

# Produce Safety Rule

Standards for the Growing, Harvesting, Packing and Holding of Produce  
for Human Consumption

**- Dr. Mauricio Castelo-**

**Expert in produce safety at FDA**



# Seven Foundational Rules

## Food Safety Modernization Act (FSMA)

- 1) Foreign Supplier Verification Programs
- 2) **Produce Safety Rule**
- 3) Preventive Controls for Human Food
- 4) Preventive Controls for Animal Food
- 5) Accredited Third-Party Certification
- 6) Intentional Adulteration
- 7) Sanitary Transportation of Food

# Produce Safety Rule

- Brief introduction to the Produce Safety Rule.
- Standards for the Growing, Harvesting, Packing and Holding of Fresh Produce.
- Resources available for implementing and complying with the produce safety rule.
- Identify and offer seminars and workshops geared towards the needs of the region and particularly towards producers within the region.



# Produce Safety Rule

- Standards for the Growing, Harvesting, Packing and Holding of Fresh Produce for human consumption.
- Science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables
- Focuses on biological hazards related to growing, harvesting, packing and holding produce
- If you are a covered farm, you must comply with the PSR

# Produce Safety Rule

## Why is produce safety important?

- Fresh produce is often consumed raw (i.e. uncooked)
- Microbial contamination on produce is extremely difficult to remove once present
- Outbreaks associated with fresh produce



# Compliance dates with the Produce Safety Rule

**VERY SMALL - US\$ 25,000 < SALES < US\$ 250,000**

2017	2018	2019	January 27, 2020	2020, 2021, 2022, 2023	January, 2024
<b>EXCEPT WATER</b>				<b>WATER*</b>	

**SMALL - US\$ 250,000 < SALES < US\$ 500,000**

2017	2018	January 28, 2019	2019, 2020, 2021, 2022	January, 2023
<b>EXCEPT WATER</b>			<b>WATER*</b>	

**LARGE - SALES > US\$ 500,000**

2017	January 26, 2018	2018, 2019, 2020, 2021	January, 2022
<b>EXCEPT WATER</b>		<b>WATER*</b>	

# Standards for the Produce Safety Rule



- Subpart A (§112.1-112.7): General provisions
- Subpart C (§112.21-112.30): Personnel Qualifications and Training
- Subpart D (§112.31-112.33): Health and Hygiene
- Subpart E (§112.41-112.50): Agricultural Water
- Subpart F (§112.51-112.60): Biological Soil Amendments of Animal Origin and Human Waste
- Subpart I (§112.81-112.84): Domesticated and Wild Animals
- Subpart K (§112.111-112.116): Growing, Harvesting, Packing and Holding Activities
- Subpart L (§112.121-112.140): Equipment, Tools, Buildings and Sanitation
- Subpart O (§112.161-112.167): Records



# Subpart A: General Provisions

## Are you covered by the Rule?

### 1) Covered Farm

- Farms with primary production and secondary activities
- Does not cover farms that have an average annual value of produce sold during the previous three-year period of \$25,000 or less (inflation adjusted)
- Farms eligible for Qualified Exemption, complying with modified requirements if:
  - » Food sales averaging less than \$500,000 per year during the previous three years (inflation adjusted); and
  - » Sales to qualified end-users exceeds sales to all others combined during the previous three years





# Subpart A: General Provisions

## Are you covered by the Rule?

### 2) Covered Produce

- Raw Agricultural Commodity
- Does not cover:
  - » Produce that is rarely consumed raw
  - » For personal consumption or consumption on the farm
  - » Produce eligible for exemption as a result of commercial processing that adequately reduces the presence of microorganisms of public health significance

### 3) Covered Activity

- Growing covered produce
- Harvesting covered produce
- Packing covered produce
- Holding covered produce, or
- Any combination of these activities.

# Subpart C: Personnel Qualifications and Training



1. Assessment of the assigned personnel functions
2. Qualifications required for carrying out assigned functions
3. Frequency of training
4. Easily understood training
5. Minimum training requirements
6. Additional training for persons involved in harvest activities
7. Training in Food Safety for Supervisors or other responsible party
8. Training Records

# Subpart D: Health and Hygiene

1. Measures to prevent ill or infected persons from contaminating covered produce
2. Hygiene practices
3. Measures to prevent visitors from contaminating covered produce or food contact surfaces



# Subpart E: Agricultural Water



- FDA issued a final rule that extends, for covered products that are not sprouts, the dates for compliance with the provisions for agricultural water:
  - - Very small companies: 26 January 2024
    - Small companies: 26 January 2023
    - All other businesses: 26 January 2022
- We do not expect the growers that are not sprouts to implement Subpart E until the new compliance dates.

# Subpart F: Biological Soil Amendments of Animal Origin (BSAAO)



1. Determine if your Biological Soil Amendment is a BSAAO
2. Determine if your BSAAO is "Treated" or "Untreated"
3. Determine the correct treatment process and the associated microbial standard for your treated BSAAO
4. Determine how to apply your BSAAO
5. Determine the requirements for handling, transporting and holding your BSAAO
6. Determine what records to keep for preserving your treated BSAAO

# Subpart I: Domesticated and Wild Animals

1. Determine the reasonable probability that animals will contaminate covered produce
2. Assessment of the relevant areas for evidence of possible contamination of produce
3. Assess the significant evidence of possible contamination of the covered produce by animals to determine if they can be harvested.

# Subpart K: : Growing, harvesting, packing and holding activities



1. Separation of covered and excluded produce
2. Identify but do not harvest covered produce that is contaminated
3. Handling harvested covered produce
4. Dropped covered produce
5. Packaging covered produce
6. Food packing materials

# Subpart L: Equipment, Tools, Buildings and Sanitation



1. Equipment and tools
2. Buildings
3. Cleaning and sanitation
4. Other sanitation measures
5. Records



# Subpart O: Records



1. General requirements for all records
2. Storage of records
3. Use of existing records
4. Record keeping
5. Format for records
6. Disclosure of records
7. Specific requirements for records

# GENERAL OVERVIEW: FDA RULE AND GUIDANCE CONTENT

FDA Rule		FDA Guidance
Codified	Preamble	
<b>Specifies minimum and legally-binding requirements, often includes the word "must"</b>	<b>Provides rationale for the provisions in the codified</b>	<b>Provides non binding recommendations, often indicated by the word "should" or "recommends".</b>
<b>Provides Definitions of terms</b>	<b>Describes FDA's thinking as the agency developed the rule</b>	<b>Describes FDA's current thinking</b>
	<b>Responds to stakeholders comments</b>	<b>Provides examples</b>



# Resources for the Rule

- FDA Produce Safety Draft Guidance Webpage:
  - Draft Produce Safety Guidance for Industry <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm606284.htm>
  - Link to the Federal Registration Notice
  - Links to the Produce Safety Rule
- Fact sheets: <https://www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm>
  - Rarely consumed raw Produce
  - Training Required for Covered Farms
- FDA in Spanish: <https://www.fda.gov/aboutfda/enespanol/default.htm#food>
- Technical Assistance Network (TAN)
  - Visit [www.fda.gov/fsma](http://www.fda.gov/fsma) and select “[Contact Us](#)”



# Resources for the Rule

- 1) [Draft Guidance for the Fresh Produce Safety Rule](#)
- 2) [FDA Technical Assistance Sheet: Fresh Produce 'Rarely Consumed Raw'](#)
- 3) [FDA Technical Assistance Sheet: Dropped Covered Produce](#)
- 4) [FDA Technical Assistance Sheet: Cyclosporiasis and Fresh Produce](#)
- 5) [FDA Technical Assistance Sheet: Training Required for a Covered Garden](#)
- 6) [FDA Technical Assistance Sheet: Biological Soil Amendments of Animal Origin](#)

# Resources for the Rule



- 7) [FDA Technical Assistance Sheet: Methodology for Equivalent Tests for Agricultural Water](#)
- 8) [FDA: What to expect from a Regulatory Inspection](#)
- 9) [Flow Chart of Coverage and Exemptions/Exclusion for Title 21 Section 112](#)
- 10) [Codified Text of the Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption](#)
- 11) [FDA Website “for industry”](#)
- 12) [FDA FSMA Technical Assistance Network \(in English\)](#)



# Implementation of the Rule

- 1) Education
- 2) Understanding potential Sources of Contamination on your Farm
- 3) Implementation of Practices
- 4) Monitoring Practices
- 5) Records

# What is the next step?

- Questions and Answers
- Identify and offer seminars and workshops geared towards the needs of the region and specifically towards covered produce

# Standards-Specific Seminars relating to the Rule



- Subpart A: General Provisions
- Subpart B: General Requirements
- Subpart C: Personnel Qualifications and Training
- Subpart D: Health and Hygiene
- Subpart E: Agricultural Water
- Subpart F: Biological Soil Amendments of Animal Origin and human waste
- Subpart I: Domesticated and Wild Animals
- Subpart K: Growing, Harvesting, Packing and Holding activities
- Subpart L: Equipment, Tools, Buildings and Sanitation
- Subpart O: Records
- Subpart P: Variances



## **Produce Safety Workshops:**

- 1) Workshop on Biological Soil Amendments of Animal Origin (BSAAO)
- 2) Workshop on Cleaning and Sanitation
- 3) Workshop on Agricultural Water

# Workshop on Biological Amendments

## (BSAAO)



### Purpose and Objectives

- Learn about the regulatory framework for Biological Soil Amendments of Animal Origin and the basics of composting,
- Learn about the underlying microbiology of composting and biosolids;
- Learn about FDA’s inspectional approach for BSAAOs and state-specific considerations for BSAAOs
- Learn about the current status of the BSAAO Risk Assessment; and
- Conduct Virtual “hands-on” activities, including a virtual composting activity and a virtual farm visit

## Purpose and Objectives

To understand:

- Applicable PSR requirements;
- Food safety risks associated with farm equipment, buildings and tools;
- the difference between and importance of cleaning and sanitizing;
- factors that influence efficacy of cleaning/sanitizing;
- Procedures (SSOPs) to manage identified risks;
- Importance of and options for verification activities.

## Aims/Objectives

- Determine the risks associated with different sources of water and distribution systems.
- Assess the water distribution equipment that can be used to protect the water on the farm.
- Demonstrate how to assess the sources of water and the water distribution system for possible health risks.
- Understand how to aseptically take a sample of water.
- Review the results of the water analysis to determine what corrective action to take.
- Distinguish between the water treatment methods, equipment required and the necessary disinfectants available for use.
- Assess the adequate resources and possible solutions for water quality on the farm.



# FSMA Proposed Rule for Food Traceability

- Applies to persons who manufacture, process, pack or hold foods on the [Food Traceability List](#) (FTL)
  - FTL includes: cucumbers, fresh herbs, leafy greens, melons, peppers, sprouts, tomatoes, tropical tree fruits, fresh-cut fruits and vegetables
  - FTL includes foods specifically listed and foods that contain listed foods as ingredients
- Some exemptions
  - For example: Annual produce sales no more than \$25,000 adjusted for inflation; produce on the RCR list; farms selling food directly to consumers; others...
- Includes entities throughout the supply chain: from farms and manufacturers, through distributors and wholesalers, to retail food establishments
- Includes domestic and foreign entities
- Public comment period extended to February 22, 2021
- For more information see:
  - [FDA Proposed Traceability Rule](#)
  - [Who is subject to the rule?](#)
  - [Exemptions At-A-Glance](#)
  - [Recently released FAQs](#)

# FSMA Proposed Food Traceability Rule

- Applies to persons who manufacture, process, pack or hold foods on the Food Traceability List (FTL)
  - FTL includes cucumbers, fresh herbs, leafy greens, melons, peppers, sprouts, tomatoes, tropical tree fruits, fresh-cut fruits and vegetables
  - FTL includes foods specifically listed and foods that contain listed foods as ingredients
- Some exemptions
  - For example: Annual produce sales no more than \$25,000 adjusted for inflation; produce on the RCR list; farms selling food directly to consumers; others....
- Includes entities throughout the supply chain: from farms and manufacturers, through distributors and wholesalers, to retail food establishments
- Includes domestic and foreign entities
- Public comment period extended to February 22, 2021
- For more information, consult:
  - [FDA Proposed Traceability Rule](#)
  - [Who is subject to the rule?](#)
  - [Exemptions At-A-Glance](#)
  - [Recently released FAQs](#)



## FDA's Division of Produce Safety

- Produce Safety Network Mailbox in Spanish: [ProduceSafetyNetworkEnEspanol@fda.hhs.gov](mailto:ProduceSafetyNetworkEnEspanol@fda.hhs.gov)



Thank you!

Dr. Mauricio Castelo

CFSAN-PSN

FDA-DPS

[Mauricio.Castelo@fda.hhs.gov](mailto:Mauricio.Castelo@fda.hhs.gov)

[ProduceSafetyNetworkEnEspañol@fda.hhs.gov](mailto:ProduceSafetyNetworkEnEspañol@fda.hhs.gov)