Final Rule on Produce Safety: for Sprouters
http://www.fda.gov/fsma
Timeline

• FDA issued proposed rule on Jan. 16, 2013.
  – Proposed standards for the growing, harvesting, packing, and holding of produce

• Extensive stakeholder outreach and input
  – Four public meetings; various outreach efforts
  – About 36,000 submissions, including over 15,000 unique comments, in response to both 2013 and 2014 documents
  – Input from various sectors of stakeholder community

• FDA issued final rule on Nov. 27, 2015.
Produce Rule Documents

- Final rule
- Qualitative Assessment of Risk (QAR)
- Regulatory Impact Analysis (RIA)
- Environmental Impact Statement (EIS) and Record of Decision (ROD)
Regulatory Framework

• Framework considers many factors associated with produce and the farming community, including
  – Diversity of operations
  – Broad range of crops and practices
• Integrated approach that draws on current scientific information, outbreak data, past experiences
  – Focuses on identified routes of contamination, rather than commodity-based
  – Includes Current Good Manufacturing Practice-like provisions; numerical criteria; and monitoring provisions
Coverage of Rule

Covers
- Domestic and imported produce
- Produce for human consumption

Does not cover
- Produce for personal or on-farm consumption
- Produce no longer a “raw agricultural commodity”
- Certain specified produce rarely consumed raw
- Farms with produce sales of $\leq 25,000$ per year

Eligible for exemption (with modified requirements)
- Produce that will receive commercial processing (“kill-step” or other process that adequately minimizes hazards)
- Qualified exemption
Farms

• “Farm” definition was revised to clarify that the relevant entity is the farm business

• First defined as part of Implementation of the Bioterrorism Act of 2002, for registration and recordkeeping regulations (21 CFR Part 1, subparts H and J)
Activities That Do Not Fall Under Farm Definition

• Manufacturing/processing that goes beyond activities within the farm definition

• Examples include:
  – Making noodles and tofu
  – Pitting dried plums, chopping herbs
  – Making snack chips from legumes
  – Roasting peanuts or tree nuts
Qualified Exemption

Farms are eligible for a qualified exemption (and must meet certain modified requirements) if:

- Less than $500,000 annual food sales; and
- Majority of food sales directly to “qualified end-users”, i.e.,
  - Consumer of the food (at any location); or
  - Restaurant or Retail food establishment located in the same state or Indian reservation, or located within 275 miles of farm

(The term “consumer” does not include a business.)
## Staggered Compliance Dates

<table>
<thead>
<tr>
<th>Size of covered farm</th>
<th>Covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of part 112)</th>
<th>Covered activities involving all other covered produce (i.e., subject to part 112, except subpart M)</th>
<th>Farms eligible for a qualified exemption (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Compliance date for certain specified agricultural water requirements</td>
<td>Compliance date for all other requirements</td>
<td>Compliance date for retention of records supporting eligibility in § 112.7(b)</td>
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<tr>
<td></td>
<td>Time periods starting from the effective date of rule (60 days after final rule is published)</td>
<td></td>
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<tr>
<td>Very small business</td>
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<td></td>
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<tr>
<td>$\leq 250,000^*$</td>
<td>3 years</td>
<td>6 years</td>
<td>4 years</td>
</tr>
<tr>
<td>Small business</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>$\leq 500,000$</td>
<td>2 years</td>
<td>5 years</td>
<td>3 years</td>
</tr>
<tr>
<td>All other businesses</td>
<td>1 year</td>
<td>4 years</td>
<td>2 years</td>
</tr>
</tbody>
</table>

* Farms with <25,000 in **produce** sales are exempt
Standards for Produce Safety

Focus on conditions and practices identified as potential contributing factors for microbial contamination

- Agricultural water
- Biological soil amendments of animal origin
- Worker health and hygiene
- Equipment, tools, buildings and sanitation
- Domesticated and wild animals
- Growing, harvesting, packing and holding activities
- Sprouts requirements
Training Requirements

- Requirements include:
  - All personnel who contact covered produce or food-contact surfaces
    - Establishes minimum content expectations for training
  - Training for supervisors
  - Record requirements
Worker Health and Hygiene

• Pathogens may be transmitted from workers to food

• Requirements include:
  – Preventing contamination by ill persons
  – Hygienic practices
  – Farms must make visitors aware of policies and give them access to toilet and hand washing facilities.
Agricultural Water - 1

- Safe and adequate sanitary quality of water
- Inspection of water system under farm’s control
- Water treatment, if a farm chooses to treat water
Agricultural Water - 2

• Tiered approach to water testing

• Stringency of microbial criteria is dependent on use:
  – For activities e.g. post-harvest wash, sprout irrigation
    • No detectable generic *E. coli*

• Corrective measures

• Records requirements
Biological Soil Amendments of Animal Origin

- Standards for “treated” and “untreated”
- Restrictions on application method depending on treatment status
- Any scientifically valid treatment process that meets the standards of 112.55(a) may be applied without restrictions, and could involve physical, chemical or biological treatment process, or a combination of these.
Growing, Harvesting, Packing, and Holding Activities

- Requirements include:
  - Separate covered and excluded produce not grown in accordance to the rule
  - Identify and not harvest covered produce that is reasonably likely to be contaminated
  - Not distributing covered produce that drops to the ground before harvest
  - Food-packing material appropriate for use
Equipment, Tools, Buildings and Sanitation

Requirements include:

- Equipment/tools: designed and constructed to allow adequate cleaning and maintenance.

- Food contact surfaces of equipment and tools must be inspected, maintained, cleaned, and sanitized as necessary.

- Buildings: size, design and construction must facilitate maintenance and sanitary operations.

- Toilet and hand-washing facilities must be adequate, and readily accessible during covered activities.
Requirements for Sprouts

- Sprout requirements include:
  - Treating seed and beans before sprouting
  - Testing spent sprout irrigation water (or sprouts, in some cases) for certain pathogens
  - Monitoring the growing, harvesting, packing, and holding environment for *Listeria* species or *Listeria monocytogenes*
  - Discontinuing use of seeds or beans when spent irrigation water (or sprouts) is associated with a foodborne illness or a positive pathogen finding
Requirements for Sprouts - 2

Significant changes in final rule include:

- Staggered compliance dates based on operation size begin 1 year after effective date of the rule; no additional time for water provisions

- Exclude soil- or substrate-grown sprouts harvested without their roots

- Criteria established for spent irrigation water testing to account for emerging pathogens

- Establish a written sampling plan and a corrective action plan for testing of spent irrigation water (or sprouts)

- New provisions to prevent contaminated product entering commerce (incl. “hold-and-release” -- must not allow sprouts to enter commerce until negative pathogen testing results are received)
Guidance

• Implementation and Compliance Guide
• Sprout Guidance
• Small Entity Compliance Guide
• Updated GAPs Guidance
For More Information

- Web site: www.fda.gov/fsma
- Subscription feature available
- To submit a question about FSMA, visit www.fda.gov/fsma and go to Contact Us
QUESTIONS/DISCUSSION