FSMA Update

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FSMA
Main Themes of the Legislation

Prevention

Enhanced Partnerships

Inspections, Compliance, & Response

Training/Educate Before Regulating

Import Safety
<table>
<thead>
<tr>
<th>Regulation</th>
<th>Proposal</th>
<th>Final</th>
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<tbody>
<tr>
<td>Preventive Controls for Human Food*</td>
<td>January 16, 2013</td>
<td>August 30, 2015</td>
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<tr>
<td>Preventive Controls for Animal Food*</td>
<td>October 29, 2013</td>
<td>August 30, 2015</td>
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<td>Produce Safety*</td>
<td>January 16, 2013</td>
<td>October 31, 2015</td>
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<tr>
<td>Foreign Supplier Verification</td>
<td>July 29, 2013</td>
<td>October 31, 2015</td>
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<td>Third Party Accreditation</td>
<td>July 29, 2013</td>
<td>October 31, 2015</td>
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<td>Sanitary Transportation</td>
<td>February 5, 2014</td>
<td>March 31, 2016</td>
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<tr>
<td>Intentional Adulteration</td>
<td>December 24, 2013</td>
<td>March 31, 2016</td>
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*Supplemental Proposals for Selected Sections – Summer 2014 Estimated
Key Implementation Challenges

• Resources for FDA and states to fully implement FSMA
• Accommodating complexity and diversity of the food and feed system
• Building efficiently on past progress—HACCP and GAPs
• Providing sufficient outreach, training, and technical assistance
• New approaches to inspection and compliance
Produce Safety—Key Points

• Focused on the 20 percent of farms that account for 90 percent of acreage
• Targeted on practices and pathways of practical importance to food safety
• Outreach and comments raising important issues FDA will address
Foreign Supplier Verification Program—Key Points

• Foundation for a modern import oversight program
  – Enhanced accountability for prevention and level playing field
• Reliance on private supply chain management
• Risk-based approach to supplier verification
• Part of a larger import oversight toolkit
Accredited 3rd Party—Key Points

• Recognizes potential role of rigorous private audits as part of public assurance system
• Very limited application under FSMA
• Opportunity for broader role, but many challenging issues to address
Next Steps

• Review written comments
• FDA is open minded on the issues of concern to stakeholders
• FDA is committed to thorough stakeholder engagement
• Issue supplemental proposals
• With input from stakeholders, including state regulatory agencies, development of a long-term implementation plan for FSMA
• Utilize the Partnership for Food Protection as a primary vehicle for achieving an Integrated Food Safety System
• View and treat states as full and equal partners
Mutual Reliance for Safer Food Supply

- Standards
- Training and Certification
- Work Planning
- Data Sharing
- Best Practices
FSMA Update

• Go to fda.gov/fsma for more information