National Association of State Departments of Agriculture Talking Points
October 11, 2013

FSMA Background:
NASDA, under the leadership of North Carolina Ag Commissioner Steve Troxler and continued under the leadership of Secretary Chuck Ross with the Vermont Agency of Agriculture, Food and Markets, is in the process of conducting a comprehensive review of four proposed rules mandated by FSMA that FDA issued regarding produce safety, manufactured foods and imported food.

NASDA members fully support the safe production of food from farm to fork and, as such, support the food safety concepts of FSMA related to produce safety and the prevention of hazards using risk-based food safety concepts.

FSMA is frequently referred to in terms such as "historic" but what makes FSMA historic?

- A mandate for sweeping reform of the current food safety system to move it from a reactive system to one that is founded on risk based preventive controls. Moving the regulation of food from reacting to food borne illness outbreaks to preventing them.
- Increased accountability for farmers, manufacturers and importers to take measures to mitigate risks associated with the production of food.
- The Act provides FDA with additional authorities in areas such as mandatory recall, administrative detention of food and access to records.
- In the area of imported foods, FSMA mandates increased control through foreign supplier verification, expedited review and entry of imports from qualified importers and the ability to stop the importation of food from facilities that deny FDA access for inspection.

One of the most important mandates of FSMA is in the requirement to build the capacity & capability of State and local programs in order to meet the mandates of the Act. To successfully implement FSMA, FDA needs to clearly define the role of the State programs and establish partnerships with agencies with food safety inspection authority. FDA needs to commit to providing resources in the form of funding, training and guidance to support State and local programs.

We fully support the mandate of FSMA to integrate state and local capacities and capabilities in the implementation of FSMA. State Departments of Agriculture or other state agencies must be involved in the development and implementation of the inspection, compliance and enforcement programs developed in support of the produce and preventive controls rules.

Proposed Rules:
In 2013 FDA issued four proposed rules:

- In January:
  - Produce Safety
  - Risk-Based Preventive Controls for human food

- In July:
  - Foreign Supplier Verification Program for Importers
  - Third Party Accreditation for Auditors to conduct food safety audits overseas

- Note that Risk-Based Preventive Controls for animal feed is currently under review in the Office of Management and Budget (OMB) and will soon be issued. In addition, FDA is also working on rules regarding safe transportation of food and intentional adulteration of food.

The proposed rules are complex; farmers, industry and State regulatory agencies are challenged to understand and interpret the nuanced provisions and exemptions.

Produce Safety Rule:

- Definition of a farm:
  - Current definition was created to exempt farms from the 2002 Bioterrorism Act and the lacks relevance to current modern farming practices and the produce rule
- Standards for Agricultural water and testing requirements:
  - EPA recreational water standard is not relevant to farmer's use of water that contacts produce during growing
  - Testing frequency will be difficult to meet
- Biological soil amendments of animal origin
  - Minimum application intervals will be difficult to meet
  - Will restrict farmer's ability to pasture animals on fallow fields off season
- Variances and Alternatives (italic added for emphasis)
  - A farmer may establish an alternative provided they "have *adequate scientific data* or information to support a conclusion that an alternative would *provide the same level of public health protection* as the applicable requirement established in this part".
  - A state may petition FDA for a variance in light of local growing conditions and must provide a statement that the variance is reasonably like to ensure that the produce is not adulterated under the Act and "*provide the same level of public health protection as the requirements*" of the rule.
    - The risk model employed by FDA to derive the standards for water and application intervals for biological soil amendments is unknown. FDA must provide this risk model, in order for a farmer or state to determine that an alternative or variance provides the same level of public health protection.
    - The science needed to support the approval of alternatives and variances does not exist. This lack of credible, peer reviewed scientific information will hamper industry and regulators in meeting the regulatory demands of FSMA.
  - State agencies will be required to submit petitions for variances; this will be an increased burden on these agencies.

Preventive Controls for Human Food:

- Definition of farm and harvesting
  - Activities traditionally conducted on farms (washing others RACs) now may be considered an operation that will subject a farm to inspection under preventive controls rule and registration under the Bioterrorism Act.
- Exemptions, rule contains 12 different exemptions that are complicated
  - Qualified Facility Exemption from preventive controls
    - The Tester Amendment provides some exemptions for facilities with less than $500,000 in sales yet facilities must notify FDA and be subject to modified requirements that are also burdensome.
  - On-farm mixed type facility exemptions from preventive controls
    - FDA has established a list of low risk food/activity combinations that provide an exemption from preventive controls. Farm will still have to register for BT act however. List is prescriptive and any deviation will result in farm being subject to full compliance with preventive controls.
- Validation of preventive controls
  - A facility must have information to validate that their processes and preventive controls are adequate to control the hazards. Again, the scientific information is not readily available.
- Supplier verification and Environmental testing

- Currently not in the rule but is under consideration by FDA. Will result in increased cost and compliance burden.

General Concerns:
In addition to specific areas of concern articulated above, NASDA has also identified some overarching areas of general concern that apply to all of the proposed rules; these are in the areas of:

- Communication and coordination with State partners and industry
  - FDA needs to work with farmers and related stakeholders to clearly define needs in training, education, outreach and guidance.
  - State Departments of Agriculture must be recognized as a valuable resource that should be involved in any contact, outreach or education with the farming community.
- Resources and Funding for State and local programs:
  - State and local agencies, including State Departments of Agriculture, will need time and resources to prepare inspection, compliance and enforcement programs to support the new rules. FDA must partner with State agencies and provide guidance and resources to facilitate the development of the necessary programs.
- Education, Training and Outreach
  - FDA must provide substantive training, guidance and scientific information to both industry and local regulators. The implementation of any new rule in the absence of appropriate guidance and support will lead to unintended consequences on the farming community and will impede the progress of protecting public health as intended by FSMA.

- **Second comment period for the rules.**
  - As we conduct our review of these four rules, we are hearing the concerns of our farming community and other stakeholders. It has become apparent that there is a lot of work to be done on these rules to ensure that the rules are right.

  - As written, these rules could potentially have significant impact and unintended consequences on the farming community and our entire food production system from farm to fork.

  - Because there are many areas that must be revised, we feel it is imperative that we have the opportunity to review and comment on the rules a second time before they are issued as final rules.

  - The hasty promulgation of these rules, without an opportunity for a second comment period to review changes prior to issuance of a final rule, would be a disservice to the work of congress and the original intent of FSMA.

  - Once a final rule is issued it is very difficult to change. Once the rules are made final our farming community and our food industry will be held to them, there will be regulatory consequences for non compliance.

FSMA creates the groundwork for us to move our food safety system into a new model of regulation where industry and regulators alike share in the responsibility for ensuring the safety of our food supply. And as important as that is, it is equally important that we make sure we get these rules right. It would be a disservice to the consumer, industry and the writers of FSMA if these rules are made final before they are made right.