

# Final Rule on Produce Safety: for Sprouters

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**FDA FOOD SAFETY**  
MODERNIZATION ACT

THE FUTURE IS NOW

# 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

Size of covered farm	Covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of part 112)	Covered activities involving all other covered produce (i.e., subject to part 112, except subpart M)		Farms eligible for a qualified exemption (if applicable)		
		Compliance date for certain specified agricultural water requirements	Compliance date for all other requirements	Compliance date for retention of records supporting eligibility in § 112.7(b)	Compliance date for modified requirement in § 112.6(b) (1)	Compliance date for all other requirements in §§ 112.6 and 112.7
	Time periods starting from the effective date of rule (60 days after final rule is published)					
Very small business ≤\$250,000*	3 years	6 years	4 years	Effective date of rule	January 1, 2020	4 years
Small business ≤\$500,000	2 years	5 years	3 years			3 years
All other businesses	1 year	4 years	2 years			N/A

\* 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

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- 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

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- 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 -1

- 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

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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](http://www.fda.gov/fsma)
- Subscription feature available
- To submit a question about FSMA, visit [www.fda.gov/fsma](http://www.fda.gov/fsma) and go to Contact Us

## Implementation Activity

- **Who Will Provide Training for the Food Industry? Public and Private Partners Working Together** - FDA's Strategy for FSMA Training
- **Food Safety in Today's Global Food System: An FDA Perspective** - A Speech by Michael R. Taylor, FDA Deputy Commissioner for Foods and Veterinary Medicine
- **User Fee Program to Provide for Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications** - Proposed Rule
- **Produce Safety** - Proposed Supplemental Rule
- **Preventive Controls for Human Food** - Proposed Supplemental Rule
- **Preventive Controls for Animal Food** - Proposed Supplemental Rule
- **Foreign Supplier Verification Programs (FSVP)** - Proposed Supplemental Rule
- **All Activity by Date**

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The modified form is designed to facilitate questions that are specific to FSMA and its implementation. Your use of the form will provide the FSMA Technical Assistance Network with the information needed to give accurate and timely responses and to improve our customer service. We hope you find our online form useful in identifying the specific nature of your inquiry and we remain open to suggestions about improving the form to meet your needs.

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You may also mail your question to the address below:

Food and Drug Administration  
5100 Paint Branch Pkwy  
Wiley Building, HFS-009  
Attn: FSMA Outreach  
College Park, MD 20740

# QUESTIONS/DISCUSSION