Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Draft Guidance for Industry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

<table>
<thead>
<tr>
<th>FDA Rule</th>
<th>FDA Guidance</th>
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**Generic Example:**

- **Codified:** Specifies minimum, legally-binding requirements, often includes the word “must”
- **Preamble:** Provides rationale for the provisions in the codified
- **FDA Guidance:** Provides non-binding recommendations, often indicated by the word “should” or “recommend”
- **FDA Rule:**
  - Provides definitions of terms
  - Describes FDA’s thinking as the agency developed the rule
  - Responds to stakeholder comments

**FDA Guidance**

- 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 and go to “Contact Us”

• Produce Safety Network
Recent Produce Guidance and Draft Guidance


- 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:
    – Go to [www.regulations.gov](http://www.regulations.gov) and enter Docket Number: FDA-2018-D-3631; or
• Updates to the Produce Safety Guidance for Industry
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption:
Draft Guidance for Industry:
Overview