

FDA's Final Rule for Preventive Controls for Human Food

IAFP

November 18, 2015

<http://www.fda.gov/fsma>

**FDA FOOD SAFETY
MODERNIZATION ACT**

THE FUTURE IS NOW



What does PCHF do?

- Revises the farm definition
- Modernizes longstanding current good manufacturing practice (CGMP) requirements
- Establishes new requirements for hazard analysis and risk-based preventive controls

Who is Covered by PCHF?

- Facilities that manufacture, process, pack or hold human food
- In general, facilities required to register with FDA under sec. 415 of the FD&C Act
 - Not farms or retail food establishments
- Applies to domestic and imported food
- Some exemptions and modified requirements apply

Food Safety Plan

- Hazard analysis
- Preventive controls
- Supply-chain program
- Recall plan
- Procedures for monitoring
- Corrective action procedures
- Verification procedures

Farms

- A farm is exempt from FDA's food facility registration requirement.
- Facilities that do not have to register with FDA are not subject to the preventive controls requirements.
 - Depending on certain factors, farms may be subject to the produce safety rule.
- PCHF revises the farm definition to reflect modern farming practices.

Primary Production Farm

- An operation under one management in one general, but not necessarily contiguous, location
- Devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities
 - The definition has been expanded to include operations that just grow crops and operations that just harvest crops.

Primary Production Farm

- In addition to these activities, a primary production farm can:
 - Pack or hold RACs (regardless of who grew or raised them)
 - Manufacture/process, pack, or hold processed foods so long as:
 - all such food is consumed on that farm or another under the same management; or
 - the manufacturing/processing falls into limited categories

Manufacturing/Processing within the Farm Definition

- Drying/dehydrating RACs to create a distinct commodity (e.g., drying grapes to produce raisins)
- Treatment to manipulate the ripening of RACs (e.g., treating produce with ethylene gas)
- Packaging and labeling RACs

Secondary Activities Farm

- An operation not located on a primary production farm that is also devoted to farming activities, like harvesting, packing and/or holding RACs.
- The primary production farm(s) that grow, harvest, and/or raise the majority of those RACs must own or jointly own a majority interest in the secondary activities farm.

Activities That Do Not Fall Under Farm Definition

- Activities that do not fall within the farm definition include manufacturing/processing that goes beyond what falls within the farm definition. As examples:
 - Pitting dried plums, chopping herbs
 - Making snack chips or flours from legumes
 - Roasting peanuts, tree nuts, or seeds (e.g., pumpkin, sunflower, or flax seeds)

Activities that Do Not Fall Under Farm Definition

- FDA expects to issue guidance on activities that fall within the farm definition and activities that do not in the near future.

Produce Packing Houses

- Produce packing houses that fall under the new farm definition → produce safety rule
- Produce packing houses that do not fall under the new farm definition → PCHF
- Specific steps necessary to ensure the safety of produce would generally be the same

Off-farm Produce Packing House

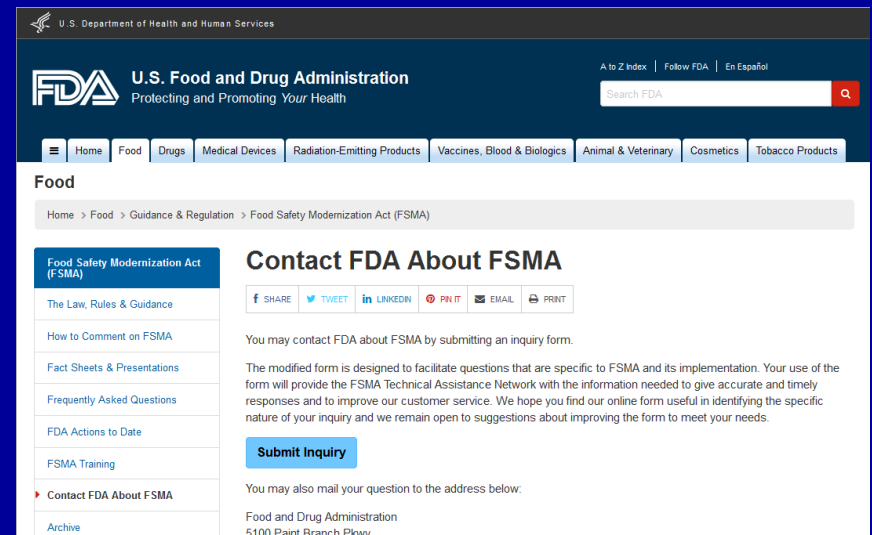
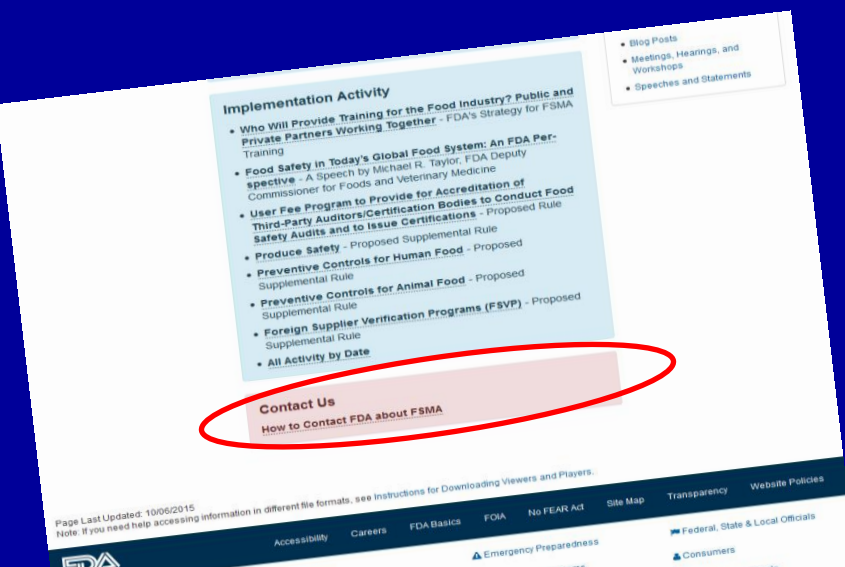
- CGMP requirements have analogues in produce safety rule (new PCHF provision allows packing house to choose)
- We expect off-farm packing houses subject to PCHF to look to the produce safety rule in developing food safety plans and establish preventive control management components

Off-farm Produce Packing House

- Food safety plan would focus on a few key preventive controls, generally with counterparts in the produce safety rule
 - Maintaining and monitoring water temperature
 - Sanitation controls
- PC management components
 - Product testing: unlikely
 - Environmental monitoring: some facilities may choose as a verification activity

Public 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



Final Rule on Produce Safety

<http://www.fda.gov/fsma>



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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

Produce
Final

- 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

Public Health Impact

- Expected decrease in illness from microbial contamination of produce (RIA)
 - 362,059 illnesses per year
 - Valued at \$976 million per year
- FDA outbreak surveillance data from 1996-2014 for produce-related outbreaks (QAR)

173 outbreaks 17,226 illnesses 68 deaths

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 - 1

- 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

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- 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

Produce
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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)					
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

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

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

Partnerships will be essential

For More Information

- Web site: www.fda.gov/fsma
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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.

Submit Inquiry

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