Food Safety Modernization Act Info Session – Revised Handout
August 1, 2013 at SOREC

At the August 1 meeting, we:
• Provided information about FSMA, the draft rules, and the FDA comment process, to help farmers and food businesses weigh in on federal policy that will affect them;
• Gathered information about farmer concerns and questions related to food safety and food safety regulations and requirements.

Down the road we will:
• Help Oregon’s small farms adapt to FSMA when it’s finalized
• Work with food safety scientists and educators to design food safety-related strategies and educational programs relevant to small farms and sustainable agriculture.

HOW TO SUBMIT COMMENTS TO FDA – DUE BY NOVEMBER 13
“The people who wrote the rules have a lot of expertise, but they aren’t the ones growing produce in this country. We need to hear from you.” – Charles Breen, U.S. FDA

Submit your comments and view already-submitted comments at www.regulations.gov:
Produce: http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0921-0001
Preventive controls: http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0920-0017

Oregon Department of Agriculture Also Wants to Hear from You ASAP
As the agency that will ultimately implement much of FSMA in Oregon, ODA is also crafting comments and wants input from Oregon farmers. Email them at oda-fsma@oda.state.or.us.

INFORMATION COVERED AT THE MEETING
These are the basics and are not meant to be comprehensive. For more info and links to additional resources, go to: http://smallfarms.oregonstate.edu/fsma

FOOD SAFETY MODERNIZATION ACT BASICS
• First major overhaul of food safety laws since 1930s
• Signed into law 2011; draft rules issued Jan. 2013
• Sustainable ag provisions (Tester/Hagen)
  – Scale- & risk-appropriate regulations for small farms selling primarily into local & regional markets (shorter supply chains, less comingling, quick traceability)
  – Allow on-farm conservation, beneficial wildlife practices
  – Complement, not contradict, organic standards
  – Minimize extra regs for low-risk, value-added processing
• Gradual roll out in coming years
DRAFT PRODUCE RULE

• “Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” – farming activities
• Focuses on microbial contamination
• Creates standards for:
  1. Agricultural water
  2. Biological soil amendments
  3. Domesticated and wild animals
  4. Growing, harvesting, packing, and holding activities
  5. Personnel qualifications and training
  6. Health and hygiene
  7. Equipment, tools, buildings, and sanitation
  8. Sprouts
• Broadens the definition of farming activities
• Includes partial exemptions for small farms selling primarily into local/regional markets.

Farms Not Covered by the Rule

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<thead>
<tr>
<th>Farms Not Covered by the Rule</th>
<th>Qualified Exempt</th>
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<tbody>
<tr>
<td>• Produce rarely eaten raw</td>
<td>• Average annual value of all food* sold (3 year avg.) less than $500,000, AND</td>
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<tr>
<td>• Produce for on-farm or personal consumption</td>
<td>sell 51% directly to consumer or retail food establishment in same state or within</td>
</tr>
<tr>
<td>• Farms selling less than $25,000 of food per year (3 yr. average)</td>
<td>275-mile radius</td>
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*all food, not just raw agricultural commodities covered by this rule; includes animal feed

FDA’s Produce Rule Fact Sheet:

FDA fact sheets about each of the 8 topic areas listed above are linked from this page:

For example, here is the FDA fact sheet for the ag water standards:

Issues for comment related to the Draft Produce Rule

We plan to comment on the following:

• Conservation practices are acknowledged as valuable (in the Act itself and the Preamble to the draft rule), but they are not explicitly protected;
• Manure and compost standards conflict with NOP regulations, which FSMA is not supposed to do:
a. NOP allows application of raw manure 4 months before harvest; the draft rule says 9 months
b. NOP does not require an interval before applying composted manure (minimizing contact with produce); the draft rule requires 45 days.
c. These conflicts may be because FDA did not consider all relevant science.

- Water quality requirements – testing, treatment, and maintenance – will significantly increase for farmers (see FDA’s ag water standards pdf, link given above, for required testing frequencies), who have little control over upstream users;
- If farmers must rely on treatment, what will be the impact on groundwater and soil health of a significant increase in application of chlorine and other antimicrobial treatments?
- FDA did not conduct an environmental review (environmental assessment or environmental impact statement), yet there may be significant environmental impacts;
- FDA proposes allowing alternatives to specific requirements (ag water testing/treatment composting treatment, application intervals for certain soil amendments) under some conditions, as long as farmers can present scientific evidence that these alternatives work. FDA says it will accept scientific data and information “developed by you,” the farmer, but FDA should be more specific about what type of evidence it will accept.

DRAFT PREVENTIVE CONTROLS RULE

- Facilities that manufacture and process food for human consumption
- Focuses on activities that change raw agricultural commodities (RAC) into processed food. A table of these activities is on p. 21 of this document: http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM345224.pdf
- Defines “farm mix-type facility”
- Two major requirements for covered facilities:
  - Hazard Analysis and Risk-Based Preventive Controls (HARP-C)
  - Updated Good Manufacturing Practices
- Also contains qualified exemptions for some activities and facilities

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<thead>
<tr>
<th>Not Covered by the Rule</th>
<th>Qualified Exempt*</th>
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<tbody>
<tr>
<td>Seafood, juice, low acid canned foods, dietary supplements, alcoholic beverages</td>
<td>Average annual value (3 year avg.) less than $500,000, AND sell 51% directly to</td>
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<tr>
<td>Activities in ‘farm’ definition</td>
<td>consumer or retail food establishment that sells direct, in same state or within</td>
</tr>
<tr>
<td>Certain facilities that only store packaged foods or raw ag commodities for processing</td>
<td>275-mile radius (Tester Hagan)</td>
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<td></td>
<td>Certain low-risk activities by small and very small businesses</td>
</tr>
<tr>
<td></td>
<td>Certain low-risk activities by very small, on-farm facilities</td>
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*As you can tell, the exemption categories are currently confusing. See p. 8-9 of this document for FDA’s list: http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM345224.pdf.

In our comments to FDA, we will ask that the agency clarify these categories, to help farmers who do some value-added processing understand which rules actually apply to them.

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ALSO, FDA is seeking comment on the income threshold to define a “very small” business for the qualified exemption: $250,000, $500,000, or $1 million.

Qualified Exempt facilities do not have to comply with HARP-C or GMPs. However, they DO have to register with FDA and:
   a) Show compliance with non-federal (i.e., state or county) food safety laws AND notify consumers of the name/complete business address of the facility, OR
   b) submit a simplified preventive controls and monitoring plan to FDA

FDA summary of the rule:
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm#summary

Issues for comment related to the Draft Preventive Controls Rule

- FSMA – the law itself – contains provisions to assure that roadside stands, farmers markets, and Community Supported Agriculture (CSA) will be defined as “retail food establishments” (not “facilities”) and thereby not be subject to the preventive controls rule. However, FDA has not yet done this, and the draft rule as written appears to make these innovative marketing approaches, which typically involve produce from more than one farm, subject to the rule;
- Similarly, the current “packing” and “holding” definitions would make CSAs, Food Hubs, and farmer co-ops that aggregate product subject to the rule, also contrary to FSMA – the law itself;
- The food processing study done by FDA as required by FSMA to inform rulemaking relies on very limited data and did not survey small food facilities (or farms); it should be redone;
- FDA is asking for comment on how to define “very small business” in this rule: $250,000, $500,000, or $1 million average annual sales? Note: crops not subject to the rules are still counted towards that income.

Issues for comment related to both draft rules

1. Losing/Regaining Exemptions, i.e., “withdrawal of modified requirements”
Qualified exempt farms and facilities can lose their exemptions and be required to comply with all requirements if FDA finds:
   - Direct link to an active investigation of an outbreak, or
   - Material conduct or conditions: If FDA “determines it is necessary to protect public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility/farm that are material to the safety of food produced or manufactured, processed, packed, or held at such facility or farm.”

In our comments, we will request that FDA clarify and specify:
   a. What conditions trigger a withdrawal (loss of exemption)? More clarity needed on the definition of “material,” “associated,” and “direct link”.

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b. Can exemptions be withdrawn for all farms growing an entire category of produce, even for farms not involved in an outbreak or “material conditions”?
c. What is the withdrawal process? Need clarity on timeline, farmer notification requirements.
d. Can exemptions be regained? Under what conditions?

2. Income thresholds for qualified exempt status for both farms and facilities are based on value of all food produced, including animal feed, not just food covered by the rule. For example, if dairy farmers want to grow and sell a very small amount of produce at a roadside stand during the summer months, their total “food” income may exceed the threshold, even if their produce sales are small in volume and direct to consumer.

3. Clarification and consistent definitions are needed in many areas, to help farmers and mixed-type facilities understand which rules and standards apply to them:
   • Clear, consistent definitions of “farm” v. “facility”
   • Clear, consistent definitions of “small” and “very small” for farms and facilities
   • Clarity about how the two draft rules interact

4. Training and capacity building to help farms and facilities comply with the rule will be critical. FSMA – the law itself – recognizes this, for example, by authorizing a new competitive grants training program, but USDA has not yet provided funding for it.

5. Economic impact analysis: FDA was required to analyze the economic impact of the rule on farms and facilities. However, that analysis contains insufficient consideration of the economic impact on local and regional food systems (e.g., CSA, food hubs, farm-to-school/institution, and other innovative marketing channels).