

The Future of Food Safety: FSMA & the State Departments of Agriculture

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Who/What is NASDA?

- NASDA is the National Association of State Departments of Agriculture
- We are a nonprofit, nonpartisan organization representing the 50 state and 4 territorial departments of agriculture
- We are located in the Washington, DC area



FSMA primer

- The FSMA was signed into law in Jan 2011
- FSMA adds authorities to the FFD&CA – it isn't a stand alone law
- FSMA establishes preventive controls adding them to cGMPs
- FDA has had authority over causes of foodborne outbreaks and adulterated products
- Levels the playing field by creating similar requirements for imported and domestic products



More on FSMA

- FFD&CA already regulated “manufactured food” production – and FSMA officially adds preventive controls –
- FFD&CA regulated medicated feed – and FSMA adds GMPs and preventive controls to the regulation of “animal food” production – newly regulated facilities
- FSMA proactively regulates fruit and vegetable producers – newly regulated farms and packing sheds



7 major rules to implement FSMA

- Preventive Controls: Animal Food
- Preventive Controls: Human Food
- Produce Safety
- Foreign Supplier Verification Program
- Third-party Accreditation
- Intentional Adulteration
- Sanitary Transportation



Why was FSMA passed?

- While we arguably have the safest food supply in the world, several highly publicized foodborne illness events made food safety front page news
 - Leafy greens
 - Cantaloupe
 - Peppers
 - And we can't forget melamine



Prevention: a new paradigm

- Prevention is an important policy change for several reasons:
 - The “old” policy is unsustainable
 - It creates a culture where everyone has a new (improved) role in assuring food safety
 - While we will never have zero events, we can improve what we know and what we do to prevent events from occurring



Prevention: a new culture

- If prevention is to work, everyone needs to do their own part:
 - Producers, Suppliers, Wholesale, Retail, Consumers...
 - Educators
 - Regulators
 - States
 - FDA



Culture Change

- FDA will have a new role, as a participant in assuring food safety, not just as an enforcement agency
- Philosophically, state programs have often been based on compliance which we believe is consistent with the role, responsibility and values Congress established in FSMA
- We all have an opportunity to make prevention work



Current states' roles

- States have cooperated with FDA for years –
 - Manufactured food programs in state health (~30 states) and agriculture (~20 states) departments
 - Feed control programs (in 47 state agriculture departments – the other 3 in universities)
 - Dairy processors – regulated through state-enacted Pasteurized Milk Ordinances
 - Fruit & Vegetable producers – only reactively



FSMA and the states - 2011

- Food Safety Policy needed to be “modernized”
- Prevention is a sound public policy
- No state currently had a Produce Safety or Feed Safety program “aligned” with the ideals of FSMA
- FSMA supports the development of an Integrated Food Safety System



FSMA and the states - 2015

- FDA needs:
 - to get the rules right
 - to change its culture
 - the states to help the agency implement all three of the major rules
- Congress needs to fund FSMA



FSMA allows states to have a role but does not require states to implement FSMA

- FSMA supports creating an Integrated Food Safety System – for a reason
 - It is inconceivable that the magnitude of changes created by FSMA can be implemented by FDA without the states
 - Congress will not fund FDA at the level it would take to implement FDA as a federal program



Educate before - and while - we regulate

- This is uncharted territory for FDA
- New levels of cooperation between federal and state program leaders will be required
- New and improved links between the regulators and the educators will be required
- Interactions between and among regulators, educators and industry will also need to increase



Developing state programs

- Look to:
 - existing programs – e. g., manufactured foods
 - Existing feed control programs are primarily “label guarantee” programs – however, existing authority regarding adulterated product is a basic tenet of food / product safety
 - New authority will be required



Developing state programs

- We live in interesting times
- Because of other federal laws creating unfunded mandates, state legislatures are not particularly interested in creating a new state program just because Congress has – regardless of the need, value and support for the program
- FDA needs to get the rules right and Congress needs to fund it



Potential Roles for States

- As partners with FDA
- As educators – state depts of agric & extension
- As regulators
- As a buffer between FDA and producers/facilities
- As compliance and technical assistance
“counselors” – including “readiness review”



Options for state involvement

- First option is for Congress to adequately fund FDA and the states for a core program
- States would seek state laws that would align with FSMA
- States would operate under states' authorities and cooperate with FDA



Options for state involvement

- Alternatively, states could operate as federal inspectors, using commissioning and credentialing
- This could be a short term stop gap solution, but is not the preferred option



Where the state departments of agriculture are today

- Did I mention getting the rules right and Congressional funding?



Getting the rules right

- FDA has listened to its stakeholders regarding the definition of “farm” and what a vertically integrated operation is.
- We are still analyzing the details for the PC rules, and we will be interested in your take of the PC: Animal Food rule and any problems that still exist in your view.



Correcting problems

- FDA has acknowledged that some issues may still exist. Some officials have indicated that the agency will deal with additional issues through guidance
- The downside to this approach is that guidance will not apply to imported products



Cooperative Agreement between NASDA and FDA – for Produce Safety

- State departments of agriculture have long had interrelations with FDA – primarily at the technical program level
- Under the Cooperative Agreement with NASDA the interactions between FDA and the state agricultural programs are now also at the policy level



Cooperative Agreement between NASDA and FDA

- Provides a link between FDA and the states regarding the implementation of the Produce safety rule.
- Allows states officials to get organized – between agriculture and public health
- Will create more consistency between state programs



Cooperative Agreement between NASDA and FDA

- The agreement deals only with Produce Safety
- It is a 5 year agreement
- It was awarded in Sept 2014
- We are in the throes of finalizing the first years deliverables
- Partners this past year include: AFDO & IFPTI



Cooperative Agreement between NASDA and FDA

- Focuses on several key elements:
 - What are the existing states' authorities?
 - What are the existing resources?
 - What would a state-centric operational plan look like?



Program management areas

- Chapter 1 Alignment and Consistency
- Chapter 2 Foundation of Law
- Chapter 3 Financial Support
- Chapter 4 Outreach/Education & Compliance/Enforcement
- Chapter 5 Work Planning
- Chapter 6 Information Sharing
- Chapter 7 Regulator Training
- Chapter 8 Laboratory Resources
- Chapter 9 Technical Assistance
- Chapter 10 Dispute Resolution
- Chapter 11 Infrastructure



Possible similar plan to implement the Preventive Controls: Animal Food rule

- Most of the philosophical underpinnings are the same for the implementation of Produce Safety and the Preventive Controls: Animal Food
- AAFCO officials have participated in NASDA's Produce Safety Operational Plan development



Possible similar plan to implement the Preventive Controls: Animal Food rule

- FDA, NASDA and AAFCO have had preliminary discussions regarding a future effort to have the federal policy and technical officials work with the states policy and technical officials to develop an implementation plan for the Preventive Controls: Animal Food rule



Funding:

- A new paradigm for federal-state program coordination:
 - Base level funding to create a workable program
 - A “menu” of program areas to choose from:
 - Education, Technical Assistance, Readiness Review
 - Compliance and Enforcement
- This concept is expandable into the other FSMA program areas as well



Funding estimates:

- \$20 M for state programs to implement the Preventive Controls: Animal Food rule
- \$40 M for state programs to implement Preventive Controls: Human Food rule
- \$45 – 55 M for state programs to implement the Produce Safety rule



Is Food Safety worth that investment?

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