

# Final Rule on Produce Safety

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**FDA FOOD SAFETY  
MODERNIZATION ACT**

**THE FUTURE IS NOW**

# Background - 1

- FDA issued proposed rule on Jan. 16, 2013.
  - Proposed standards for the growing, harvesting, packing, and holding of produce
- FDA issued supplemental notice of proposed rulemaking on Sept. 29, 2014.
  - Described FDA's thinking on specific issues related to:
    - coverage of rule, water quality, raw manure, wildlife conservation, and withdrawal of qualified exemption

# Background - 2

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- Final comment period closed on December 15, 2014
- 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

# 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.)

# Variances - 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 - 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
- Tiered approach to water testing
- Specific microbial criteria for water used for certain purposes
- Corrective measures
- Records requirements

# Agricultural Water-2

## Water used during growing activities for produce other than sprouts

- Frequency of testing dependent on water source
  - Lower frequency for untreated groundwater
  - Higher frequency for untreated surface water
- Microbial Water Quality Profile (MWQP)
  - Initial survey to develop MWQP
    - Minimum of 2 years, but no more than 4 years
  - Annual survey to update MWQP using a rolling dataset
  - Re-characterize MWQP under certain conditions
- Enables farms to understand their water source to determine appropriate use

# Agricultural Water - 3

Stringency of microbial criteria is dependent on use:

- For activities e.g. post-harvest wash, sprout irrigation
  - No detectable generic *E. coli*
- For growing activities such as non-sprout irrigation
  - GM of 126 CFU/100 mL or less generic *E. coli* and STV of 410 CFU/100 mL or less generic *E. coli*
    - Allows for microbial die-off in-field, between last irrigation and harvest, of up to 4 consecutive days
    - Allows for microbial reduction or removal post-harvest, including through commercial practices or storage

# 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

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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.

# 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

# Impact on Wildlife and Animal Habitat

- Codified provision (developed in consultation with USDA's NRCS and the U.S. Fish and Wildlife Services):
  - Regulation does not authorize “taking” of endangered or threatened species; or require measures to destroy animal habitat or exclude animals from outdoor growing areas

# 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)

# 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)						
<b>Very small business</b> ≤\$250,000*	3 years	6 years	4 years	Effective date of rule	January 1, 2020	4 years
<b>Small business</b> ≤\$500,000	2 years	5 years	3 years			3 years
<b>All other businesses</b>	1 year	4 years	2 years			N/A

\* Farms with <25,000 in produce sales are exempt



# Costs and Benefits

- Annualized benefits (at 7%) of averting approximately 331,964 produce-related illnesses = \$925M (\$976M at 3%)
- Annualized costs (at 7%) = \$366M (\$387M at 3%)

# Guidance

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

# Education, Outreach, Training and Technical Assistance Partnerships

- Alliances
  - Produce Safety Alliance
  - Sprout Safety Alliance
  - Food Safety Preventive Controls Alliance
- FDA/USDA-NIFA Collaboration: National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program
- Training through Cooperative Agreements

# 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](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](#)



# QUESTIONS/DISCUSSION