North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner

State Implementation of FSMA

71st Annual Meeting
Southern Legislative Conference

Biloxi, Mississippi
Food Safety Modernization Act (FSMA)

- Signed into law January 4, 2011
- Focus on prevention
- Provides new enforcement authorities
- Directs the creation of an integrated food safety system in partnership with state and local authorities
Current Status:

- All 7 Final Rules have been issued
- Alliance Training being delivered
- Guidance Under Development
- Compliance Dates Rapidly Approaching
Focus on Produce Safety Rule

Establishes science-based minimum standards for the safe growing, harvesting, packing and holding of fruits and vegetables for human consumption.

Focus on routes of microbial contamination

- Risk-based, considers practices and commodities
- Includes provisions for alternatives and variances
Standards for Produce Safety

- Personnel qualifications and training
- Health and hygiene
- Agricultural water
- Biological soil amendments of animal origin
- Domesticated and wild animals
- Growing, harvesting, packing and holding activities
- Equipment, tools, buildings and sanitation
- Specific requirements for sprouts
Impact on Agribusiness

- Cost of potential facility upgrades and assistance to develop food safety plans;
- Employee Training;
- Potential changes in routine business practices;
- Impact of multiple audits; and
- Potential increased cost of production
Overarching Concerns

- Equal treatment of domestic and foreign producers in compliance and enforcement
- Must ensure education before regulation-training for industry and regulators
- Technical assistance and guidance documents are needed before and during implementation
- Resources are needed for State agencies to implement rules *
# Compliance Dates: Produce Safety Rule

<table>
<thead>
<tr>
<th>Size of covered farm</th>
<th>Covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of part 112)</th>
<th>Covered activities involving all other covered produce (i.e., subject to part 112, except subpart M)</th>
<th>Farms eligible for a qualified exemption (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Compliance date for certain specified agricultural water requirements</td>
<td>Compliance date for all other requirements</td>
<td>Compliance date for retention of records supporting eligibility in § 112.7(b)</td>
</tr>
<tr>
<td>Time periods starting from the effective date of rule (60 days after final rule is published)</td>
<td></td>
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<tr>
<td>Very small business ≤$250,000*</td>
<td>3 years</td>
<td>6 years</td>
<td>4 years</td>
</tr>
<tr>
<td>Small business ≤$500,000</td>
<td>2 years</td>
<td>5 years</td>
<td>3 years</td>
</tr>
<tr>
<td>All other businesses</td>
<td>1 year</td>
<td>4 years</td>
<td>2 years</td>
</tr>
</tbody>
</table>
State Implementation of FSMA

NASDA Technical Working Group
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70 subject matter experts representing policy, operations, food, feed and produce safety expertise.

- 23 State Departments of Agriculture
- National Associations
Charge

- Develop and implement a systematic process to review and provide comments to FDA on all 7 proposed foundational rules; and

- Develop an operational strategy for FSMA implementation by state programs

Leadership

Bob Ehart, Senior Policy Advisor, NASDA
Joe Reardon, Assistant Commissioner, NCDA&CS
NASDA FSMA Implementation Framework

- Describes the components and processes for the development of a state FSMA inspection program
- Establishes a systematic implementation approach with clear goals and objectives
- Will build a foundation of uniformity, consistency and equivalency among regulatory programs - state and federal.
Elements of NASDA FSMA Implementation Framework

- Alignment & Consistency
- Foundation of Law
- Financial Support
- Education/Outreach & Compliance/Enforcement
- Work Planning

- Information Sharing
- Regulator Training
- Lab Resources
- Technical Support
- Dispute Resolution
- Infrastructure
Required Components of a FSMA inspection program:

- Regulatory Authority/Foundation of Law
- Staffing
- Training
- Industry Outreach and Education
- Inspection, Compliance and Enforcement
- Technical Assistance for industry
- Laboratory Resources
Resources for State Implementation

FDA Provides $21.8 Million to States for Produce Safety
Future

- Outreach, education and technical assistance needed for industry and regulators.
- Guidance is needed in advance of compliance dates.
- Support to land grant universities and cooperative extension programs is necessary.
- Collaboration and cooperation among regulatory agencies is critical.