Good Manufacturing Practices

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What are GMPs?

Applicability of GMPs

The Importance of GMPs
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
Enacted by Congress, the PFDA marked the 1st major federal consumer protection law with respect to food processing.
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 ...”
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.
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.
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). 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.
Under the **FSMA**, GMPs previously contained in the 21 CFR 110 were updated to the new 21 CFR 117 Subpart B.
GMPs are considered the **foundation** (or a **prerequisite** program) of a food safety system.
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
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.
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Produce Safety Rule

GMP

Farms

Facilities

Preventive Controls
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

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE
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.

https://www.pma.com/content/articles/2014/05/building-blocks-by-zagory
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<th>Current GMPs (Part 117)</th>
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<th>Produce Safety Rule (Part 112)</th>
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<td>• Maintenance and sanitation processes</td>
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<td>• Plant design and construction</td>
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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.
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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*.

[Link to recall information](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.

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.
“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.”
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).
Thank you!

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