

FDA Food Safety Modernization Act

Overview & New Proposed Rules



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Organicology | Portland, OR | February 2013

FDA Food Safety Modernization Act

Implementation & scope of the law

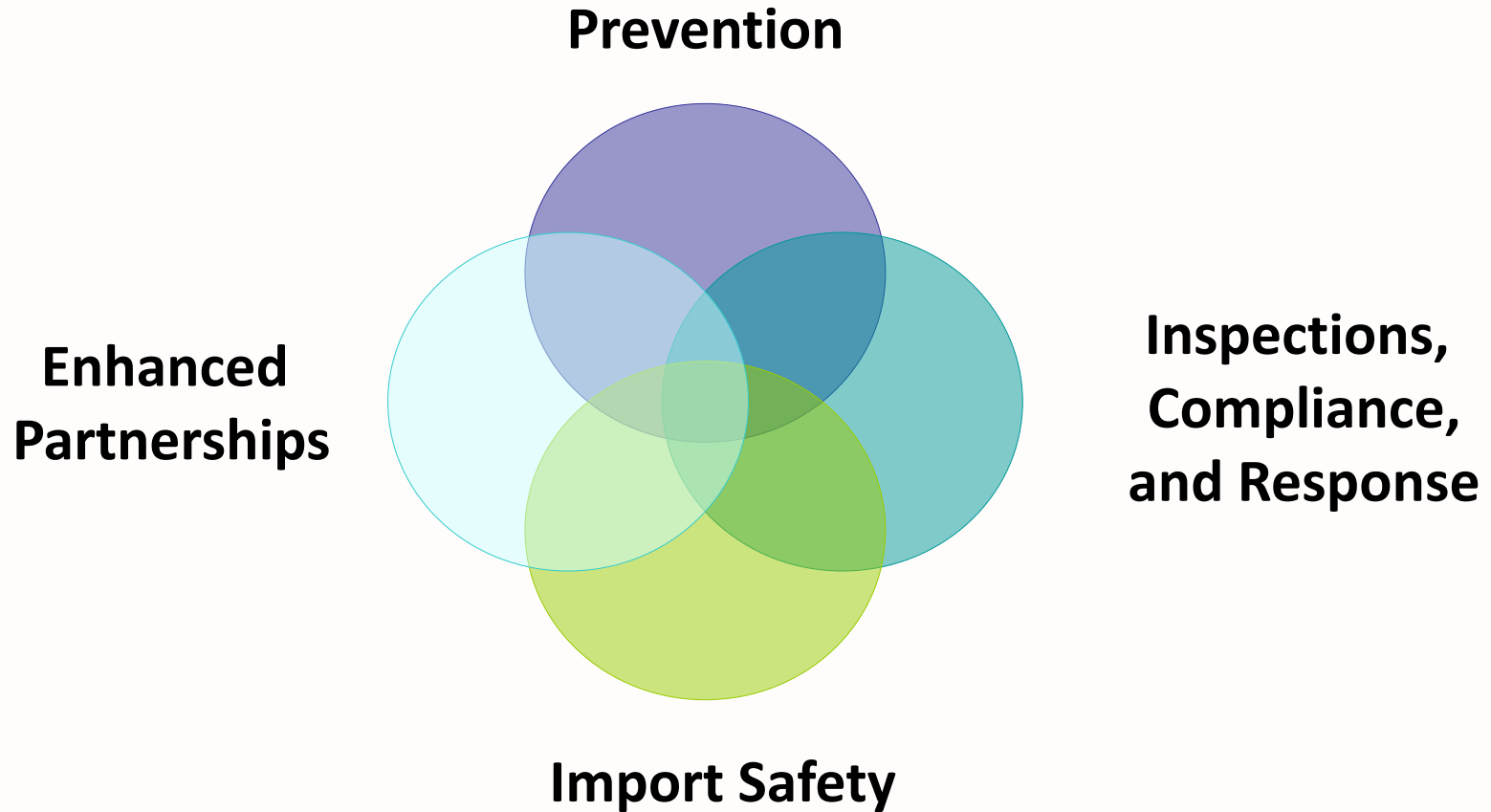
Signed into law January 4th, 2011: Largest expansion of FDA's food safety authority since the 1930s

- Requires food facilities to identify potential food safety hazards and develop & implement preventive control plans
- Directs FDA to establish fruit & vegetable harvesting standards
- New system of import oversight
- Directs FDA to inspect facilities & imported foods more frequently
- Expands authority to conduct mandatory recall of contaminated foods
- Directs FDA to collect fees related to re-inspections and recalls
- Requires FDA to establish product tracing system, testing, & improve data on foodborne illness



FDA Food Safety Modernization Act

Main Themes of the Legislation



FDA Food Safety Modernization Act

Why was the law created?

- **Globalization**
- **More foods in the marketplace**
- **Centralization of the food system**
- **15 percent of U.S. food supply is imported**
- **Growing population – about 30% are “at risk” for foodborne illness**
- **Food illness is a significant burden!!!**
 - **About 48 million (1 in 6) Americans get sick each year**
 - **128,000 are hospitalized & 3,000 die**



FDA Food Safety Modernization Act

Significant changes relevant to organic



Sec. 105: Standards For Produce Safety

Proposed Rule was published Jan 2013

Organic Trade Association lobbied the HELP Committee staff, and several Senate offices to include language to prevent requirements from contradicting with organic methods and materials.



The proposed rulemaking in the case of production that is certified organic, ***must not*** include any requirements that conflict with or duplicate the requirements of the NOP.

Comment Period was extended from 60 to 120 days!



FDA Food Safety Modernization Act

Significant changes relevant to organic

Sec. 105 1 year after enactment of the law, publish a proposed rule to establish science-based minimum standards for safe production and harvesting - **in coordination with NOP**

Sec. 110 (Building Domestic Capacity) 2 years - Report to Congress on programs and practices to promote food safety including description of impact of requirements on organic farms and facilities;

Sec. 209 Improving the training of state, local, territorial, and tribal food safety officials (**Stabenow amendment**);

- Resources and guidance for technical assistance to be provided through the states and local governments for operations that will be subject to the new law



FDA Food Safety Modernization Act

Other important components

The Act requires the produce standards to:



Take into consideration conservation and environmental practice standards established by federal conservation and environmental agencies;



Reduce unnecessary paperwork and streamline requirements for farmers and small processors;



Give small businesses regulatory flexibility such as additional time to comply;



Provide exemptions or modified requirements to small farms and food processors (defined by sales) that sell directly to consumers or to farms engaged in low or no-risk on-farm processing



FDA Food Safety Modernization Act

Five Proposed Rules Establish Framework

Just Released:

- Produce Safety Standards - Published Jan. 2013
- Preventive Controls for Human Food - Published Jan. 2013

Coming Soon:

- Foreign Supplier Verification Program
- Preventive Controls for Animal Food
- Accredited Third Party Certification



FDA New Proposed Rules

Produce Safety and Preventative Control Rule

“Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food” [**Preventive Control Rule**]

- Mandates the adoption, implementation, and ongoing documentation of the operation of a science-based preventive food safety system for most processing, handling, and warehousing operations



“Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” [**Produce Rule**]

- Focuses on produce safety and mandates the on-farm adoption of various risk-prevention measures by growers, farms, and mixed-type facilities



FDA Proposed Produce Safety Rule

Key Principles

- Considers risk posed by practices, not commodities
- Science- and Risk-based
 - Focus on identified routes of microbial contamination
 - Excludes certain produce rarely consumed raw
 - Excludes produce to be commercially processed (documentation required)
- Flexible
 - Additional time for small farms to comply
 - Variances
 - Alternatives for some provisions



FDA Proposed Produce Safety Rule

Produce Safety Standards

Focus on identified routes of microbial contamination

- Agricultural water
- Biological soil amendments of animal origin
- Domesticated and wild animals
- Specific requirements for sprouts
- Equipment, tools, buildings and sanitation
- Growing, harvesting, packing and holding activities
- Worker health and hygiene



FDA Proposed Produce Safety Rule

Agricultural Water

- Intended to, or likely to, contact the harvestable portion of covered produce or food-contact surfaces
- Establish requirements for inspection, maintenance, and follow-up actions
- Require treatment of agricultural water that is not safe for its intended use
- Establish specific quality requirements
- Specific quality requirements and follow-up action when water does not meet quality standards
- Records to support water quality



FDA Proposed Produce Safety Rule

Biological Soil Amendments

- Establish requirements for determining the status of a biological soil amendment of animal origin as treated or untreated
- Prohibit the use of human waste for growing covered produce except in compliance with EPA regulations
- Establish requirements for treatment of biological soil amendments of animal origin (chemical, physical, composting)
 - Application intervals apply depending on treated/untreated and type of treatment
 - Records to support treatment



FDA Proposed Produce Safety Rule

Domesticated and Wild Animals

- Produce Rule would not prohibit the use of on-farm domesticated working animals
- Requires covered farms to take measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce
- Requires a waiting period between grazing and harvesting if there is reasonable probability that animals will contaminate covered produce
- Records



FDA Proposed Produce Safety Rule

Equipment, tools, buildings & sanitation

- Requirements related to:
 - Equipment and tools that contact covered produce and
 - Instruments and controls (including equipment used in transport)
 - Buildings used for covered activity (fully or partially closed) or store food contact surfaces (i.e. harvest containers)
 - Domesticated animals in and around fully-enclosed buildings
 - Pest control
 - Hand-washing and toilet facilities
 - Sewage, trash, plumbing, and animal excreta



FDA Proposed Produce Safety Rule

Worker Health & Hygiene



- Establish qualification and training requirements for all personnel who handle (contact) covered produce or food-contact surfaces and their supervisors
- Require documentation of required training
- Establish hygienic practices and other measures needed to prevent persons including visitors, from contaminating produce with microorganisms of public health significance



FDA Proposed Produce Safety Rule

Sprouts

- Special concern with respect to human pathogens, as compared with other covered produce, because of the warm, moist, and nutrient-rich conditions
- Establish measures for sprout safety
- Require that you test the growing environment for *Listeria* spp. or *L. monocytogenes* and that you test each production batch of spent irrigation water or sprouts for *E. coli* O157:H7 and



FDA Proposed Produce Safety Rule

Who would be covered?

Farms that grow, harvest, pack or hold most produce in raw or natural state (raw agricultural commodities - RACs)

Farms and “farm” portions of mixed-type facilities

Domestic and imported produce

Farms with annual sales > \$25,000 per year

Limitations on coverage are proposed



FDA Proposed Produce Safety Rule

Covered Produce?

- “Produce” defined as fruits and vegetables
- Produce includes mushrooms, sprouts, herbs and tree nuts
- Produce does not include grains
- Some limitations on covered produce



FDA Proposed Produce Safety Rule

Limitations on Coverage

- Produce for personal or on-farm consumption



- Produce not a Raw Agricultural Commodity
 - Certain produce rarely consumed raw
 - Produce that will receive commercial processing
 - Farms with sales of \$25,000 or less per year
- **Qualified exemption and modified requirements**



FDA Proposed Produce Safety Rule

Limitations on Coverage

- As required by Congress, farms would be **partially exempt** from the proposed rule if they meet two requirements.
 - First, they must have food sales averaging less than \$500,000 per year during the last three years (adjusted for inflation).
 - Second, their sales to qualified end-users must exceed their sales to others during the same period.

Above \$250,000 and no more than \$500,000	Small Business
Above \$25,000 and no more than \$250,000	Very Small Business
\$25,000 or less	Excluded From Coverage



FDA Proposed Produce Safety Rule

Limitations on Coverage

Proposed Standards for Produce Safety - Coverage and Exemptions/Exclusions for Proposed 21 PART 112

<p>Does your farm grow, harvest, pack or hold produce? Sections 112.1 and 112.3(c)</p> <p style="text-align: center;">YES ↓</p>	<p>NO →</p>	<p>You are NOT covered by this rule.</p>
<p>Is your produce rarely consumed raw? Section 112.2(a)(1)</p> <p style="text-align: center;">NO ↓</p>	<p>YES →</p>	<p>This produce is NOT covered by this rule.</p>
<p>Is your produce for personal/on-farm consumption? Section 112.2(a)(2)</p> <p style="text-align: center;">NO ↓</p>	<p>YES →</p>	<p>This produce is NOT covered by this rule.</p>
<p>Does your farm manufacture/process, pack, or hold produce that is not a "Raw Agricultural Commodity (RAC)"? Section 112.2(a)(3)</p> <p style="text-align: center;">NO ↓</p>	<p>YES →</p>	<p>Produce that is not a RAC is NOT covered by this rule.</p>
<p>Is your produce intended for commercial processing with a "kill step"? Section 112.2(b)(1)</p> <p style="text-align: center;">NO ↓</p>	<p>YES →</p>	<p>This produce is NOT covered by this rule, EXCEPT as per Sections 112.(b)(2) and (3)</p>
<p>Does your farm on average (in the previous 3yrs) have < \$25k annual food sales? Section 112.4(a)</p> <p style="text-align: center;">NO ↓</p>	<p>YES →</p>	<p>You are NOT covered by this rule.</p>
<p>Does your farm on average (in the previous 3yrs) as per Section 112.5:</p> <ul style="list-style-type: none"> • have < \$500k annual food sales, AND • a majority of the food (by value) sold directly to "qualified end-users"? <p>"Qualified End-User" Section 112.3(c) means:</p> <ul style="list-style-type: none"> • the consumer of the food ("consumer" is not a business) OR • a restaurant or retail food establishment that is located— <li style="margin-left: 20px;">(i) in the same State as the farm that produced the food; OR <li style="margin-left: 20px;">(ii) not more than 275 miles from such farm. <p style="text-align: center;">NO ↓</p>	<p>YES →</p>	<p>You are EXEMPT from this rule except as per Section 112.6</p>
<p>You are COVERED by this rule.</p>		



FDA Proposed Produce Safety Rule

Alternatives Permitted

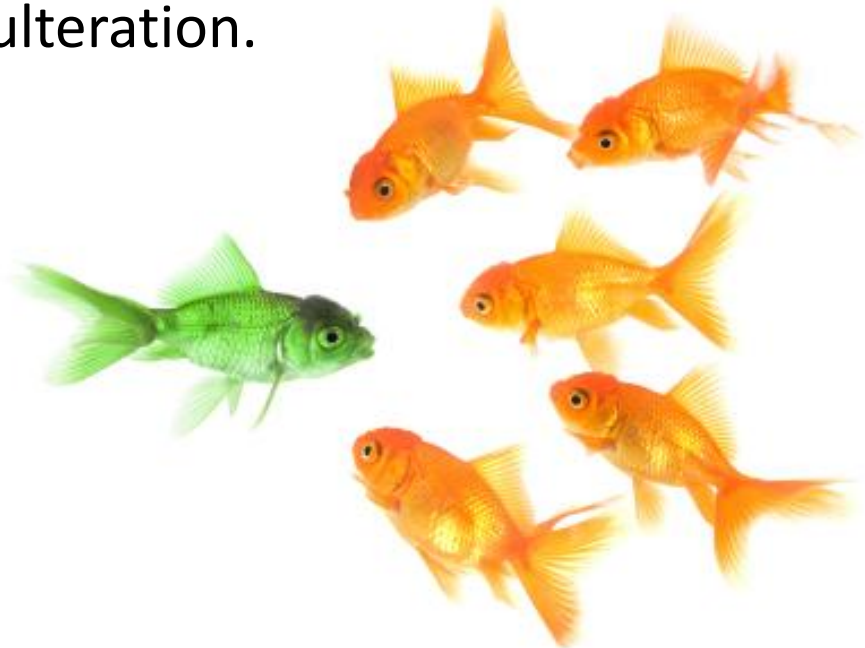
- Farms may establish alternatives to certain requirements related to water and biological soil amendments of animal origin
- Alternatives must be scientifically established to provide the same amount of protection as the requirement in the proposed rule without increasing the risk of adulteration



FDA Proposed Produce Safety Rule

Variances

- A state or foreign country may petition FDA for a variance from some or all provisions if deemed necessary in light of local growing conditions.
- Practices under the variance would need to provide the same level of public health protection as the proposed rule without increasing the risk of adulteration.



FDA Proposed Produce Safety Rule

Record Keeping

The proposed rule would require certain records, for example, to document that certain standards are being met

Example: agricultural water testing results

Records already kept for other purposes need not be duplicated

Electronic records would be acceptable but not required

A food safety plan is recommended but not required

Records must be kept for two years after the date the record was created.

Offsite storage permitted 6 months following creation provided onsite within 24 hour request



FDA Proposed Produce Safety Rule

Qualitative Assessment

- Draft qualitative assessment of risk helps to inform proposed rule
- Provides a scientific evaluation of potential adverse health effects resulting from human exposure to hazards in produce
- Available for public comment as part of the proposed rule



FDA Proposed Produce Safety Rule

Effective and Compliance Dates

Effective Date: 60 days after the final rule is published

Compliance Dates:

- **Very small farms**

- Average annual value of food sold $> \$25,000$ and $\leq \$250,000$
- Four years after the effective date to comply
- For some water requirements, six years

- **Small farms**

- Average annual value of food sold $> \$250,000$ and $\leq \$500,000$
- Would have three years after the effective date to comply
- Would have five years for some water requirements

- **Other covered farms**

- Other covered businesses would have to comply two years after the effective date
- Would have four years for some water requirements



FDA Proposed Preventive Controls

Summary of Requirements

- Hazard Analysis and Risk-Based Preventive Controls
 - Each facility would be required to implement a written food safety plan that focuses on preventing hazards in foods
 - Hazard Analysis & Preventive Controls
 - Monitoring
 - Corrective Actions
 - Verification
 - Record Keeping
- Updated Good Manufacturing Practices



FDA Proposed Preventive Controls

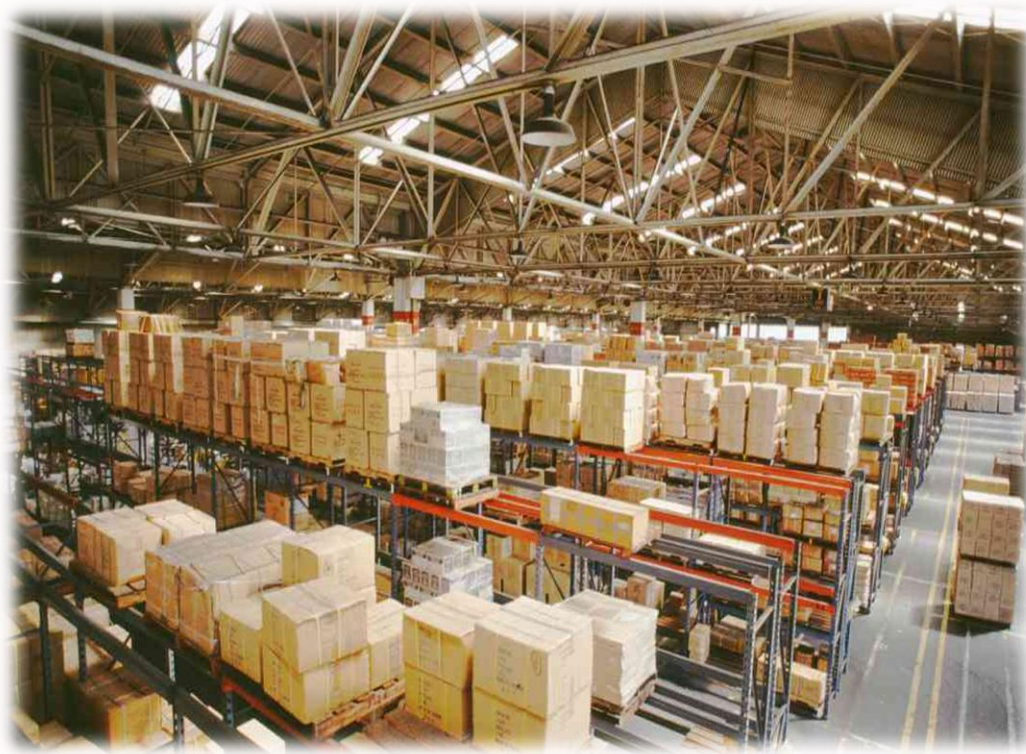
Who is Covered

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

Applies to domestic and imported food

Some exemptions and modified requirements are being proposed



FDA Proposed Preventive Controls

Preventive Controls Required

- Process controls
- Food allergen controls
- Sanitation controls
- Recall plan



In addition, seeking comment on supplier approval and verification program.



FDA Proposed Preventive Controls

Verification Required

- Validation
- Calibration
- Review of records



In addition, FDA is seeking comment on review of complaints, finished product and environmental testing.



FDA Proposed Preventive Controls

Updated Good Manufacturing Practices

- Protection against allergen cross-contact
- Updated language; certain provisions containing recommendations would be deleted
- Comments requested on mandating training and whether rule should require, rather than recommend, certain provisions



CGMPs would still apply to exempt facilities!!



FDA Proposed Preventive Controls

Exemptions and Modified Requirements

“Qualified” facilities:

- Very small businesses (3 definitions being proposed—less than \$250,000, less than \$500,000 and less than \$1 million in total annual sales)
- OR**
- Food sales averaging less than \$500,000 per year during the last three years AND
 - Sales to qualified end users must exceed sales to others



FDA Proposed Preventive Controls

Exemptions and Modified Requirements

- Foods subject to low-acid canned food regulations (microbiological hazards only)
- Foods subject to HACCP (seafood and juice)
- Dietary supplements
- Alcoholic beverages



FDA Proposed Preventive Controls

Exemptions and Modified Requirements

Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment

Certain storage facilities such as grain elevators that store only raw agricultural commodities intended for further distribution or processing

Facilities that are subject to the Proposed Produce Rule



FDA Proposed Preventive Controls

Farm Related Exemptions

Activities within the definition of “farm,” including farm activities that are covered by the proposed produce rule

Certain low-risk manufacturing/processing, packing and holding activities conducted by small/very small businesses on farms for specific foods



FDA Proposed Preventive Controls

Effective and Compliance Dates

Effective Date: 60 days after the final rule is published

Compliance Dates:

- **Small Businesses**—a business employing fewer than 500 persons would have two years after publication.
- **Very Small Businesses**—a business having less than \$250,000 (or alternatively \$500,000 or \$1 million) in total annual sales of food would have three years after publication to comply.
 - Very small businesses are considered “qualified” facilities and subject to modified requirements
- **Other Businesses**—a business that does not qualify for exemptions would have one year after publication of the final rule to comply.



FDA Food Safety Rules

How to Comment on the Proposed Rules

www.regulations.gov



Link to rules on

www.fda.gov/fsma

Comment period is

120 days:

May 16th, 2013



FDA FSMA & Proposed Rules

Conclusion

- Organic systems rely on preventative practices so we are already ahead of the curve
- The organic sector continues to be scrutinized for being at high-risk for food safety issues
- We must support and ensure food safety in all organic systems
- We must stay **engaged in the rulemaking process** and ensure that requirements do not duplicate, conflict or put undue burden on organic operations



On-farm Food Safety Resources

Will you be ready?



WSDA Bridging the GAP

- <http://agr.wa.gov/inspection/GAPGHP/>
 - University of Minnesota SOP Templates
 - Cornell University Online GAPs Produce Safety Course
 - On-Farm Food Safety Project
 - Create a customized food safety plan!

Community Alliance With Family Farmers (GAPs)

- <http://caff.org/programs/foodsafety/gaps/>



Web Resources

Additional Information on Topics



Thank You



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