Food Safety Modernization Act Webinar

Sponsored by CSG Regional Offices
Eastern Regional Conference
Midwestern Legislative Conference
CSG-WEST
Southern Legislative Conference
and
State Agriculture and Rural Leaders

October 3, 2014
AGENDA

Welcome and Housekeeping: Lauren Greer, SLC
Introductions: Lauren Greer, SLC

Roland McReynolds, Carolina Farm Stewardship Association
Leah Wilkinson, American Feed Industry Association
Robert Hahn, OFW Law
Joe Reardon, North Carolina Department of Agriculture

Questions, moderated by Carolyn Orr, ERC, MLC, SARL
Adjourn
This webinar is being recorded. The recording and presentation slides will be available later at csgmidwest.org and slcatlanta.org.

To reduce noise on the phone lines, all participants will be in “listen-only” mode during the presentations.

The speakers will answer questions after the presentations.

To interact with the speakers, participants have two options:

- Click on the “raise hand” icon in the webinar console. Click the icon again to put your hand down if your question has already been answered.
- Type questions using the “questions” pane in the webinar console.

Telephone users who wish to ask a question must enter the audio PIN.

If you selected “Mic & Speakers” as your audio choice, please test your system’s settings prior to asking a question.
Speakers

Roland McReynolds

Leah Wilkinson

Robert Hahn

Joe Reardon
FDA revised Food Safety Modernization Act proposed Rules

**Proposed Rule for Produce Safety**
[http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm)

**Proposed Rule for Preventive Controls for Human Food**
[http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm)

**Proposed Rule for Preventive Controls for Animal Food**
[http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm)

**Proposed Rule for Foreign Supplier Verification Programs (FSVP)**
[http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm)
Want to comment on the new rules?

The FDA will accept comments on the revised provisions until December 13, 2014, while continuing to review comments already received on the original proposed rules.

No additional comments will be accepted on the original proposals. FDA will consider both sets of comments—on the original proposed rules and on the revisions—before issuing final rules in 2015.
Joe Reardon
Assistant Commissioner for Consumer Protection
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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.
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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FSMA and Animal Food

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CSG FSMA Webinar: October 3, 2014
Topics to be Presented

• Food Safety Modernization Act:
  • What the animal food supplemental rule does and doesn’t say
  • AFIA’s reaction/concerns/questions
  • What happens next
FSMA Applies To:

- All Ingredient Processing
- All Feed Manufacturing
- Pet Food
- Feed & Ingredient Imports
- Transportation
FSMA Animal Food Round 1:

- FDA issued CGMP and Preventive Control Rule for Animal Food – Oct. 29, 2013
- Comment period closed March 31
- FDA used human food rule as basis
- AFIA’s main concerns:
  - Who’s covered
  - No separate rules
    - Instead use “where appropriate/for intended use”
  - Compliance dates
FSMA Animal Food Round 2:

- FDA issued **Supplemental** CGMP and Preventive Control Rule for Animal Food – Sept. 29, 2014
- Comment period closes Dec. 15
- FDA acknowledged animal food is different from human food
- FDA made some improvements...more to go
- Not everything is re-proposed here
FSMA Supplemental Changes

CGMP’s and Preventive Controls for Animal Food

Revised CGMP’s
• Mostly rewritten
  • Simplified
  • More relevant to animal food
• Removed “ill employee” provisions
• Added 507.28 “Holding and distribution of human food by-products for use as animal food”
  • For clarity on requirements

Hazard ID/Preventive Controls
• “Significant hazard”
• Added Supplier Verification
• Added Product Testing and Environmental Monitoring
  • As “verification of implementation and effectiveness”
  • Allows flexibility – “as appropriate to the facility, animal food and nature of preventive control
• High cost – low benefit
• Changes to “farm” definition (Integrated operations)
• Compliance dates for CGMPs and PCs:
  • Large and other firms: 12 months post publication
  • Small (less than 500 employees): 2 years
  • Very Small (less than $2.5 mill): 3 years
  • Should CGMPs and PCs be phased in?
    • AFIA says YES: 1, 2, 3 years CGMPs; 2, 3, 4 years PCs
<table>
<thead>
<tr>
<th>PHASE</th>
<th>TIMING</th>
<th>TOPIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Summer-Winter 2014</td>
<td>Overview of the Food Safety Modernization Act Proposed Rules and AFIA Recommendations; Fundamentals for Complying with FSMA</td>
</tr>
<tr>
<td>Phase II</td>
<td>Spring 2015</td>
<td>Completing an Effective Hazard Analysis; Implementing Preventive Controls; Requirements for Effective Corrective Actions</td>
</tr>
<tr>
<td>Phase III</td>
<td>Summer-Fall 2015</td>
<td>Developing an Effective Animal Food Safety Plan</td>
</tr>
</tbody>
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What Should You Do?

www.safefeedsafefood.org
FDA’s Animal Food Webpage:

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm

Questions?
FSMA
FDA’s Supplemental Proposed Rules

Robert Hahn
Olsson Frank Weeda Terman Matz PC

October 3, 2014
Four Supplemental Proposed Rules

• Produce Safety
• Preventive Controls for Human Food
• Preventive Controls for Animal Food
• Foreign Supplier Verification Programs
Produce Safety

• Narrows coverage
  – Farm or farm mixed-type facility exempt if average annual sales of produce of $25,000 or less
Produce Safety

• Clarifies line between “farm” and “facility,” so that fewer entities subject to both rules
  – Farm may engage in field coring (“harvesting”)
  – Farm may engage in activities incidental to “packing” (e.g., sorting, grading)
  – Farm may engage in activities incidental to “holding” (e.g., fumigating, weighing, mixing lots of same RAC)
  – Farm may pack RACs grown on another farm not under the same ownership
Produce Safety

• Clarifies line between “farm” and “facility” (cont’d)
  – Farm may engage in “manufacturing/processing” food, provided that:
    • All such food is consumed on that farm or another farm under the same ownership;
    • Such activities consist only of packaging and labeling of RACs; or
    • Such activities consist only of drying/dehydrating RACs to create a different commodity, and packaging and labeling of the dried commodity.
Produce Safety

• Agricultural water standard
  – Would apply EPA 2012 recreational water quality criteria (RWQC)
  – Allow producers to meet standard by leaving time interval between last irrigation and harvest, using a specific die-off rate of 0.5 log per day (or another rate supported by scientific data)
  – Allow producers to meet standard by leaving an appropriate time interval between harvest and end of storage, using appropriate die-off rate and/or removal rate (for activities such as commercial washing)
Produce Safety

• Biological soil amendments
  – Remove 45-day minimum application interval for composted manure
  – Reconsider 9-month minimum application interval for raw manure
  • FDA is deferring a decision on the appropriate interval pending further actions: research, risk assessment, and steps to encourage produce growers to transition to use of compost
  • FDA unlikely to object to compliance with NOP
Produce Safety

• Animal encroachment
  – Clarify that regulations do not require “taking” of threatened or endangered species in violation of Endangered Species Act
  – Clarify that regulations do not require exclusion of animals from outdoor growing areas, or destruction of animal habitat, or clearing borders
  – BUT, if animal intrusion does occur, producer still must evaluate whether covered produce may be harvested
Preventive Controls for Human Food

• "Farm" definition
  – Expands activities a "farm" may conduct without becoming a "facility" subject to FDA registration and preventive controls
  – FDA requests comments on current requirement that a "farm" be "in one general physical location"
  – FDA intends to add to list of on-farm low-risk activity/food combinations (that are exempt when conducted by a small or very small business)
PC’s for Human Food

• Exemption for facilities solely engaged in storage of RACs (other than fruits and vegetables) for further distribution or processing
  – Would include facilities that engage in activities incidental to “packing” and “holding”
  – Such as: fumigating, grading, weighing, drying, blending lots, applying preservatives to protect against mold
PC’s for Human Food

• Definition of “very small business”
  – Define as less than $1 million in total annual sales of human food, adjusted for inflation
  – A “very small business” is a “qualified facility” subject to modified requirements
  – A “very small business” has 3 years after publication of final rule to comply
PC’s for Human Food

- Hazard analysis
  - Must consider economically motivated adulteration (if there is a pattern of EMA of that food in the past)
  - Must consider environmental pathogens (only for RTE foods exposed to the environment prior to packaging if packaged food will not receive a treatment to control the environmental pathogen)
PC’s for Human Food

• Environmental monitoring
  – A verification activity
  – Testing for an environmental pathogen (or appropriate indicator organism)
  – Would be required only if contamination of a RTE food with an environmental pathogen is identified as a significant hazard (i.e., RTE food is exposed to an environmental pathogen prior to packaging and packaged food will not receive a treatment to control the pathogen)
PC’s for Human Food

• Product testing
  – A verification activity
  – Testing for a pathogen (or appropriate indicator organism) or “other hazard”
  – Would be required only if appropriate in light of the facility, the food, and the nature of the preventive control
    • FDA appears to leave this determination to the facility
PC’s for Human Food

• Supplier controls
  – A preventive control
  – Require receiving facility to implement supplier control program for raw materials and ingredients for which it has identified a significant hazard

• “Receiving facility” defined as a facility that receives raw materials or ingredients and manufactures/processes them
PC’s for Human Food

• Supplier verification activities
  – Onsite audits of supplier;
  – Sampling/testing of raw material or ingredient (by either receiving facility or supplier);
  – Review of supplier’s food safety records; or
  – Other appropriate verification activities.

• Instead of onsite audit, receiving facility may rely on inspection of supplier by FDA or foreign food safety authority recognized by FDA as comparable or equivalent
PC’s for Human Food

• Supplier verification activities (cont’d)
  – BUT, if SAHCODHA hazard identified, receiving facility must conduct annual onsite audits, unless it documents determination that other verification activities (or less frequent onsite audits) will provide adequate assurance that hazard is controlled
PC’s for Human Food

• Supplier verification activities (cont’d)
  – Alternative verification activities would apply where the supplier is a farm or a “qualified facility”
  – Supplier must have written procedures to ensure all raw materials and ingredients received from approved suppliers. BUT, where necessary, may receive from unapproved suppliers on a temporary basis, provided perform adequate verification activities prior to acceptance.
PC’s for Human Food

• Exclusions from Current Good Manufacturing Practice (CGMP) regulations
  – “Farms”;  
  – Activities of farm mixed-type facilities with the definition of “farm”;  
  – Holding or transportation of RACs;  
  – Hulling, shelling, and drying of nuts (but not roasting or other manufacturing/processing); and  
  – Fishing vessels not required to register with FDA.
THANK YOU

QUESTIONS?