



## **State Implementation of the FSMA Produce Safety Rule**

### **Issue**

The Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011. The final rules are in place and some of the requirements began in September, 2016. The Tennessee Department of Agriculture (TDA) signed a cooperative agreement with the Food and Drug Administration (FDA) to begin implementing the rule. TDA is at a decision-making point, should the state continue to implement the rule or pass it back to the FDA?

If you grow produce on your farm, see the FDA Coverage and Exemption decision tree at the end of this paper to find out if you fall under the FSMA Produce Safety Rule. Generally, a producer will be regulated under the rule if fruits and vegetables grown are typically consumed raw, and the producer has an average annual value of produce sold during the previous three-year period of \$25,000 or more.

### **Background**

FSMA aims to ensure the food supply is safe by shifting the focus of regulators from responding to contamination outbreaks to preventing illness. After years of rulemaking, FSMA Preventive Controls for Human Food Rule is now final, and compliance dates for some businesses began in September 2016. The rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. Key requirements under the FSMA Produce Safety Rule deal with the water, biological soil amendments, animals, worker training, and equipment used for growing fruits and vegetables. There are also special rules dealing with the growing of sprouts. For more specifics on the key requirements, the Produce Safety Rule can be found at:

<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472887.pdf>

In September 2016, the FDA began working with 42 states, including Tennessee, to implement FSMA through cooperative agreements. These states received FDA grants to develop produce safety programs that will deliver education and technical assistance to farmers, as well as provide the needed inspection, compliance, and oversight. The reasoning behind these agreements is states can leverage federal resources to establish or expand their own produce safety programs in order to implement FSMA.

FDA acknowledges the states have already built relationships with farmers and understand local circumstances. At this point, FDA does not intend to conduct regular inspections of all farms covered under FSMA, but the farms must maintain the requirements. The states with cooperative agreements will be expected to perform these inspections.

TDA has begun meeting with stakeholders, seeking their input about how or if the state should implement this rule. It has been expressed that TDA will seek to be a source of education to producers first, instead of regulation first. During initial meetings, stakeholders expressed interest in this approach. It is believed the rule will be better received by producers through education rather than heavy-handed regulation.

Initial discussions with stakeholders indicated producers would rather interact with state regulators rather than federal regulators. For TDA to continue implementing this rule, legislative hurdles may have to be overcome. For FDA to fully sign off on the state implementation, the Tennessee General Assembly would need to adopt the

federal standards within Tennessee law. Also, the General Assembly would need to budget for state implementation when the initial FDA grant expires.

If you grow produce on your farm, see the FDA Coverage and Exemption decision tree on the next page for the FSMA Produce Safety Rule.

### **Questions**

1. What is the perception/knowledge of FSMA Produce Safety Rule by producers?
2. What are the pros/cons of TDA being the regulatory authority for the FSMA Produce Safety Rule in Tennessee?
3. If it were decided that TDA should implement FSMA Produce Safety Rule, what would expectations be of the department by producers?
4. If it were decided that TDA should implement FSMA Produce Safety Rule, should farm registration be mandatory or voluntary?

### **Farm Bureau Policy**

#### Food Safety (partial)

With changing technology, the process of maintaining a safe product from the field to the table can always be improved. Policies and procedures that build trust and reliability in agriculture should reflect the latest in technology and research. Regulatory oversight should not impede the farmers' ability to produce. The risks versus the benefits should be considered in any food safety legislation or regulatory proposals. On-farm authority of government agencies should not be expanded. A trace back system should only be used to find and address the point of contamination, rather than simply be a punishment for producers and add costs. Quality assurance programs, research from agricultural colleges and education of food handlers throughout the food supply chain should take priority over expansion of the regulatory process. Increased costs to producers from on-farm inspections and standards should be a last resort of any legislative or regulatory initiative to improve food safety.

We encourage the Tennessee Department of Agriculture to assist producers and processors in achieving "third party" audit certification. We also encourage the department to provide food safety training to farmers' market participants.

## STANDARDS FOR PRODUCE SAFETY Coverage and Exemptions/Exclusions for 21 PART 112

The Preventive Controls for Human Food rule clarified the definition of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same definition is used in the Produce Safety rule (section 112.3(c)). Below are basic criteria that determine whether an operation that meets the definition of "farm" is subject to the produce rule.

