

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

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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

- Proposed Rules on Produce Safety standards and Preventive Controls for Human Food published Jan. 4, 2013
 - 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



What Will Local, Organic Food Industry be Looking For? (cont'd)

- 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

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