



# Food Safety Modernization Act

## The Rules

Create a New Food Safety System Based on  
Prevention From Farm to Table

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## Final Rules

- Preventive Controls for Human Food
- Preventive Controls for Food for Animals
  - Establishes GMPs for Animal Food Production
  - Feed mills associated with farms not covered if raising animals and the feed mill are under the same management
- Standards for Produce Safety
- Foreign Supplier Verification Program for Importers of Food for Humans and Animals
  - Program that Importers must have in place to Verify that their Foreign Suppliers are Producing Food in a manner that provides the same level of Public Health Protection as the Preventive Controls and Produce Safety Regulations
- Accredited-Third Party Certification
  - Voluntary Program for the Accreditation of third party certification bodies to conduct food safety audits and issue certifications of foreign facilities and the foods they produce for humans and animals

## Proposed Rules

- Sanitary Transportation of Human and Animal Food
  - Prevent practices that create food safety risks such as failure to refrigerate; inadequate cleaning between loads; failure to protect food during transport
- Focused Mitigation Strategies to Protect Food against Intentional Adulteration
  - Requires domestic and foreign facilities to address vulnerable processes in their operations to prevent acts on the food supply intended to cause large-scale public harm

## Produce Rule

- Exemptions
  - Produce that is not a raw agricultural commodity
  - Produce that is rarely consumed raw
  - Food grains
  - Farms that have an average annual value of produce sold during the previous three years of \$25,000 or less
  - Qualified Exemption (Modified requirements; can be withdrawn)
    - Food Sales averaging less than \$500,000
    - Sales to consumer of the food; restaurants and retailers in the same state or not more than 275 miles away must exceed sales to all others combined

**U.S. FOOD & DRUG ADMINISTRATION**

**STANDARDS FOR PRODUCE SAFETY**  
Coverage and Exemptions/Exclusions for 21 PART 112

The Preventive Controls for Human Food rule clarified the definition of a farm to cover two types of farm operations: primary production farms and secondary activities farms. The same definition is used in the Produce Safety rule (section 112.3(a)). Below are basic criteria that determine whether an operation that meets the definition of "farm" is subject to the produce rule.

Does your farm grow, harvest, pack or hold produce? (Section 112.3(a))	NO X	Your farm is NOT covered by this rule.
YES		
Does your farm on average in the previous three years have \$25K or less in annual produce sales? (Section 112.3(a))	YES X	Your farm is NOT covered by this rule.
NO		
Is your produce one of the commodities that FDA has identified as rarely consumed raw? (Section 112.3(a)(1)) If you grow, harvest, pack or hold more than one produce commodity, you must ask this question separately for each one to determine whether that particular produce commodity is covered by this rule.	YES X	This product is NOT covered by this rule.
NO		
Is your produce for personal/farm consumption? (Section 112.3(a)(2))	YES X	This produce is NOT covered by this rule.
NO		
Is your produce intended for commercial processing (i.e., for substantially reducing pathogens for export, commercial processing with a "kill step")?	YES X	This produce is eligible for exemption from the rule, which means that you must comply with certain minimum food safety practices, as per Sections 112.3(a)(3) through 112.3(a)(4).
NO		
Does your farm on average in the previous three years (as per Section 112.3) have: - \$500K annual food sales, AND - a majority of the food (by value) sold directly to "qualified end-users"? (Section 112.3(a)) "Qualified end-user" as defined in Section 112.3(a) means: - the consumer of the food OR - a restaurant or retail food establishment that is located-- (i) in the same State or the same Indian reservation as the farm that produced the food OR (ii) not more than 275 miles from such farm. (The term "consumer" does not include a business.)	YES C	Your farm is eligible for a qualified exemption from this rule, which means that you must comply with certain minimum food safety practices, as per Sections 112.3(a)(3) and 112.3(a)(4).
NO		
<b>YOU ARE COVERED BY THIS RULE.</b>		

## Key Requirements

- Agricultural Water
  - Microbially safe for washing hands; food-contact surfaces; directly contacting produce during and after harvest; sprout irrigation
  - Irrigation water – generally the recreational standard 126 or less of generic E. coli
  - Corrective actions required for water not meeting the microbial criteria
  - Testing of water required

## Key Requirements

- Biological Soil Amendments
  - Raw Manure
    - FDA conducting a risk assessment
    - Currently application at least 120 days prior to harvest for crops that touch the soil; 90 days prior to harvest not in contact with the soil
  - Stabilized Compost
    - Scientifically valid composting used to treat biological soil amendments
    - Applied in a manner that minimizes contact with produce during and after application

## Key Requirements

- Sprouts
  - Measures to prevent the introduction of pathogens into or onto seeds or beans
  - Testing of spent sprout irrigation water or in process-sprouts from each production batch
  - Testing the growing, harvesting, packing and holding environment for *Listeria*
  - Taking corrective actions for positive samples

## Key Requirements

- Worker Training and Health and Hygiene
  - Prevent contamination by ill or infected persons
  - Hygienic practices
  - Measures to prevent visitors from contaminating cover produce or food contact surfaces
  - Worker Training

## Key Requirements

- Equipment, Tools and Buildings
  - Appropriate storage, maintenance and cleaning of equipment and tools
  - Covers greenhouses, germination chambers, toilet and hand-washing facilities, packing equipment, harvest tools and baskets, packing sheds

## The Good News

- Produce Rule Requirements are consistent with the MDA GAP/GHP and USDA GAP/GHP programs
  - Water Quality – number of tests required are more than required for GAP/GHP – same standards
- MDA and UMD have worked together since 2009 to provide resources to assist farmers implementing GAP and GHP practices
  - Four to five regional training sessions per year
    - Basic and Advanced courses
  - MDA GAP program
  - Specialty Crop funded position at UMD to work one to one with farmers to implement GAP/GHP
  - Produce Rule requires specific training approved by FDA through the Produce Safety Alliance
    - UMD educators have already taken the required Produce Safety Alliance Train the Trainer course
    - Three to four FSMA sessions will be held in 2016