



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

**Food Safety Modernization Act
Update and State Initiatives**

NC Food Safety and Defense Task Force
2015 Annual Conference

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Joseph W. Reardon

Assistant Commissioner, Consumer Protection



Food Safety Modernization Act FSMA

- Signed into law January 4, 2011
- Focus on prevention and risk-based preventive controls
- Provides new enforcement authorities including authority to ensure safety of imported foods
- Directs the creation of an integrated food safety system in partnership with State and local authorities.



Why is this law necessary?

- **Globalization**

- 1 in 6 FDA regulated food products is imported

- **Food supply more high-tech and complex**

- More complex foods in the marketplace
- New hazards in foods not previously seen

- **Shifting demographics**

- Growing “at risk” population



The Public Health Imperative

- **Foodborne illness is a significant burden**
 - About 48 million (1 in 6 Americans) get sick each year
 - 128,000 are hospitalized
 - 3,000 die
- **Immune-compromised individuals more susceptible**
- **Foodborne illness is not just a stomach ache—it can cause life-long chronic disease**



Proposed Foundational Rules

- Produce Safety *
- Preventive Controls for Human Food *
- Preventive Controls for Food for Animals *
- Foreign Supplier Verification Program *
- Third Party Accreditation
- Intentional Adulteration
- Sanitary Transportation of food



Current Status

- FDA is under a court ordered consent decree to issue final rules in 2015 and 2016
- Compliance begins 1 - 2 year after final the rules are issued; small and very small facilities each have an additional year to comply
- Implementation efforts are ongoing



Compliance Dates

Compliance Dates (After Effective Date)	Preventive Controls (Human and Animal)	Produce Safety
Final Rule Issued	Aug 30, 2015	Oct 31, 2015
Effective Date	60 days	60 days
Other	1 year (2016)	2 years (2017)
Small	2 years (2017)	3 years (2018)
Very Small	3 years (2018)	4 years (2019)

(+ 2 additional years for some water requirements)



State Implementation of FSMA

NASDA Technical Working Group





Established in 2013 by the NASDA Food Regulation Committee

- Steve Troxler, Commissioner, NCDA & CS
- Katy Coba, Director, Oregon Department of Agriculture
- Jamie Clover-Adams, Director, Michigan Department of Agriculture and Rural Development
- Chuck Ross, NASDA Past President and Secretary, Vermont Agency of Agriculture Food & Markets



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 TWG Membership

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

- 23 State Departments of Agriculture
 - National Associations

AAFCO

AFDO

IFPTI



Comprehensive and Systematic Rules Review Process

- Analysis and cross reference of rules, supporting documentation and existing regulatory provisions
- Developed and submitted comments to all 7 original and 4 supplemental proposed rules
 - 250 pages of comments
 - 22 months; 2 hour calls; twice a week
- Will conduct similar analysis after final rules are issued



Overarching Concerns

- Must ensure equal treatment of domestic and foreign producers in compliance and enforcement
- Extensive training and technical assistance for industry; must have education before regulation
- Resources are needed for State agencies to implement rules
- Support needed for research institutions, academia, and cooperative extension programs
- Very broad in scope, from farm to fork



Key Specific Concerns

- Impact of the definition of farm on industry covered under produce and preventive controls rules
- Water quality standards and testing frequencies in the produce rule
- Complex exemptions and modified requirements in preventive controls rules
- Requirements for on-farm mixed-type facilities



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



NASDA FSMA Operational Plan

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



Elements of NASDA FSMA Operational Plan

- Foundation of Law;
- Financial Support;
- Dispute Resolution;
- Education/Compliance and Enforcement;
- Work Planning;
- Information Sharing;
- Regulator Training;
- Laboratory Resources;
- Technical Support;
- Standardization; and
- Infrastructure



Programmatic Considerations for State Implementation of FSMA Rules

- Agency plan for FSMA implementation:
 - Education and Outreach
 - Inspection/Compliance and Enforcement
- Current status of programmatic capacity and capability:
 - Assessment of existing resources and infrastructure to identify additional needs related to FSMA inspection programs



Infrastructure needed to implement a FSMA inspection program:

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



Future

- Continued development of operational plan in coordination with FDA
- Collaboration and cooperation among regulatory agencies is critical
- Funding is necessary to build the necessary infrastructure, capacity and capability
- Technical assistance to industry and regulators is essential

We must educate before we regulate



Thank you!

Joseph W. Reardon
Assistant Commissioner,
Consumer Protection