

# **Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Draft Guidance for Industry**

Overview

# Food Safety Modernization Act (FSMA)

## Implementation for Produce



- 2011: FSMA passed into law
- 2013: Proposed Produce Safety Rule published
- 2014: Supplemental Notice
- 2015: Final Produce Safety Rule published
  - Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
- 2018: Draft Compliance and Implementation Guidance for Industry released
  - Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry

# Draft Produce Safety Guidance for Industry

- Topics covered:
  - Chapter 1: General Provisions (Subpart A)
  - Chapter 2: Personnel Qualifications and Training (Subpart C)
  - Chapter 3: Health and Hygiene (Subpart D)
  - Chapter 4: Biological Soil Amendments of Animal Origin and Human Waste (Subpart F)
  - Chapter 5: Domesticated and Wild Animals (Subpart I)
  - Chapter 6: Growing, Harvesting, Packing and Holding Activities (Subpart K)
  - Chapter 7: Equipment, Tools, Buildings and Sanitation (Subpart L)
  - Chapter 8: Records (Subpart O)
  - Chapter 9: Variances (Subpart P)

**GENERAL OVERVIEW:**  
**FDA RULE AND GUIDANCE CONTENT**

**FDA Rule**

**FDA  
Guidance**

**Codified**

**Preamble**

Specifies minimum, legally-binding requirements, often includes the word "must"

Provides rationale for the provisions in the codified

Provides non-binding recommendations, often indicated by the word "should" or "recommend"

Provides definitions of terms

Describes FDA's thinking as the agency developed the rule

Describes FDA's current thinking

Responds to stakeholder comments

Provides examples

# Overall Approach: Background and Introduction



- Overall Approach
- Background and Introduction
  - Provides our current thinking, recommendations, and examples
    - We cannot, nor have we attempted to, describe every possible scenario
  - Intended to help the owner, operator or agent in charge of a covered farm comply with the requirements of the Produce Safety Rule

# Overall Approach: Chapters



- Help you develop procedures, processes and practices to meet the requirements in a way that best fits your operation
  - Evaluate specific aspects of your operation
- Summarize key recommendations
- Account for changes that occur over time and infrequent practices
- Examples

# Additional Resources



- FDA Produce Safety Draft Guidance Webpage: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm606284.htm>
  - Draft Produce Safety Guidance for Industry
  - Link to the Federal Register Notice
  - At-A-Glance Overviews and Glossary
  - Links to the Produce Safety Rule
- Factsheets: <https://www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm>
  - Rarely Consumed Raw Produce
  - Biological Soil Amendments of Animal Origin
- Technical Assistance Network (TAN)
  - Visit [www.fda.gov/fsma](http://www.fda.gov/fsma) and go to “Contact Us”
- Produce Safety Network

# Recent Produce Guidance and Draft Guidance



- Guidance for Industry: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: What You Need To Know About The FDA Regulation – Small Entity Compliance Guide
- Draft Guidance for Industry: Compliance with the Recommendations for Implementation of the Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprouts
- Draft Guidance for Industry: Guide to Minimize Food Safety Hazards of Fresh-cut Produce





# Next Steps:

## Draft Produce Safety Guidance for Industry

- Public Meetings
- Comment Submission
  - Encouraged to submit comments by April 22, 2019
  - Federal Register Notice - see Background section for questions that we seek specific comments, information or data:
    - <https://www.federalregister.gov/documents/2018/10/22/2018-23006/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption-draft>
  - Go to [www.regulations.gov](http://www.regulations.gov) and enter Docket Number: FDA-2018-D-3631; or
  - Go to [https://www.regulations.gov/document?D=FDA\\_FRDOC\\_0001-8821](https://www.regulations.gov/document?D=FDA_FRDOC_0001-8821)
- Updates to the Produce Safety Guidance for Industry

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