FSMA’s Produce Safety Rule

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Mississippi Department of Agriculture & Commerce

Cindy Hyde-Smith, Commissioner
FSMA Background

- Signed into law on January 4, 2011, by President Obama
- Passed after several food outbreaks in the 2000s
- Affects food at all stages (e.g., growing, harvesting, processing, transporting)
- Focuses on food safety prevention rather than reacting to food-borne illnesses and outbreaks
- Considered the most sweeping food safety reform since 1938 (enactment of Food, Drug, and Cosmetic Act)
- Grants FDA new regulatory powers, including mandatory recall
PSR in the context of FSMA

- Preventive Controls for Human Food (9/2015)
- Preventive Controls for Animal Food (9/2015)
- Produce Safety Rule (11/2015)
- Foreign Supplier Verification Program (FSVP) Rule (11/2015)
- Accredited Third-Party Certification (11/2015)
- Sanitary Transportation Rule (4/2016)
- Intentional Adulteration Rule (5/2016)
PSR Requirements

• The Produce Safety Rule requires farms and farmers to meet certain requirements in certain areas:
  – Worker health, hygiene, and training
  – Compost
  – Animals (wild and domestic)
  – Water
  – Records
PSR Compliance Dates

• “All other businesses” ($500,000 in average annual produce sales) – January 2018

• “Small business” ($250,000 but less than $500,000 in average annual produce sales) – January 2019

• “Very small business” (greater than $25,000 but less than $250,000 in average annual produce sales) – January 2020
Exemptions

- There are some exemptions, although they are not always easy to determine
- Foods that are not usually eaten raw are not covered
- There are some monetary limits
- If farm activities include a "kill step" that kills pathogens, a farm might not be covered
- In general, a farm should consider itself covered unless FDA says otherwise
What does FDA intend?

- FDA does NOT want to be the primary on-the-farm inspector
- It’s much cheaper and easier for FDA to farm this work out to states
- Also, many states think that they have more power if they have their own state programs. So NASDA has been working with FDA to develop a state program framework. MDAC has been involved with these calls and meetings for some time
- FDA wants states to do the work so that FDA doesn’t have to (even though FDA will always have authority and have final say)
State Programs

• States that choose to have their own programs must decide if they have the legal authority to make these inspections, and if they don’t, they must get authority.

• Then they are responsible for making sure they create (and maintain) a program that is in alignment with the federal rules; misalignment could result in program failure.

• As of February, 42 states were in the process of pursuing state programs (38 Departments of Ag).
Where Mississippi Stands (1)

• It’s unclear how many farms are affected in our state (FDA could not tell us; they referred us to NASS data)

• FDA developed a tier model; a state’s tier determines how much money the state would receive in a 5 year cooperative agreement with FDA

• FDA ranked MS a Tier 4 state (Tier 1 being states with the most farms; Tier 5 being states with the fewest farms). FDA used 2012 NASS data to determine this
Where Mississippi Stands (2)

• Had Mississippi competed for FDA’s cooperative agreement, we could have been awarded a total of ~$3.6 million for 2016-2021 to implement a state PSR program, educate farmers, and begin making on-farm inspections.

• Money from the cooperative agreement can’t be used for any purposes other than the PSR (as described in a state’s agreement with FDA).
Reasons MDAC Has Not Advocated Adopting A Produce Safety Rule Program At The State Level (1)

1. We have not seen any signs of future benefits – for our department, for consumers, or for our farmers

2. As of now, there is no funding after 2021 (will states have to pay?). And funding could be reduced before then

3. As of now, we don’t know what an actual FDA on-farm inspection will look like.
Reasons MDAC Has Not Advocated Adopting A Produce Safety Rule Program At The State Level (2)

4. Implementing a state program would essentially double produce laws against farmers

5. MDAC does not currently have statutory authority to conduct these inspections; we also lack authority to enter into any cooperative agreements with FDA even for FSMA educational purposes

6. We believe there is more risk in developing a state PSR program before all questions are answered; there is less risk in waiting until FDA has more things finalized
Reasons MDAC Has Not Advocated Adopting A Produce Safety Rule Program At The State Level (3)

7. Even when a state develops a state program, FDA still controls

8. Our food inspectors are not specialized in handling the intricacies of parts of this rule, such as water quality, soil amendments, and biological wastes

9. Not only do we not know how many farms are affected in our state, but we don’t know where they are
Reasons MDAC Has Not Advocated Adopting A Produce Safety Rule Program At The State Level (4)

10. In March, MDAC met with state health dept reps; they agreed that because of the unknowns, lack of foreseeable benefits, and unforeseeable future funding, adopting a state program at this time was not ideal.

11. As far as we know, Mississippi has never had a produce foodborne illness outbreak; why rush into building a program now?
Reasons MDAC Has Not Advocated Adopting A Produce Safety Rule Program At The State Level (4)

12. The goal of the Produce Safety Rule and FSMA is to have a uniform system in place to prevent foodborne illness outbreaks; but a result we are noticing with state implementation is 42 different states doing things 42 different ways; it’s not uniformity, it’s patchwork.
Current MDAC Activities Regarding the PSR

- We have great concerns that many affected farmers will not be prepared for inspections when they begin.
- We recently worked with Mississippi State to have a Train-the-Trainer program so that extension workers around the state could receive accredited FDA-approved certifications to lead their own grower training courses.
Current MDAC Activities Regarding the PSR (2)

- MDAC will continue to provide information to farmers upon request; we will also continue to try to work with Mississippi State to train growers.
- We will also continue to participate in FDA/NASDA discussions and monitor the progress of the Produce Safety Rule in other states.
- Continue to offer GAP/GHP audits.
To summarize

• We would like to see FSMA become more settled and consistent; we don’t want to contribute to the patchwork

• We would like to see the benefits to the farmers and consumers of this state; so far we have not seen any
Thank you

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