Current Good Manufacturing Practices (CGMPs) for Food and Dietary Supplements

Following Current Good Manufacturing Practices (CGMPs) help to ensure the safety of food. CGMP regulations generally address matters including appropriate personal hygienic practices, design and construction of a food plant and maintenance of plant grounds, plant equipment, sanitary operations, facility sanitation, and production and process controls during the production of food.

In 1969, FDA established CGMPs in the Code of Federal Regulations (CFR) (21 CFR Part 110 (https://www.ecfr.gov/cgi-bin/text-idx?SID=2706d807d96ce5fe9a3e874e38ab459d&mc=true&node=pt21.2.110&rgn=div5)). In September 2015, the agency modernized the CGMPs and established them in new Part 117 (21 CFR Part 117 (https://www.ecfr.gov/cgi-bin/text-idx?SID=3f7125891958b3eb9380856f26065b5c&mc=true&node=pt21.2.117&rgn=div5)), along with new requirements for hazard analysis and risk-based preventive controls which where were issued as part of the implementation of the FDA Food Safety Modernization Act (FSMA) (/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma).

In addition to the CGMPs in Part 117, FDA has issued CGMPs specific to certain types of food.

CGMPs in CFR 21 Part 117

In 21 CFR Part 117 (https://www.ecfr.gov/cgi-bin/text-idx?SID=3f7125891958b3eb9380856f26065b5c&mc=true&node=pt21.2.117&rgn=div5), FDA established a CGMP regulation as part of the "Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food (/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food)" rule.

Part 117 establishes requirements for CGMPs and for hazard analysis and risk-based preventive controls for human food (PCHF) and related requirements.

Generally, domestic and foreign food facilities that are required to register with FDA by Section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act) must comply with the requirements for risk-based preventive controls in Part 117 (unless an exemption applies). The modernized

CGMPs generally apply to establishments that manufacture, process, pack, or hold food and apply to some activities that are exempt from the preventive controls requirements, such as juice and seafood processing.

Additional CGMPs for Certain Types of Food

Dietary Supplements - 21 CFR Part 111 (https://www.ecfr.gov/cgi-bin/text-idx?SID=3f7125891958b3eb9380856f26065b5c&mc=true&node=pt21.2.111&rgn=div5)
For additional information, see Dietary Supplements Guidance Documents & Regulatory Information (/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/dietary-supplements-guidance-documents-regulatory-information).

Infant Formula - 21 CFR Part 106 (https://www.ecfr.gov/cgi-bin/text-idx?SID=3f7125891958b3eb9380856f26065b5c&mc=true&node=pt21.2.106&rgn=div5)
For additional information, see Infant Formula Guidance Documents & Regulatory Information (/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/infant-formula-guidance-documents-regulatory-information).

Low-acid Canned Foods - 21 CFR Part 113 (https://www.ecfr.gov/cgi-bin/text-idx?SID=3f7125891958b3eb9380856f26065b5c&mc=true&node=pt21.2.113&rgn=div5)
Acidified Foods - 21 CFR Part 114 (https://www.ecfr.gov/cgi-bin/text-idx?SID=3f7125891958b3eb9380856f26065b5c&mc=true&node=pt21.2.114&rgn=div5)
For additional information, see Acidified & Low-Acid Canned Foods Guidance Documents & Regulatory Information (/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/acidified-low-acid-canned-foods-guidance-documents-regulatory-information).

Bottled Water - 21 CFR Part 129 (https://www.ecfr.gov/cgi-bin/text-idx?SID=3f7125891958b3eb9380856f26065b5c&mc=true&node=pt21.2.129&rgn=div5)
For additional information, see Bottled Water/Carbonated Soft Drinks Guidance Documents & Regulatory Information (/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/bottled-watercarbonated-soft-drinks-guidance-documents-regulatory-information).

Related Resources

Food Defect Levels Handbook (/food/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements/food-defect-levels-handbook)
Title 21, Code of Federal Regulations, Part 110.110 allows the Food and Drug Administration (FDA) to establish maximum levels of natural or unavoidable defects in foods for human use that present no health hazard. These "Food Defect Action Levels" listed in this booklet are set on this premise--that they pose no inherent hazard to health.

Filth and Extraneous Materials Program (/food/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements/filth-and-extraneous-materials-program)
The filth and extraneous materials program at the FDA supports the agency's mission by ensuring manufacturers comply with the Federal Food, Drug, and Cosmetic Act and by preventing adulterated foods from reaching consumers.

Historical Background

In 2004, FDA initiated an effort to modernize its CGMP regulations (21 CFR Part 110 (https://www.ecfr.gov/cgi-bin/text-idx?SID=2706d807d96ce5fe9a3e874e38ab459d&mc=true&node=pt21.2.110&rgn=div5)). The agency hosted three public meetings to solicit comments, data, and scientific information about the current state of quality management techniques, quality systems approaches, and voluntary industry standards concerning CGMPs as well as other controls used by food manufacturers and processors to prevent, reduce, control, or eliminate foodborne hazards that may occur during food production, processing, or storage.

- Food CGMP Modernization Report (2005) (/food/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements/food-current-good-manufacturing-practice-modernization-report-2005)
- Good Manufacturing Practices for the 21st Century for Food Processing Study (2004) (/food/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements/good-manufacturing-practices-gmps-21st-century-food-processing-2004-study)
- Backgrounder on the Final Rule for Current Good Manufacturing Practices (CGMPs) for Dietary Supplements (/food/dietary-supplements-guidance-documents-regulatory-information/backgrounder-final-rule-current-good-manufacturing-practices-cgmps-dietary-supplements)
- Public Meeting Questions and Answers (2004) (https://public4.pagefreezer.com/browse/FDA/06-02-2024T14:35/https://www.fda.gov/food/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements/questions-and-answers-2004-public-meetings-current-good-manufacturing-practice-regulations) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- 1986 Final Rule (https://cdn.loc.gov/service/ll/fedreg/fr051/fr051118/fr051118.pdf)
- 1979 Proposed Revision (https://cdn.loc.gov/service/ll/fedreg/fr044/fr044112/fr044112.pdf)
- 1969 Final Rule (https://cdn.loc.gov/service/ll/fedreg/fr034/fr034080/fr034080.pdf)

- 1967 Proposed Rule (https://cdn.loc.gov/service/ll/fedreg/fr032/fr032242/fr032242.pdf)