

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

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- 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

- 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:

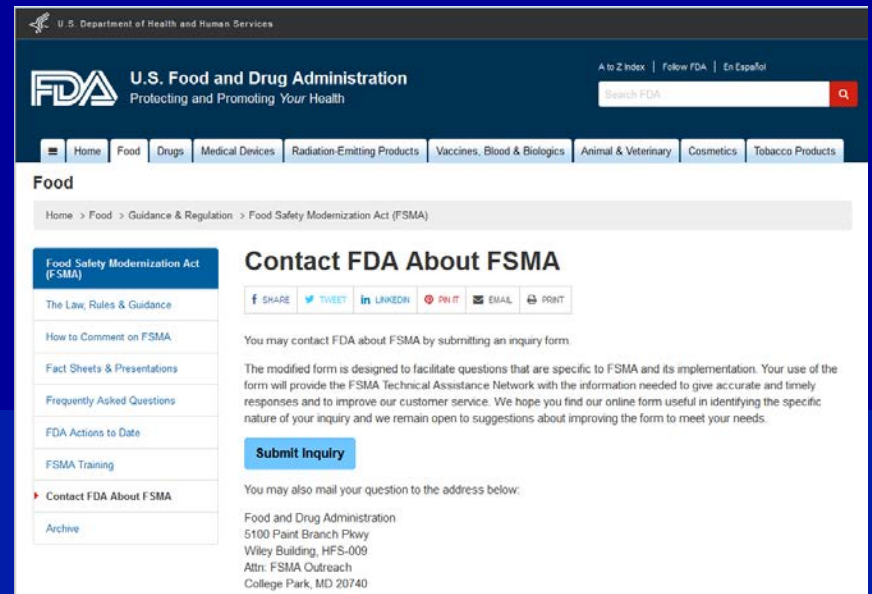
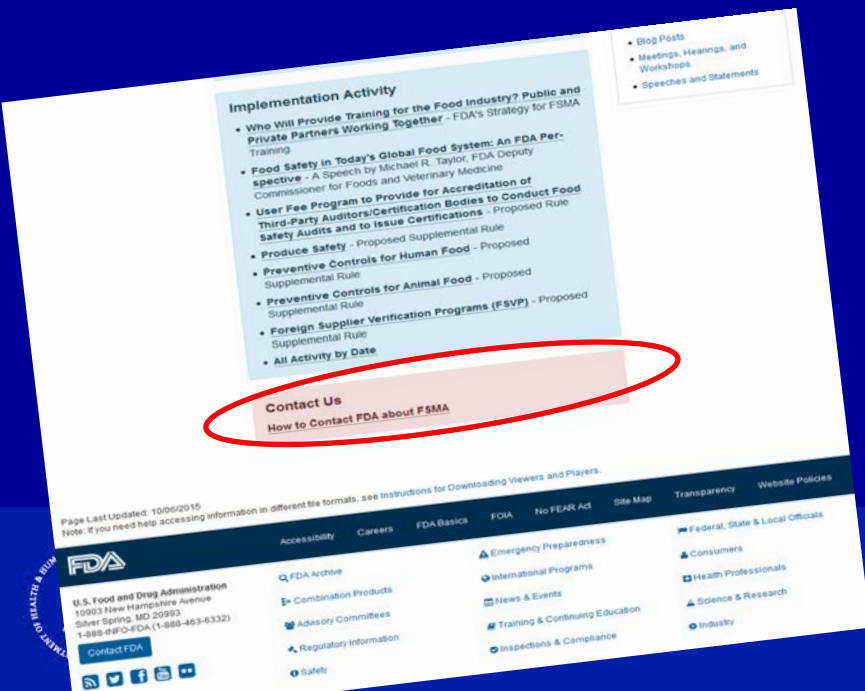
- Staggered compliance dates based on operation size begin 1 year after effective date of the rule; no additional time for water provisions
- Exclude soil- or substrate-grown sprouts harvested without their roots
- Criteria established for spent irrigation water testing to account for emerging pathogens
- 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
- Subscription feature available
- To submit a question about FSMA, visit www.fda.gov/fsma and go to [Contact Us](#)



QUESTIONS/DISCUSSION