FSMA Update
NCSL Meeting - 2014

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FSMA
Main Themes of the Legislation

Prevention

Enhanced Partnerships

Inspections, Compliance, & Response

Training/ Educate Before Regulating

Import Safety
<table>
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<tr>
<th>Regulation</th>
<th>Proposal</th>
<th>Final</th>
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<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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<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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<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
How FDA Will Operate Differently

• FDA will speak with one voice
• Inspection, compliance functions specialized
• Invest in regulator training to promote consistent inspections, decision making
• Investigators and subject matter experts work together to drive correction of problems
• Educate before we regulate
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
Company’s Food Safety Culture Guides FDA Approach

- Targeted, risk-based inspection models
- Wider range of inspection, sampling, testing and data collection activities
- Improve risk-based work planning through targeted data collection and more timely data analysis and program evaluation
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 in supplemental proposals
- Maintain alternatives and variance options
Foreign Supplier Verification Program—Key Points

• Level playing field for domestic and imported foods
• Importers are accountable for the safety of the foods they bring into the US
• Foundation for a modern import oversight program
• Reliance on private supply chain management
• Risk-based approach to supplier verification
Accredited 3\textsuperscript{rd} 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
FSMA Implementation

• What is changing?
  – FDA will operate differently
  – Risk based
  – FDA will educate before and while it regulates
  – Focus on working with industry to achieve high rates of compliance instead of building legal cases
  – Company’s food safety culture will guide FDA’s approach
  – Working with states early to design an effective implementation plan
Next Steps

• Review written comments
• FDA is open minded on the issues of concern to stakeholders
• FDA is committed to ongoing 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
• Work with state stakeholders to educate around the need for additional resources
Mutual Reliance for Safer Food Supply

- Standards
- Training and Certification
- Work Planning
- Data Sharing
- Best Practices
More Information Available

• Web site: http://www.fda.gov/fsma
• Subscription feature available
• Send questions to FSMA@fda.hhs.gov