA: 500 GMP/Full Scope Preventive Control inspections
  • State: 231 GMP/Full Scope Preventive Controls inspection
  • All other registered food facilities: GMP/Limited Scope Preventive Control inspections
• Required Training
  • GMP/Limited Scope PC webinar
  • Preventive Controls for Human Food Regulators Course
Preventive Controls for Human Food

- Very Small Businesses – subject to preventive controls requirements in September 2018
- Qualified facilities
  - Business with average annual sales of <$500,000 and at least half the sales to consumers or local retailers or restaurants (w/in same state or w/in 275 miles)
  - OR
  - Very small business (including any subsidiaries and affiliates) averaging less than $1 million, adjusted for inflation, per year, etc.
  - Can self-attest to exempt from Subparts C & G
  - Self attestation – started on October 1, 2018

Preventive Controls for Human Food

- Modified Requirements (Subpart D)
  - Warehouses solely engaged in the storage of unexposed packaged food that requires refrigeration for safety
  - Exempt from 21 CFR Subparts C and G
  - Assessed against 21 CFR Subparts A, B, D and F
  - Monitoring storage times/temperatures
  - Monitoring records
  - General record keeping requirements
- Qualified Facilities
  - Self-attestation – available Oct. 1st.
  - Submitted every two years – same as facility registration
  - Exempt from 21 CFR Subparts C and G
  - Attests to one of two provisions
  - Assessed against 21 CFR Subparts A, B, D and F
  - Guidance published in May 2016

Types of FY19 Human Food PC Inspections

<table>
<thead>
<tr>
<th>Type of Inspection</th>
<th>Training</th>
<th>21 CFR 117 Scope</th>
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</thead>
<tbody>
<tr>
<td>GMP</td>
<td>In transition</td>
<td>Subparts A, B and F</td>
</tr>
<tr>
<td>GMP/Modified requirement Qualified Facility</td>
<td>In transition</td>
<td>Subparts A, B and F, Modified requirements D</td>
</tr>
<tr>
<td>GMP/Modified requirement Warehouses/Storage/Refrigeration</td>
<td>In transition</td>
<td>Subparts A, B and F, Modified requirements D</td>
</tr>
<tr>
<td>GMP/Limited Scope PC</td>
<td>GMP/Limited Scope PC Webinar</td>
<td>Focus on Subpart A, B, F. Broad-based assessment of PC systems. May trigger Full PC</td>
</tr>
<tr>
<td>GMP/FT Scope PC</td>
<td>FDA GMP/Limited Scope PC Webinar</td>
<td>2018-2019 PC Regulator course</td>
</tr>
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**FDA Observations**

Preventive Controls – Human Food

- Observations based on public health rather than regulatory requirements
- Significant observations – documented
- Non-significant observations – discussed
- Tracking voluntary corrective actions

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**Field Activities**

**Successes**

- Food Safety Staff and industry participating in training together
- Food Safety Staff partnering to implement system based inspection approach
- Food Safety Staff inspecting to public health rather than regulatory requirements
- Food Safety Staff learning and working more closely together in the implementation of the regulations

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**Field Activities**

**Challenges**

- Clear communication of purpose of inspection.
- Longer inspection times and more participants on inspections, partly due to OJE.
- Consider feedback from industry, consumers, and state partners.
- Obtaining copies of documents for information purposes rather than supporting evidence for an observation.
Looking Forward

• Continue focus on education, training and technical assistance for our food safety staff and industry
• Continue issuing draft guidance
• Continue to implement systems based inspections that focus on public health
• Continue to collaborate with regulated industry to ensure compliance and understanding of their role in food safety

Have a FSMA Question?
FDA Food Safety Modernization Act (FSMA) website

Thank You
You