

Final Rule on Produce Safety

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**FDA FOOD SAFETY
MODERNIZATION ACT**

THE FUTURE IS NOW

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 not 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

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 to “qualified end-users”, i.e.,
 - Consumer of the food; 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.)

Variations - Flexibility

- A state, tribe, or foreign country may petition FDA for a variance from some or all provisions
 - if necessary in light of local growing conditions
 - Practices under the variance need to provide the same level of public health protection as the rule and not increase the risk that produce is adulterated

Alternatives – Flexibility

- Farms may establish alternatives to certain, specified requirements only
- Farm must have scientific information that the alternative provides the same level of public health protection as the relevant requirement and does not increase the likelihood of adulteration

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

Agricultural Water

- Safe and adequate sanitary quality of water
- Inspection of water system under farm's control
- Water treatment, if a farm chooses to treat water
- Tiered approach to water testing
- Specific microbial criteria for water used for certain purposes
- Corrective measures
- Records requirements

Biological Soil Amendments of Animal Origin

- Standards for “treated” and “untreated”
- Restrictions on application method depending on treatment status
 - Application-to-harvest interval for certain “untreated” BSAs of animal origin is [reserved]
 - Currently working on risk assessment
- Processes for meeting “treated” standard for BSAs of animal origin, including two examples for composting
 - The microbial standards are not testing 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.

Equipment, Tools, Buildings and Sanitation

Produce
Final

- 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.

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

Domesticated and Wild Animals

- Unified requirements for grazing, working, and wild animals:
 - Assess, as needed, relevant areas during growing for potential animal contamination;
 - If significant evidence of potential contamination is found (e.g., animal excreta, animal observation or destruction),
 - Evaluate whether covered produce can be harvested
 - Take steps throughout the growing season to ensure that covered produce that is reasonably likely to be contaminated will not be harvested

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

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

Guidance

- Implementation and Compliance Guide
- Sprout Guidance
- Small Entity Compliance Guide
- Updated GAPs Guidance

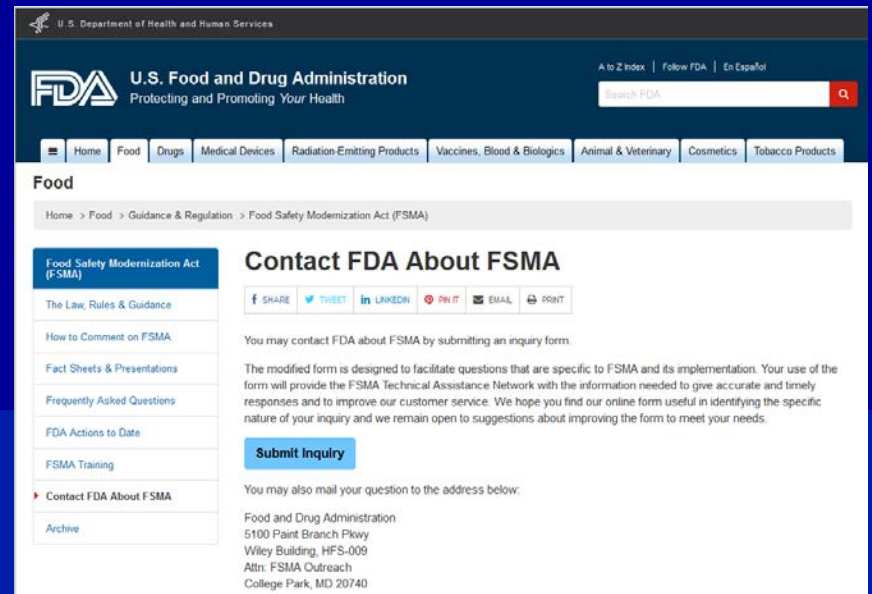
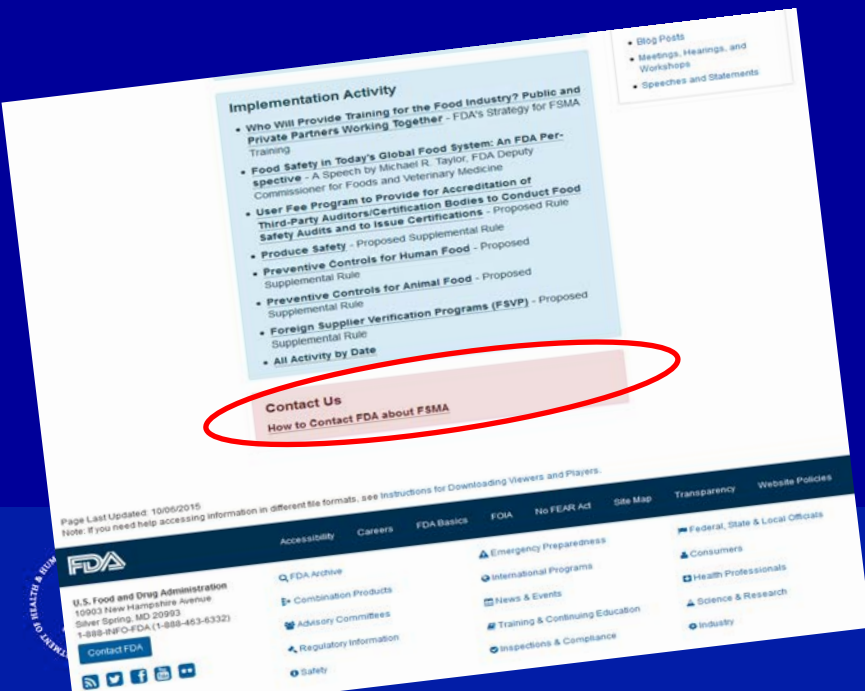
FDA's Role in Education, Outreach, Training, and Technical Assistance

- FDA Guidance documents
- National Technical Assistance Network
- Information Center

Partnerships will be essential

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