Discussion on FSMA & Its Implementation

Bob Ehart
Senior Advisor
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 Major Rules have been issued
- Alliance Training is being delivered
- Guidance is Under Development
- Compliance Dates are 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 for some parts of the rule
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 a food safety plan, where needed
- Employee training
- Potential changes in routine business practices
- Impact of multiple audits and inspections
- Potential increased cost of production
## 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>
<td></td>
<td></td>
</tr>
<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>
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 *
State Implementation of FSMA

NASDA Technical Working Group
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 & Science Advisor
Joe Reardon, Assistant Commissioner, NCDA&CS
NASDA TWG

84 subject matter experts representing policy, operations, food, feed and produce safety expertise

- 24 State Departments of Agriculture
- National Associations
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

Chapters

- 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

Competition A Only & Competition A / B Map

**Competition A** includes Infrastructure, Education, Technical Assistance, and Inventory Program.

**Competition A/B** includes Competition A components AND an Inspection, Compliance and Enforcement Program.
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
There still are policy considerations to be developed before the rules are implemented

- How will states go about implementing the Produce Safety rule?
- What other programs will states be involved in?
- There are several issues that will require FDA to modify its existing program in order to get the rules right, e.g.,
  - Agricultural water?
  - Packing sheds?
Difficulties states may have in establishing a program

- Adequacy of long term funding
- “Model” bill issues
- The timeframe in FSMA did not include a transition period – states have “state” requirements too.
So, why establish a state program?

- Farmers have been clear that they want the state, particularly the state department of agriculture, to be a buffer between FDA and the farm.
- The safety of the food supply is expected.
- Contrary to some people’s beliefs, FSMA isn’t going to just go away.
Questions?

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