



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

## **State Implementation of FSMA**

**71<sup>st</sup> 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



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# 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 \*



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# Compliance Dates: Produce Safety Rule

Size of covered farm	Covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of part 112)	Covered activities involving all other covered produce (i.e., subject to part 112, except subpart M)		Farms eligible for a qualified exemption (if applicable)		
		Compliance date for certain specified agricultural water requirements	Compliance date for all other requirements	Compliance date for retention of records supporting eligibility in § 112.7(b)	Compliance date for modified requirement in § 112.6(b)(1)	Compliance date for all other requirements in §§ 112.6 and 112.7
Time periods starting from the effective date of rule (60 days after final rule is published)						
<b>Very small business</b> ≤\$250,000*	3 years	6 years	4 years	Effective date of rule	January 1, 2020	4 years
<b>Small business</b> ≤\$500,000	2 years	5 years	3 years			3 years
<b>All other businesses</b>	1 year	4 years	2 years			N/A

From FDA FSMA Webinar: Final Rule for Produce Safety



# State Implementation of FSMA

## NASDA Technical Working Group



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# NASDA Technical Working Group

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

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## 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.



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# 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:

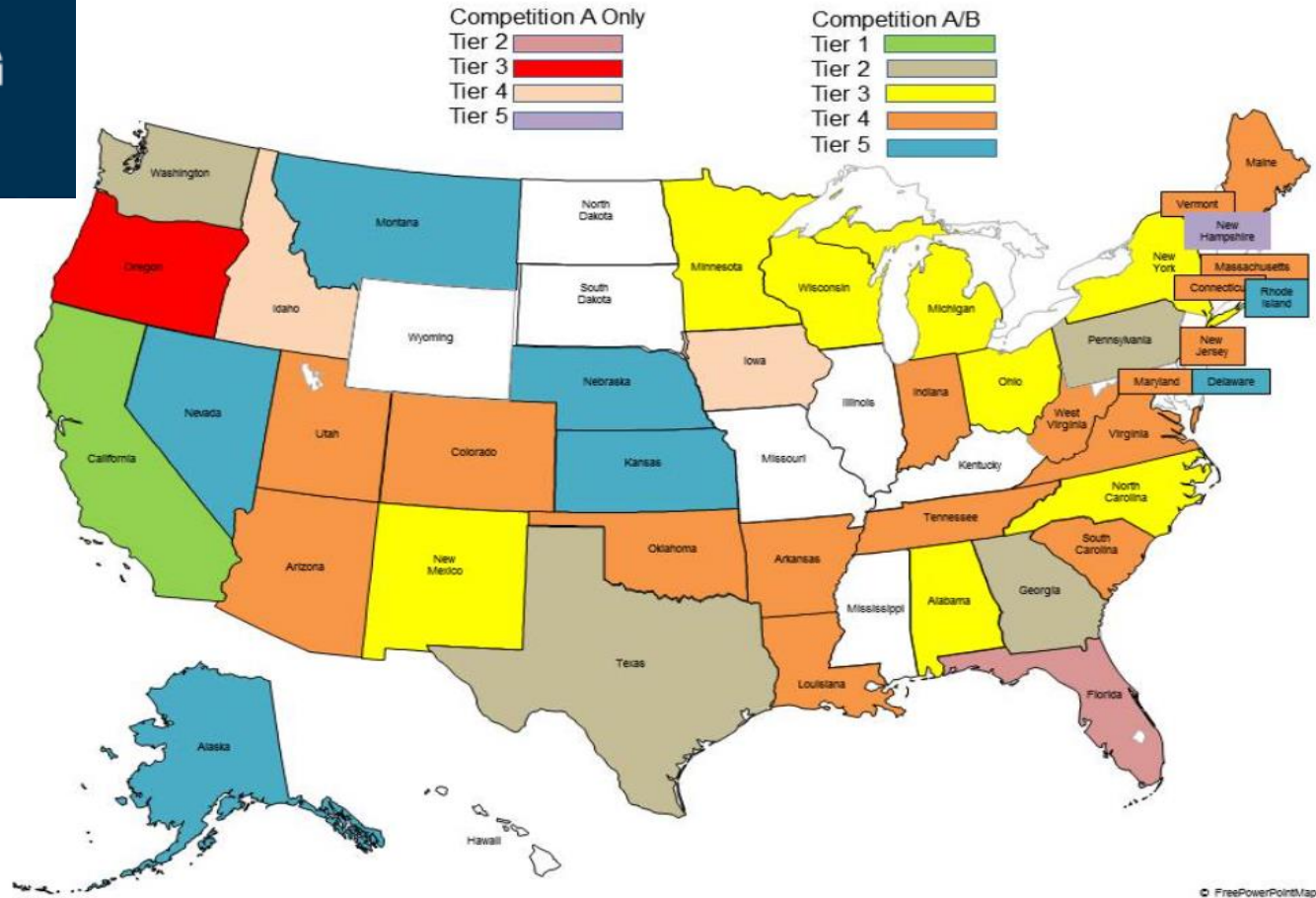
- ▶ Regulatory Authority/Foundation of Law
- ▶ Staffing
- ▶ Training
- ▶ Industry Outreach and Education
- ▶ Inspection, Compliance and Enforcement
- ▶ Technical Assistance for industry
- ▶ Laboratory Resources



# Resources for State Implementation

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**FDA** U.S. FOOD & DRUG  
ADMINISTRATION



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Constituent Updates

## FDA Provides \$21.8 Million to States for Produce Safety

# Future

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- ▶ 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



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