

Citrus Food Safety Workshop
Visalia Convention Center
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Good Manufacturing Practices

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What are GMPs?

Applicability of GMPs

The Importance of GMPs



Code of Federal Regulations

Good Manufacturing Practices (GMPs) are basic sanitary and processing requirements for producing safe and wholesome food

- Under **Title 21 of the Code of Federal Regulations (21 CFR)**, they describe the methods, equipment, facilities, and controls for processing and handling food.
- They are an important part of regulatory control over the safety of the nation's food supply. They serve as one basis for **FDA inspections**.

Pure Food
and Drug Act

• 1906

Federal Food,
Drugs, and
Cosmetics Act

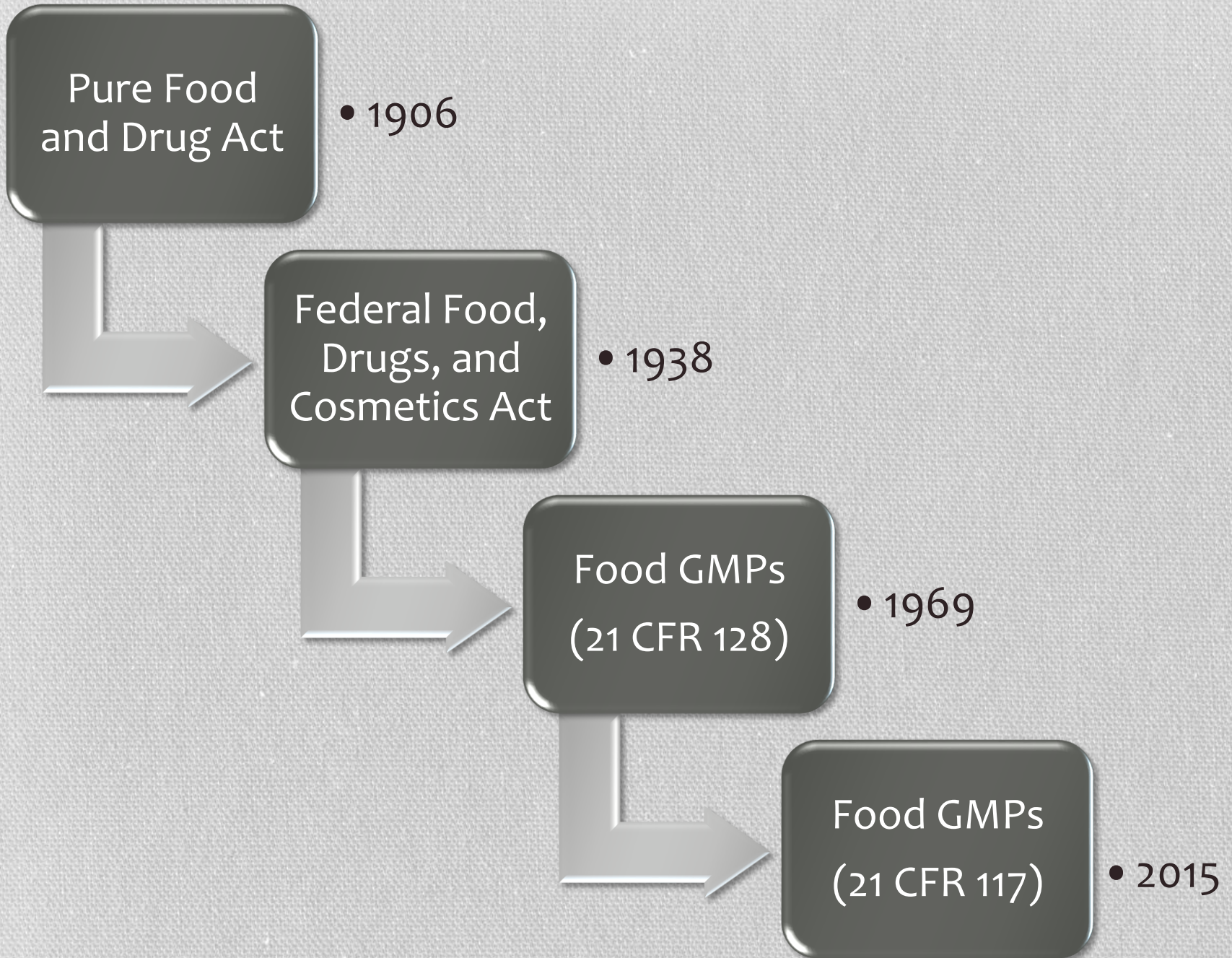
• 1938

Food GMPs
(21 CFR 128)

• 1969

Food GMPs
(21 CFR 117)

• 2015



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and Drug Act

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Enacted by Congress, the PFDA marked the **1st major federal consumer protection law with respect to food processing**

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(21 CFR 117)

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Section 402 (a) (1) “A food shall be deemed to be **adulterated** if it bears or contains any poisonous or deleterious substance which may render it injurious to health ...”

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Section 402 (a) (1) “A food shall be deemed to be **adulterated** if it bears or contains any poisonous or deleterious substance which may render it injurious to health ...”

Food GMPs

The FDCA provides the regulatory basis for today's food GMPs. Section 402 (a)(4) of the Act considers that **food may be adulterated if it is prepared, packed, or held under insanitary conditions** whereby it may have become contaminated with filth or rendered injurious to health

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Food GMPs
(21 CFR 128)

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Food GMPs
(21 CFR 117)

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They were initially published as **Part 128** of the Code of Federal Regulations (CFR). In 1977, Part 128 was re-codified and published as **Part 110** of the CFR

Pure Food and Drug Act

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By 1986, in addition to the **umbrella GMPs** (Part 110), **industry-specific GMPs** were included in 21 CFR for infant formula (Part 106), thermally processed low-acid canned foods (Part 113), acidified foods (Part 114), and bottled drinking water (Part 129)

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Food GMP
(21 CFR 128)

Under the **FSMA**, GMPs
previously contained in
the 21 CFR 110 were
updated to the new **21
CFR 117 Subpart B**

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Food GMP
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Under the **FSMA**, GMPs
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CFR 117 Subpart B**

GMPs are considered
the **foundation** (or a
prerequisite program)
of a food safety system

Food GMPs
(21 CFR 117)

• 2015



Code of Federal Regulations

21 CFR Part 117 - Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food

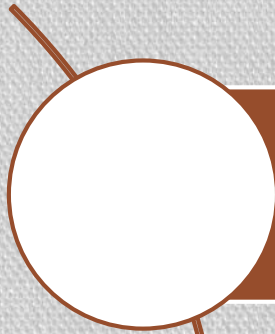
- Subpart A–General Provisions
- Subpart B–Current Good Manufacturing Practice
- Subpart C–Hazard Analysis and Risk-Based Preventive Controls
- Subpart D–Modified Requirements
- Subpart E–Withdrawal of a Qualified Facility Exemption
- Subpart F–Requirements Applying to Records That Must Be Established and Maintained
- Subpart G–Supply-Chain Program



Code of Federal Regulations

21 CFR Part 117 Subpart B - Current Good Manufacturing Practice

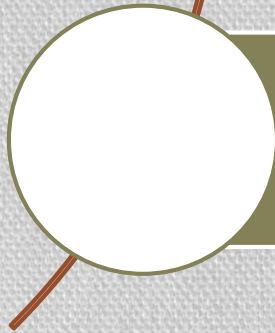
- Personnel.
- Plant and grounds.
- Sanitary operations.
- Sanitary facilities and controls.
- Equipment and utensils.
- Processes and controls.
- Warehousing and distribution.
- Holding and distribution of human food by-products for use as animal food.
- Defect action levels.



What are GMPs?



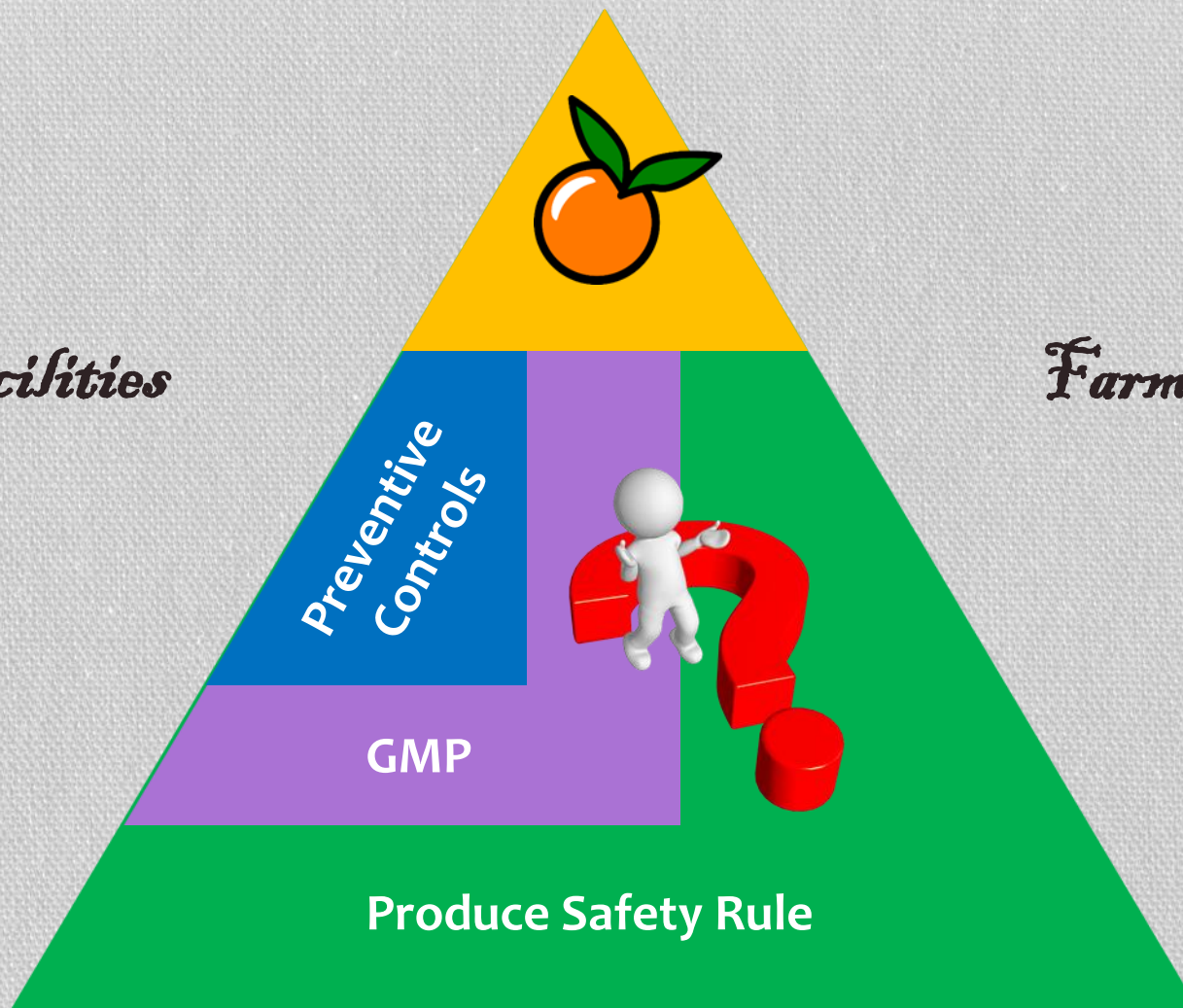
Applicability of GMPs

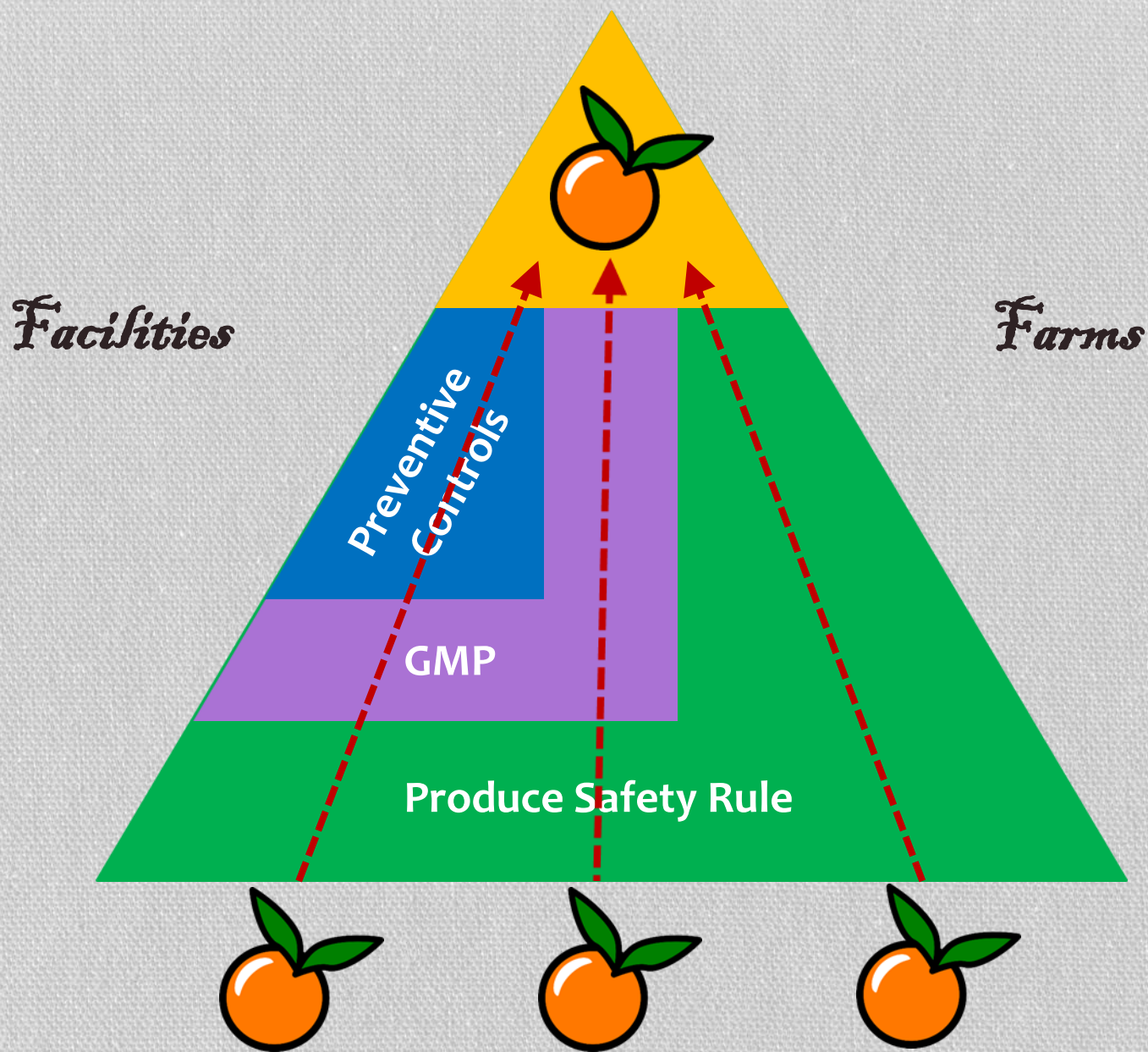


The Importance of GMPs

Facilities

Farms





Current GMPs under 21 CFR 117 Subpart B have the force of law for off-farm packing operations

- Not all packinghouses are considered the same under the FSMA
 - Packinghouses under the “**farm**” definition are regulated under the **Produce Safety Rule**.
 - Packinghouses that need to register as “**facility**” are subject to the **Preventive Controls Rule**.
- **GMPs** is a **prerequisite program** for developing an effective food safety system under the **Preventive Controls Rule**.

Preventive Food Safety Systems

Food Safety Plan

Including procedures for monitoring, corrective action and verification, as appropriate

Hazard Analysis

Recall Plan

Process Control

Supply-chain Program

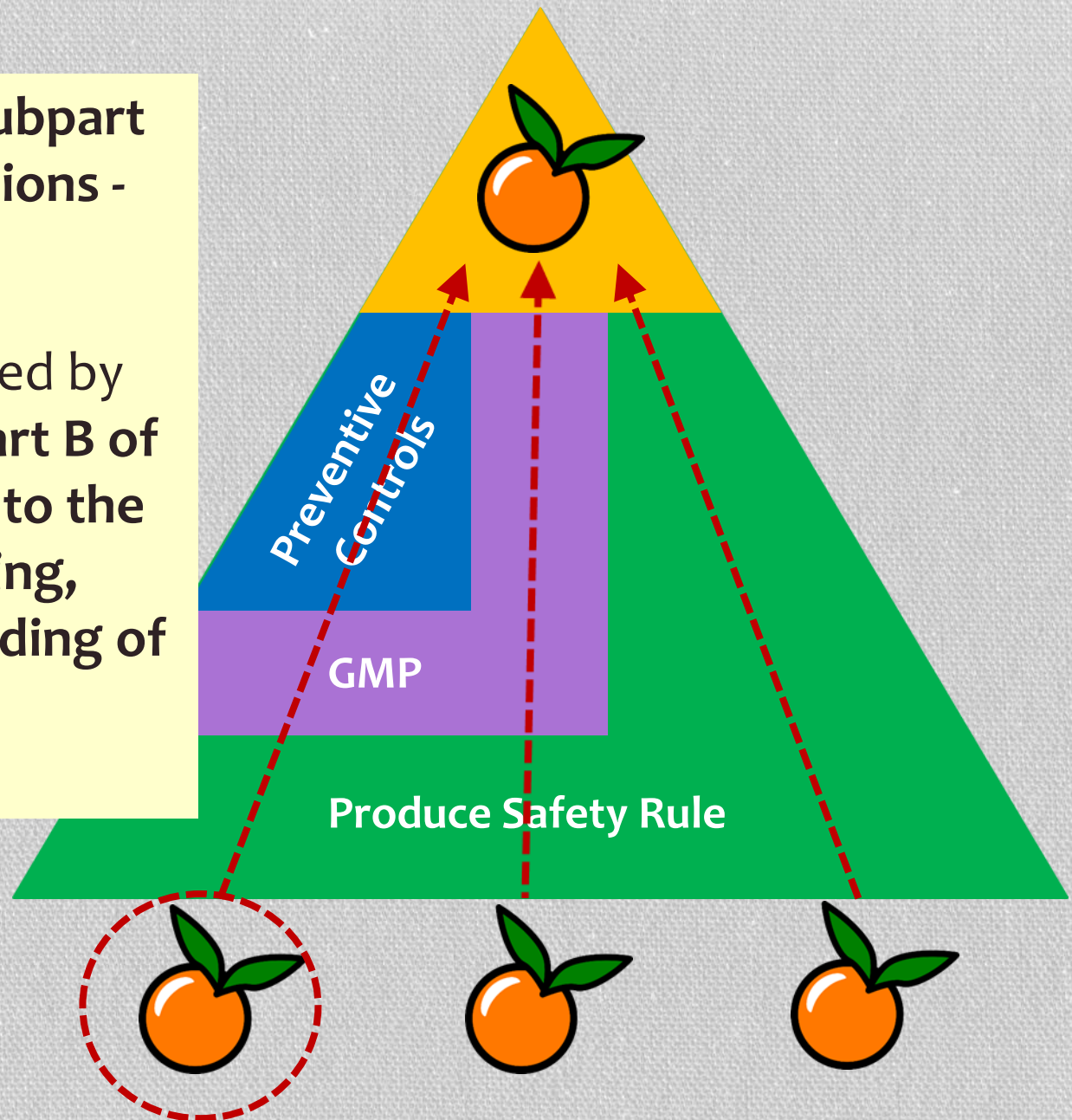
Allergen Control

Sanitation Control

GMPs and Other Prerequisite Programs

**21 CFR Part 117 Subpart
A General Provisions -
Sec. 117.8 :**

Except as provided by
117.5(k)(1), **subpart B** of
this part applies to the
off-farm packaging,
packing, and holding of
raw agricultural
commodities.



Current GMPs also are applicable to on-farm packing

- While harvest crews and on-farm packing and cooling operations are not subject to GMPs, provisions in the Produce Safety Rule are similar in nature and intent.
- In general terms, this statute mandates that food companies follow GMPs to assure the packing and processing environments are clean, and that no unacceptable substances enter the food product.

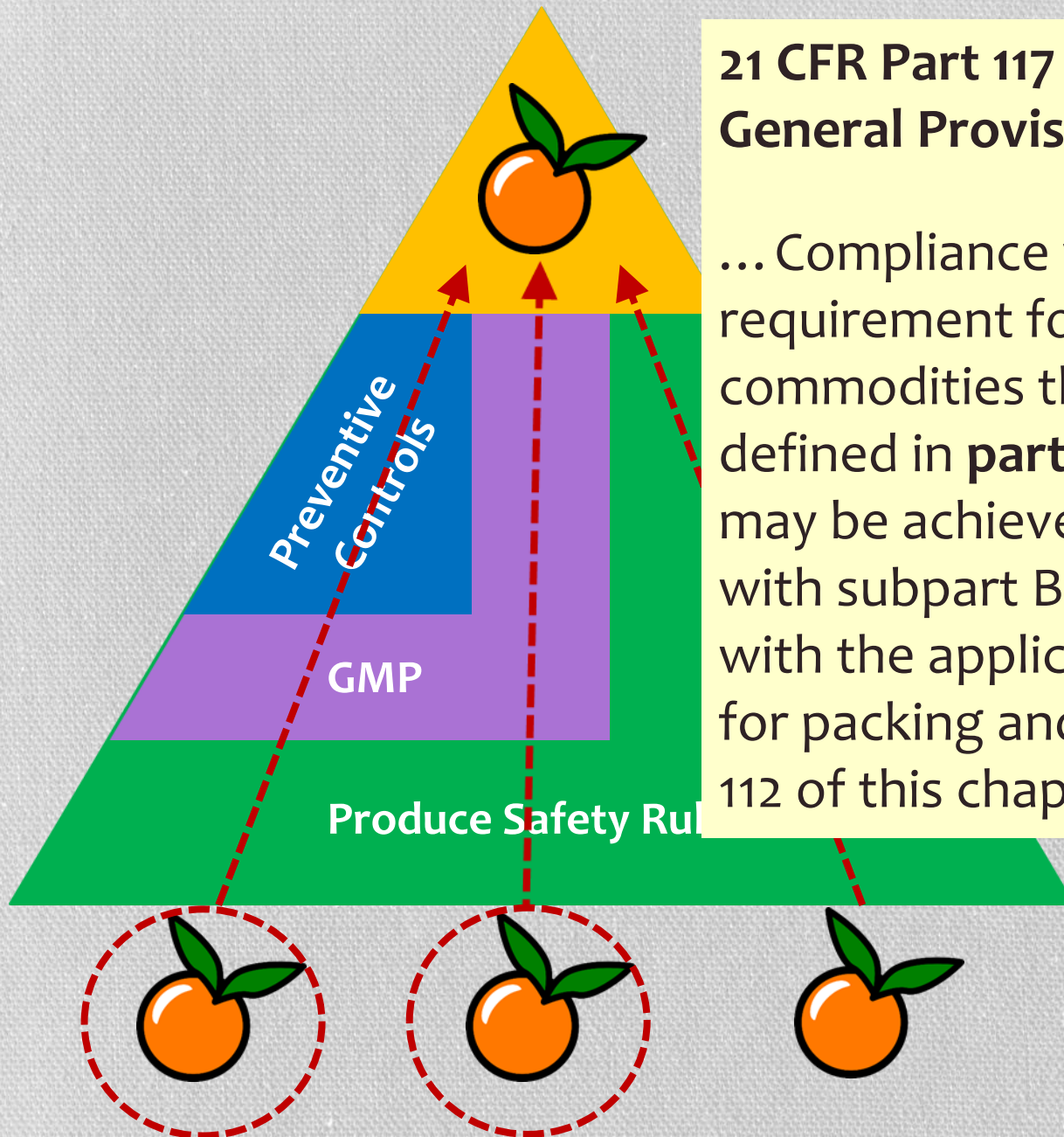


Current GMPs (Part 117)

- Personnel
- Plant and grounds
- Sanitary operations
- Sanitary facilities
- Equipment and utensils
- Processes and controls
- Warehousing and distribution
- Holding & distribution of human food by-products for use as animal food.
- Defect action levels

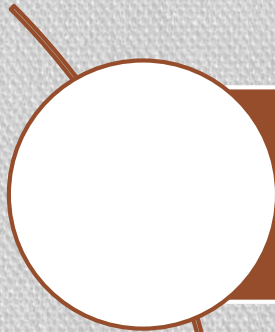
Produce Safety Rule (Part 112)

- Maintenance and sanitation processes
- Personal hygiene standards
- Water supply
- Pest control
- Plant design and construction
- Training

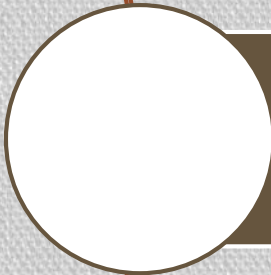


21 CFR Part 117 Subpart A General Provisions - Sec. 117.8 :

... Compliance with this requirement for raw agricultural commodities that are produce as defined in **part 112** of this chapter may be achieved by complying with subpart B of this part or with the applicable requirements for packing and holding in part 112 of this chapter



What are GMPs?



Applicability of GMPs



The Importance of GMPs

Recent examples of food safety issues

- Avocado recall (March 2019)
 - An avocado company recalled California-grown whole avocados due to *Listeria monocytogenes* concerns.
 - The recall was triggered by positive test results on **environmental samples** taken during a routine government inspection at its California **packing facility**.



<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/henry-avocado-recalls-whole-avocados-because-possible-health-risk#recall-photos>



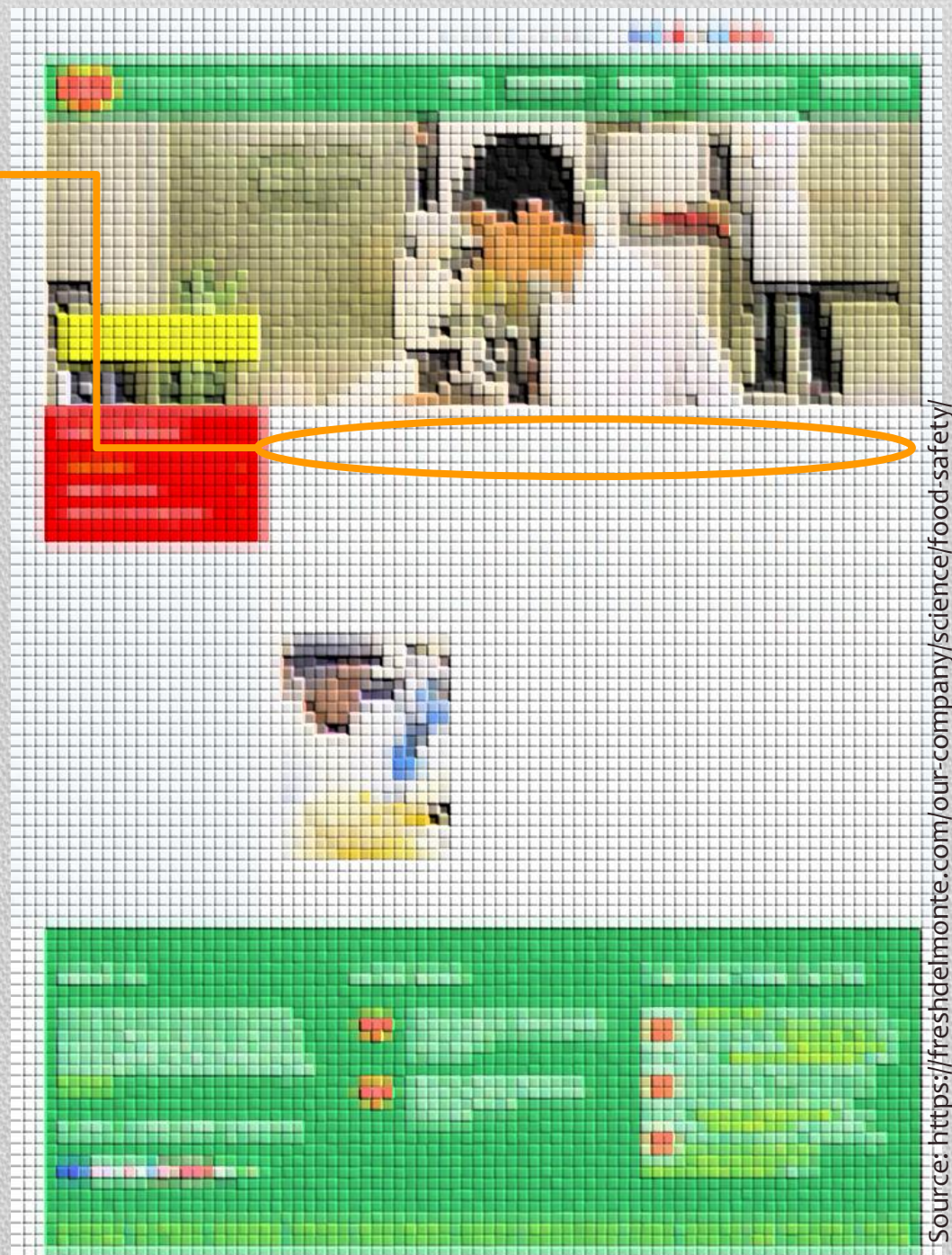
■ Stone fruit recall (January 2019)

- A fruit distributor recalled peaches, nectarines and plums shipped to retailers in 18 states due to potential *Listeria monocytogenes* contamination.
- The recall was the result of a routine sampling program by the **packinghouse** which revealed that the finished products (**packed fruits**) contained the bacteria.



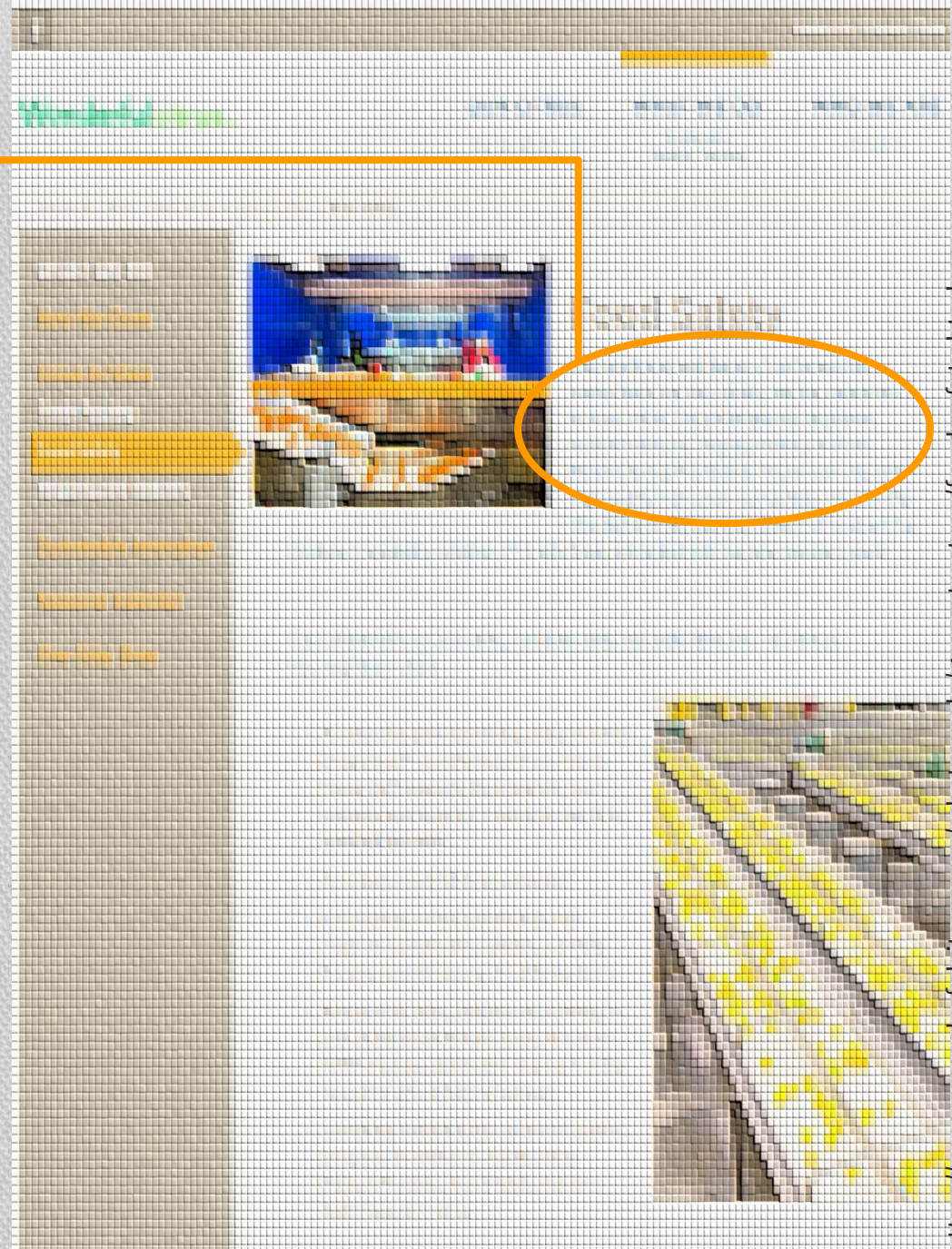
A produce company's webpage information

Significant efforts and resources go into maintaining food safety programs that include good agricultural and good manufacturing practices (GAPs and GMPs) in our farms, as well as SSOPs, environmental microbial testing and HACCP programs in our fresh cut plants.



A citrus company's webpage information

“The health and well-being of customers has always been our top priority. We are committed to food safety. Our **packinghouse** employees receive extensive, ongoing training in **Good Manufacturing Practices** to ensure that only safe, high-quality fruit leaves our facilities.”



USDA Fact Sheets - Food Safety Practices to Expect from Your Fresh Produce Distributor

School nutrition
operators should ensure
that fresh produce is
purchased from
reputable **suppliers** that
adhere to the Food and
Drug Administration's
(FDA) Current Good
Manufacturing Practices
(**cGMPs**).

USDA Food and Nutrition Service
U.S. DEPARTMENT OF AGRICULTURE

CONTACT US REPORT FRAUD ASK THE EXPERT USDA.GOV

HOME DATA & RESEARCH GRANTS NEWSROOM OUR AGENCY PROGRAMS

Produce Safety Fact Sheets

PROGRAMS > FOOD SAFETY > PRODUCE SAFETY > FACT SHEETS

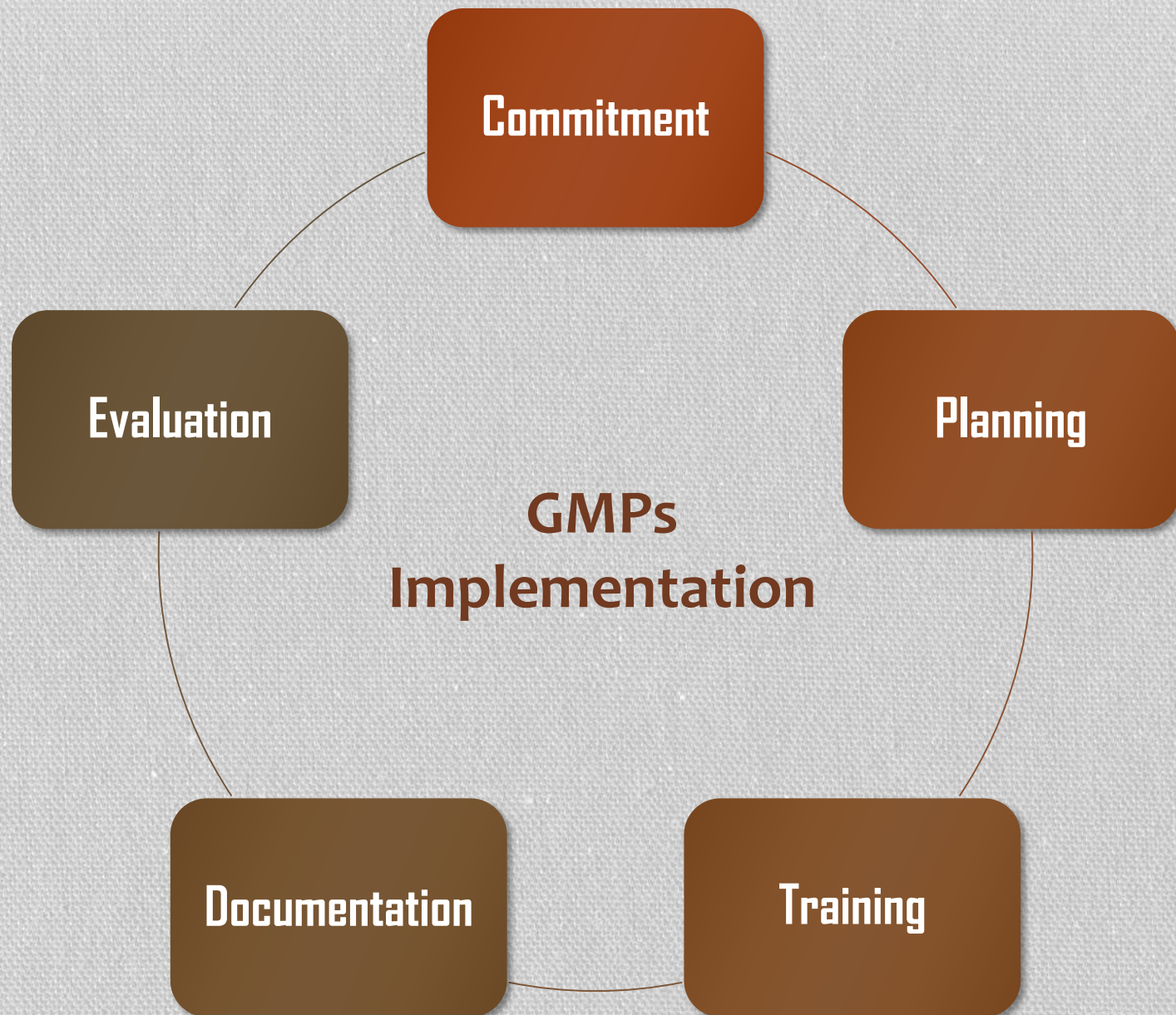
Resource Type
Technical Assistance

Use these resources to expand your knowledge about specific topics related to produce safety.

- [Storing Fresh Produce](#)
- [Conducting a Mock Recall of Produce in a School Nutrition Operation](#)
- [Preserving Locally Harvested Produce in School Meals](#)
- [Food Safety Practices to Expect from Your Fresh-Cut Produce Processor](#)
- [Take Advantage of Nature's Bounty: Consider Vacuum Seal](#)
- [Food Safety Practices to Expect from Your Fresh Produce Distributor](#)
- [Best Practices: Handling Fresh Produce in Schools](#)
- [Handling Fresh Produce in Classrooms](#)
- [Handling Fresh Produce on Salad Bars](#)
- [Verifying On-Farm Food Safety](#)
- [Ensuring Traceability of Fresh Produce](#)
- [Food Safety Tips for School Gardens](#)

12/02/2015

<https://www.fns.usda.gov/ofsp/produce-safety-fact-sheets>



Thank you!

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