FDA’s Supplemental FSMA Rules: Issues for Local Food Systems and Organic Producers

Roland McReynolds, Esq.
Carolina Farm Stewardship Association
About Carolina Farm Stewardship Association

• Member-based, farmer-driven non-profit with a mission to advocate, educate, and build the systems to support a sustainable food system in the Carolinas centered on local and organic agriculture
• Heavily engaged in FSMA legislative process
• Active in developing comments on FSMA proposed rules on behalf of sustainable ag
• Provides food safety training tailored to diversified and organic farms
• GAP training videos for diversified farms on YouTube
FSMA Regs: The First Round

  - Comment period ended Nov. 2013
- Proposed Rule on Foreign Supplier Verification published July 26, 2014
  - Comment period ended Jan. 2014
- Proposed Rule on Preventive Controls for Animal Feed published Oct. 25, 2013
  - Comment period ended March 2014
- Federal Judge in Northern District of CA has set June 2015 as final deadline for all FSMA rules
Agriculture United for the First Time Ever

- National Association of State Depts. of Agriculture calls for ‘do over’ on proposed rules
- Farmers, food & animal feed makers expressed strong reservations about many portions of the rules
- Produce industry outcry from large, medium and small entities alike
- In Dec. 2013, FDA pledged to republish at least parts of Produce and Preventive Controls for Human Food proposed rules for further public comment
And Now, FDA’s Supplemental Rules

- Sept. 29 FDA published revised proposed rules covering limited portions of
  - Produce Standards
  - Preventive Controls for Human Food
  - Preventive Controls for Animal Feed
  - Foreign Supplier Verification
- Comment deadline for all re-proposals is Dec. 15, 2014
FDA’s Proposed Revisions

- **Caveat emptor**: FDA’s supplemental rules have been available for public review for less than two weeks
- Hundreds of pages of material
- Any analysis at this stage can only be preliminary
- Limited scope of re-proposals: Many important industry concerns not addressed
FDA’s Proposed Revisions

- Produce Standards: Changes related to
  - Use of manure and compost as fertilizer
  - Agricultural water
  - Withdrawal of qualified exemptions for small direct-marketing farms
  - Definitions of farm and farming activities
  - Addition of specific language related to conservation practices
FDA’s Proposed Revisions

- Preventive Controls for Human Food: Changes to
  - Definitions of farm and farming activities
  - Definition of ‘very small business’ exempt from certain provisions of the rule
  - Withdrawal of qualified exemptions for small and direct-marketing firms
  - Addition of requirements for environmental testing
  - Addition of requirements for supplier verification
  - Addition of requirements for end-product testing
What Will Local, Organic Food Industry be Looking For?

- Farm Definition: FDA expanding range of traditional farming activities that it recognizes as farming, not food processing, but only when those activities take place on farms

- Issues for further evaluation:
  - Did FDA adequately capture the full range of traditional farm activities?
  - Why require non-farm establishments that conduct the same low-risk packing and storage activities as farms to register as food processing facilities?
What Will Local, Organic Food Industry be Looking For? (cont’d)

- Definition of Very Small Business under Preventive Controls for Human Food rule: FDA proposes $1 million in sales of human food as threshold for qualified exemption under Preventive Controls for Human Food
- Previously proposed options of $250k, $500k or $1 million in total food sales (including animal feed)
- Only 1% of food supply subject to modified requirements for qualified facilities at $1 million threshold
What Will Local, Organic Food Industry be Looking For? (cont’d)

- Environmental Testing: FDA proposes to require human food facilities to conduct environmental testing for pathogens/pathogen indicators.

- Potential issues:
  - What is the cost to industry?
  - How will it be enforced?
  - How practical or scientifically valid is this requirement as a preventive control?
What Will Local, Organic Food Industry Looking For? (cont’d)

- Product Testing: FDA proposes to require human food facilities to conduct product testing for pathogens/pathogen indicators

- Potential issues:
  - What is the cost to industry?
  - How will it be enforced?
  - How practical or scientifically valid is this requirement as a preventive control?
What Will Local, Organic Food Industry be Looking For? (cont’d)

- Supplier Verification: FDA proposes to require human food facilities to ensure that their suppliers are in compliance with FSMA

- Potential issues:
  - What is the cost to industry?
  - How will it be enforced?
  - How practical or scientifically valid is this requirement as a preventive control?
  - Will this requirement discourage facilities from buying from qualified exempt farms and food companies?
What Will Local, Organic Food Industry Will be Looking For? (cont’d)

- Process for Withdrawal of Qualified Exemptions from Farms and Human Food Facilities: FDA proposes changes to process for removing a small farm or food business’ qualified exemption from the Produce and Preventive Controls rules
- A response to concerns from those sectors about lack of due process.
What Will Local, Organic Food Industry be Looking For? (cont’d)

- Use of Manure and Compost: Farm industry expressed concerns that there was insufficient science to support FDA’s original proposals of a 9-month withdrawal period between the application of raw manure and harvesting crops, and a 45-day withdrawal period between the application of treated compost and harvesting crops.

- FDA removing withdrawal period for treated compost, and postponing decision on manure withdrawal period.
Agricultural Water: Farm industry and state agencies expressed concern that there was insufficient science to support FDA’s original proposals for the testing and treatment of water used in growing RAC.

Re-proposals are complex, major study required.
Conclusions

- Still too early to judge the potential impact of proposed changes
- States should be paying close attention to FDA’s Operational Strategy for Implementing FSMA
Roland McReynolds
Executive Director
Carolina Farm Stewardship Association
PO Box 448
Pittsboro, NC 27312
(919) 542 2402
roland@carolinafarmstewards.org
www.carolinafarmstewards.org