FSMA COMMENTS FOR FOOD HUBS

October 23, 2013
Presentation Outline

- Technical Orientation
- Welcome / Introduction

Jeff Farbman
Wallace Center at Winrock International

- Food Hubs and FSMA
- Questions and Answers
- Upcoming Opportunities, etc.
WALLACE CENTER at WINROCK INTERNATIONAL

• Market based solutions to a 21st Century food system
• Work with multiple sectors – business, philanthropy, government
• Healthy, Green, Affordable, Fair Food
• Scaling up Good Food
NATIONAL GOOD FOOD NETWORK: VISION
NATIONAL GOOD FOOD NETWORK: GOALS

Supply Meets Demand

• There is abundant good food (healthy, green, fair and affordable) to meet demands at the regional level.

Information Hub

• The National Good Food Network (NGFN) is the go to place for regional food systems stories, methods and outcomes.

Policy Change

• Policy makers are informed by the results and outcomes of the NGFN and have enacted laws or regulation which further the Network goals.

http://ngfn.org | contact@ngfn.org
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Sarah Hackney
National Sustainable Agriculture Coalition (NSAC)

- Questions and Answers
- Upcoming Opportunities, etc.
THE FOOD SAFETY MODERNIZATION ACT: KEY ISSUES AND ACTION STEPS FOR FOOD HUBS!

Sarah Hackney, Grassroots Director, NSAC
Welcome!

On the Agenda for this Webinar:

- **Food Safety and Food Hubs** – What’s the Connection and Why Should I Get Involved?
- **What is the Food Safety Modernization Act?**
  - Rules Overview
  - Issues with the Rules
- **Take Action on FSMA Today!**
  - How Can I Get Involved?
NSAC is an alliance of grassroots organizations that advocates for federal policy reform to advance the sustainability of agriculture, food systems, natural resources, and rural communities.

- Started in 1988; currently have 100 member organizations from around the country – The Wallace Center is a member!
- We bring farmers and grassroots advocates across the country to the policy table in DC
- Our job is to make sure that federal policy helps farmers succeed while protecting the environment and keeping our food safe and accessible!
- Speaking today: Sarah Hackney, Grassroots Director
Everyone has a role in ensuring safe food
Focus on highest risk
One size does not fit all
Based on scientific evidence when possible
Why Should I Get Involved in FSMA?

Unless they are improved, the proposed FSMA rules could...

- Have a huge impact on farmers across the country – especially organic and sustainable growers – and the innovative efforts like food hubs seeking to foster more local and regional connections between growers and eaters.

- Make it harder for beginning farmers to get started and succeed.

- Reduce choices for consumers at local markets and make local food harder to find.
Overview of Food Safety Modernization Act

- First major overhaul to food safety laws since the 1930s
- Debated in Congress in 2009-2010
- Signed into law January 4, 2011
- Main pieces of the bill:
  - Title I: Preventing food safety problems
    - Standards for Produce Safety
    - Preventive Controls for Facilities
  - Title II: Detecting and responding to food safety problems
  - Title III: Improving safety of imported food
  - Title IV: Miscellaneous provisions
Sustainable Agriculture Provisions in FSMA

- Scale appropriate regulations
- Protection of on-farm conservation and wildlife practices
- Complement – not contradict – National Organic Program regulations
- Minimize extra regulations for low-risk processing that is part of value-added production
- Streamline and reduce unnecessary paperwork for farmers and small processors
- Allow farm identity preserved marketing as an option in place of government trace-back controls
- Funding for training through new competitive grants program
- Flexibility for small and very small businesses
Where We Are Now

- PROPOSED regulations for produce safety and food facilities released for public comment on January 4, 2013
- Comment period extended twice
- Deadline for public comment is November 15!
Proposed Produce Rule

- Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
  - Personnel qualifications and training
  - Health and hygiene
  - Agricultural water
  - Biological soil amendments of animal origin
  - Domesticated and wild animals
  - Growing, harvesting, packing, and holding activities
  - Equipment, tools, buildings, and sanitation
  - Sprouts
Proposed Preventive Controls Rule

- Focuses on facilities that manufacture and process food for human consumption
- Two major requirements:
  - Hazard Analysis and Risk-Based Preventive Controls (HARPC)
  - Updated Good Manufacturing Practices
- Codifies “farm mixed-type facility” – an operation subject to the Produce Rule AND the Preventive Controls Rule
Three primary tiers of regulation:

- Exemption (one or both rules)
- Modified Requirements (one or both rules)
- Fully Subject to a Rule (or both rules)
Exemptions

- Produce rarely consumed raw
- Produce for personal or on-farm consumption
- Farms selling an annual average value of food during a 3-year period that is less than $25,000

Modified Requirements

- Produce that will receive commercial processing
- Farms that qualify under Tester-Hagan Amendment
Tester-Hagan Requirements in Produce Standards

- Average annual monetary value in previous 3-year period less than $500,000 AND
- Sell 51% or more directly to a consumer or retail food establishment in the same state or within a 275-mile radius

THEN

- Provide information on label or sign at the point of sale
What is a “facility”?

- Manufacturing/processing, packing, and holding food
- Includes activities done on-farm
- Activities done to your agricultural products vs. activities done to someone else’s agricultural products
- Out of sync with the reality of farming
Proposed Preventive Controls Rule: Who’s Affected?

Exemptions from HARPC requirements

- Certain on-farm low-risk processing activities (jams, maple syrup) by small and very small businesses
- Seafood, juice, low acid canned foods, dietary supplements, alcoholic beverages
- Activities within the ‘farm’ definition
- Certain facilities that only store packaged foods or raw agricultural commodities (not F&V) for further processing
Proposed Preventive Controls Rule: Who’s Affected?

- Modified Requirements
  - Facilities that qualify under Tester-Hagan Amendment:
    - “Very small business” OR
    - Average annual monetary value in previous 3-year period less than $500,000 AND
    - Sell 51% or more directly to a consumer or retail food establishment in the same state or within a 275-mile radius that sells food directly to consumers
Proposed Preventive Controls Rule: Who’s Affected?

- **Modified Requirements**
  - Submit documentation of status AND
  - Submit documentation of compliance with other non-Federal food safety law AND provide notification to consumers OR
  - Submit documentation identifying potential hazards and monitoring of preventive controls
Proposed Produce Rule: Issues

Manure and compost
- 9 month interval between application of manure and harvest; 45 day interval between application of compost and harvest

Concerns:
- Discourages the use of manure and compost made with animal material
- Conflicts with National Organic Program regulations
- Inconsistent with conservation practice standards
- Based on very limited scientific evidence

Explain your current practices and urge FDA not to exceed the organic standard
Proposed Produce Rule: Issues

On-farm natural resource conservation

Concerns:

- Does not explicitly protect or promote conservation practices
- Does not incorporate co-management considerations
- Lack of clarity on grazing standards
- Recently started an Environmental Impact Statement process

Explain your current practices and urge FDA to be proactive about conservation
Water and water testing

- Testing, treatment, regular maintenance and inspection of water system

Concerns:
- Weekly water testing for surface water; monthly for groundwater
- Testing for generic e. coli (EPA recreational water standard)
- Water treatment
- Significant costs and not science-based

Explain how the standard will impact you and urge FDA to come up with a risk-based, scientific water standard
Proposed Produce Rule: Issues

- Integrated approach
  - Tentative conclusion to adopt an “integrated” vs. “commodity-specific” approach
  Support:
  - Important for diversified farmers
  - Commodity organizations prefer commodity-by-commodity approach

Explain your farming system and urge FDA to stick with an integrated approach
Failure to clarify exemption for direct marketers

- Under FSMA, CSAs, roadside stands, farmers markets, and other direct-to-consumer sale platforms are considered “retail food establishments” that do NOT have to register as a facility with FDA.

Concern: FDA has not clarified this exemption from the Preventive Controls Rule and certain CSAs and direct marketers will be subject to additional inappropriate regulation if they trigger the “facility” definition.

Explain how you market your products and urge FDA to fix this issue.
Options for definition of “very small business”:
- $250,000 in gross sales of all food
- $500,000 in gross sales of all food
- $1,000,000 in gross sales of all food

Concerns:
- “All food” not “covered product”
- If not realistic, small facilities regulated like big facilities

Explain your gross sales and urge FDA to support $1,000,000 in covered product
Issues in Both Proposed Rules

What is a “farm”? What is a “facility”?

Concerns:

- Confusion around foundational definitions like “farm” and “facility”
- Assumption that farms only produce raw agricultural commodities and don’t prepare and sell food through markets and supply chains
- When you pack or hold someone else’s agricultural products, you may be a “facility”
- Introduce new term, “farm mixed-type facilities,” subject to both rules

Activities that occur on-farm – including to someone else’s agricultural products – should not make a farm a “facility”
Issues in Both Proposed Rules

Failure to adequately implement scale- and supply-chain appropriate options

Concerns:
- Failure to clarify key terms
- Failure to require an evidentiary standard for withdrawal
- Failure to establish a reasonable process around withdrawal and restitution of status

FDA must define key terms, require evidence for a withdrawal, and create a process of getting status as a “qualified exempt” farm or “qualified” facility back.
Costs of compliance

- High costs without adequate training and technical assistance
- Produce rule:
  - “Very small” farm: $4,697 annually
  - “Small” farm: $12,972 annually
  - “Large” farm: $30,566 annually
- Preventive Controls: $13,000 per year to comply with HARPC

Concerns:
- Risk of farms going out of business
- Increased barriers for beginning farmers
- Further concentration in farming

FDA must base cost estimates on realistic assumptions and decrease compliance costs
The take-home issues for food hubs

• The Produce Rule may impact your growers.

• You almost certainly will be considered a facility under the Preventive Controls Rule and you may be subject to part or all of the regulations depending on the scale of your operation.

• You should familiarize yourself with the proposed regulations for facilities – including HARPC.

• Meaning: WE NEED YOU TO COMMENT!
If you are a food hub, you will almost certainly be required to register as a facility with FDA and be subject to inspection. In addition:

- **If your business is based on a farm, is a “small” or “very small business” AND you are doing only types of packing and holding that fall onto FDA’s “low risk” list, then you may be eligible for exemption from HARPC.**

- **If you meet the Tester-Hagan threshold because you are either a “very small business” or meet the two-part eligibility test based on gross sales and percent of direct sales, you may be eligible for the modified requirements.**

- **If your business is not based on a farm or is not eligible for modified requirements under Tester-Hagan (see above), you are likely to be subject to full HARPC requirements.**
Your Comments WILL HAVE AN IMPACT:

- The rules are still in draft form – and FDA is legally bound to seek public input before they’re finalized.

- Eat food? You are a stakeholder! Grow food? You are a stakeholder! You don’t need to be an expert.

- The #1 best way for us to improve the rules: the open comment period!

- FDA will read every comment. Individual comments written by stakeholders – that’s you – are the most impactful by far. You can also sign petitions or form letters – but the best thing to do is take a few moments to submit your own comments!
Take Action on FSMA Today!

☐ **How do I comment?**
  - You can comment ONLINE or via MAIL.

☐ **What should I say?**
  - Tell your story – make it personal
  - Use data when you have it
  - Include a clear “ask” for FDA (how should the rules change?)
  - Asking questions is fine too – including if it’s unclear if your farm or farming practices would be affected
Take Action on FSMA Today!

The comment period is open until

November 15, 2013

So get on it!
3 Things to Do

- Get Informed!
- Take Action!
- Spread the Word!
Resources for Farmers, Organizations, and Consumers

http://sustainableagriculture.net/fsma

- **GET INFORMED**
  - Dig deeper into the issues
  - Check out sample comments to FDA

- **TAKE ACTION**
  - Commenting templates for consumers and farmers – with questions so you can customize them (FMC is working on a template for market managers)
  - Step by step instructions for using Regulations.gov or mailing in a comment
  - Sign the petition too!

- **SPREAD THE WORD**
  - Social media sharing tools and materials you can use
  - Sign up for FSMA updates
Food Hub-Specific Resources

Find these here:
http://sustainableagriculture.net/fsma

- Specific Guidance for Food Hubs:
  - http://sustainableagriculture.net/fsma/who-is-affected/

- Specifics on what HARPC would require:

- Guidance on the Modified Requirements:
  - http://sustainableagriculture.net/fsma/learn-about-the-issues/modified-requirements-for-qualified-facilities/
The Food Safety Modernization Act: Learn More, Act Today!

#fixFSMA - Stand Up for Food and Farms Today!

Click here to take action!

Everyone has a role in ensuring safe food from field to fork. The Food Safety Modernization Act (FSMA) is the first major overhaul of our nation's food safety practices since 1938, and it includes
Food Safety Modernization Act: Stand Up Today for Food and Farms!

You know your farmer, you know your food:
Now stand up for your farmer, stand up for your food!

The US Food and Drug Administration has proposed new rules this year that will have a huge impact on how fresh fruits and vegetables are grown and processed in the US. This is a big deal for farmers and eaters! Everyone has a role in ensuring safe food from field to fork – but FDA’s new proposed rules as written will unfairly burden family farmers, target sustainable and organic farming, and reduce the availability of fresh, local food in our communities. Right now, we have a chance to tell FDA that this is unacceptable – and we need your help to do it.

FDA’s new food safety rules must:

- Allow farmers to use sustainable farming practices, including those already allowed and encouraged by existing federal organic standards and conservation programs.
- Ensure that diversified and innovative farms, particularly those pioneering models for increased access to healthy, local foods, continue to grow and thrive without being stifled.
- Provide options that treat family farms fairly, with due process and without excessive costs.

Are you a farmer or food processor? Start here.

Are you a concerned consumer? Start here.
8. **Issue: Definition of “Very Small Business”** – The rules set modified requirements for small and very small businesses, but FDA has not settled on a definition for “very small business” and most of their options are unrealistic. Without a realistic definition, many very small businesses will be regulated like big facilities.

**[Help FDA understand why this matters:** If you operate a processing facility, food hub, or do processing on your farm, which option for the definition of “very small business” would you fall under, if any? If FDA calculated the definition of “very small business” not based on all food but based on processed food, how would that change your status, if at all?]

**Recommendation to FDA:** FDA should adopt the $1,000,000 threshold for a very small business and make sure that it is based on the value of regulated product, not the value of all food. This would focus the full regulations on big businesses that produce the vast majority of covered farm and food products, while focusing modified requirements on smaller farms and businesses that represent the majority of producers but only minority of product in the food supply.

3. **Comments Covering Both the Proposed Preventive Controls Rule and the Produce Rule:**
FSMA: We need your help

- Submit comments!
- Help get more organizations and allies to submit comments and conduct outreach!
- Reach out to farmers, processors, and others who will be affected!

*Use all the tools we’ve got: grassroots action, media outreach, events, networking, all of it – we need everyone to speak out today!*
QUESTIONS?

COMMENT DEADLINE: NOVEMBER 15, 2013

Contact us:
fsma@sustainableagriculture.net

For more information, visit
NSAC’s FSMA Action Center:
http://sustainableagriculture.net/fsma
Questions and Answers

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- The Survey: Findings
- The Survey: Implications
- Questions and Answers

- Upcoming Opportunities, etc.
Webinars are Archived

TOPICS!

http://ngfn.org/webinars
NGFN Webinars

- 3rd Thursday of each month
  3:30p EST (12:30p PST)

- Nov 21 - Tools for Improving Farmer Financial Skills
- Dec 12 – Food Banks as Regional “Good Food” Partners

http://ngfn.org/webinars
National Food Hub Conference

- Multiple tracks for food hub managers and staff
- Networking and learning for support organizations, consultants and agencies
- "Ask an Expert" - slots of one-on-one time to dig deep with various technical assistance experts
- Food hub and food business tours
- Opportunities to learn from your peers, network, and feel a part of an incredibly energetic community
- Excellent local food from Eastern Carolina Organics, Firsthand Foods, and other local suppliers.

http://ngfn.org/hubs2014
Tons of Resources!

- **www.FoodHub.info**
  - Food Hub “hub”
  - Research
  - Case studies
  - List and map of hubs across the country
  - ... and much more.

- And remember to sign up for our food hub community of practice!
  - Just let us know of your interest in the post-webinar survey.
Get Connected, Stay Connected

http://ngfn.org/database

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