

CURRENT GOOD MANUFACTURING PRACTICES: AN OVERVIEW



What Are the Current Good Manufacturing Practices and Why Are They So Important?

Current Good Manufacturing Practices (CGMPs) are the foundation of any food safety system. The CGMPs outline the minimum requirements for the methods, facilities, and controls used in production and packing of food to ensure its safety ([FDA 2018](#)). The CGMPs are enforced by the Food and Drug Administration (FDA) and are described in Part 117, Subpart B, of Title 21 of the Code of Federal Regulations (CFR). The word “current” emphasizes that food producers are obligated to use the latest modern technologies and solutions that enhance the food safety system. The CGMPs are minimum requirements, and food producers may establish their own, more stringent, requirements ([FDA 2020](#)).

The CGMPs are also one of the foundational programs of the FDA’s Food Safety Modernization Act (FSMA) Preventive Controls for Human Food (PCHF) rule. Following the CGMPs can minimize or eliminate the risk of food contamination, thus ensuring that consumers purchase not only a safe but also a wholesome product. Not complying with the CGMPs can lead to the production of hazardous food products, recalls, or fines.

CGMPs Requirements

The CGMPs provide recommendations and requirements for all aspects of the food production process. Most of the CGMPs requirements are very general and give food producers the flexibility to develop operating procedures that will work best for their establishments.

The CGMPs are divided into nine sections. See the following section *Summary of CGMPs Requirements* for descriptions of

each of the CGMPs sections, based on the information presented in [Part 117, Subpart B, of the Title 21](#) (e-CFR 2020a).

Summary of CGMPs Requirements

Derived from CFR 21, Part 117, Subpart B.

Personnel

- Any person with the symptoms of an illness or with open lesion must report such health conditions to their supervisors and be excluded from work task that can lead to adulteration of food, food-contact surfaces, or packaging.
- All employees handling food, working near food-contact surfaces, and food-packaging supplies are required to:
 - Wear protective clothes.
 - Maintain personal cleanliness.
 - Wash hands thoroughly.
 - Remove all loose jewelry and other items that can drop into food, packaging, or machines.
 - Wear, if appropriate, gloves, hairnets, beard covers, headbands, and caps.
 - Store personal belongings in appropriate areas.
 - Consume food, drink beverages, use tobacco, or chew gum only in allowed zones.

The Plant and Grounds

- Grounds surrounding a food plant must be kept in a state that will prevent food from adulteration.
 - The required maintenance of grounds includes:
 - i. Proper storage of equipment, litter and waste removal, cutting weeds or grass, and draining areas to prevent the presence of pests.
 - ii. Maintaining the roads, paths, and parking lots in a good condition to mitigate risk of food adulteration in places where food is exposed.

- iii. Removing excess undesirable water that can cause contamination of food by infiltration or can increase pest breeding.
 - iv. Maintaining disposal systems in an appropriate manner.
 - v. Where necessary, providing suitable protection against pests.
- The size and design of the plant should enable appropriate maintenance, cleaning, and sanitizing procedures. The floors, walls, and ceilings must be maintained in a clean and good condition. Handwashing stations, break rooms, restrooms, and all places where manufactured food is exposed must be equipped with satisfactory lighting. The ventilation and air-blowing system should be installed in a manner that will prevent cross contamination of food with dust, odors, and vapors.

Sanitary Operations

- The food production plant must be kept clean and in a condition that prevents food adulteration. Substances used in cleaning and sanitizing must not contain pathogens, must be safe, and must be purchased from a reliable source. There are several types of chemicals allowed for use in a food production facility, including cleaning and sanitizing agents, chemicals required for laboratory testing, or chemicals used for equipment maintenance and operation. All these materials need to be properly labeled and stored to avoid the risk of adulteration of food, contamination of food-contact surfaces, or contamination of packaging supplies. Procedures must be established to eliminate pests from the areas where food is manufactured, processed, packaged, and held.
- Food-contact surfaces used at any step of the food production process must be clean and in sanitary condition. Surfaces of equipment used in the processing of foods, but that are not in direct contact with food, must also be kept clean to prevent cross contamination of food, food-contact surfaces, and packaging supplies.
- The equipment and tools used for cleaning must be maintained, clean, and stored in a designated location to prevent food-contact surfaces from allergen cross contamination.

Sanitary Facilities and Controls

Food production facilities must have proper sanitary services and accommodations, such as:

- *Water supply.* The quality of the water must be suitable for the designated process and must be supplied from an appropriate source. The water that is in direct contact with food, food-contact surfaces, or packaging supplies must meet satisfactory sanitary standards.
- *Plumbing.* To provide water, remove sewage and liquid waste from the plant, and prevent backflow and cross contamination.
- *Toilet facilities and handwashing facilities.* Must be readily accessible and regularly maintained.

- *Waste disposal.* Waste must be promptly removed and disposed of to reduce the possibility of creating odors and attracting pests.

Equipment and Utensils

- All machines and tools used in the food production process must be cleanable and maintained in a manner that will prevent allergen cross contamination. The material used for the production of food-contact surfaces must be resistant and made of materials that are harmless (nontoxic). Joints on food-contact surfaces must be smoothly bonded to prevent buildup of food residues, thus decreasing the risk of microbial growth and allergen cross contamination. Machines and tools present in the facility which do not come into contact with food must also be maintained in a clean and sanitary condition.
- Equipment used for food manufacturing must be designed in a manner that allows for appropriate cleaning and sanitation.
- The temperatures in the freezer and cold storage compartment must be monitored to ensure control of microbial growth. Instruments used for measuring and regulating the temperature, pH, available water content, and other parameters related to microbial growth control in food must be adequate, precise, and calibrated.

Processes and Controls

- All steps in the food production process, including handling and storage of raw materials, manufacturing, processing, handling, and storage of final product, must be controlled and performed in a manner that will ensure the safety of the food.
- The packaging must be safe and appropriate to the type of product.
- Raw materials and additional ingredients must be examined and approved for use in the food production process. Raw materials must be stored under appropriate conditions and in a way that will prevent allergen cross contamination. For example, frozen ingredients must be kept frozen; undesired thawing can support the growth of pathogenic microorganisms or adulterate ingredients.
- Before use, raw materials must be washed, if needed, using water meeting the sanitary standards. If water is being reused and is in direct contact with food, the sanitary standards of water must be maintained to prevent food contamination.
- Raw materials must be safe for the consumer. They have to be free of pathogens or treated during processing operations so that the pathogens will be eliminated. Presence of natural toxins, pests, undesirable microorganisms, or extraneous material must be controlled and appropriately addressed according to FDA regulations.
- All surfaces that are in direct contact with food, including equipment, tools, and packaging, must be cleaned and sanitized to prevent food contamination from pathogenic microorganisms or allergens. Cleaning and sanitizing operations must be supervised by qualified individuals.

- The conditions of manufacturing, processing, packing, and holding must minimize the potential for microbial contamination, allergen cross contact, and deterioration of food. In case of sanitation failures and possible food contamination, appropriate corrective actions must be performed to examine if the product is safe and can be released, designated for rework, or if it needs to be discarded.

Storage and Distribution

- The finished product must be handled in a sanitary manner to protect it from contamination or allergen cross contact.

Storage and Distribution of Human Food By-products for Use as Animal Feed

- Food by-products directed for feeding animals that will not receive further processing, must be stored under conditions that will prevent contamination. Perishable foods intended for use as animal feed must be refrigerated.
- All human food by-products directed for use as animal food must be correctly labeled and shipped in sanitary conditions (clean shipping containers and bulk vehicles).

Defect Action Levels

- Natural or unavoidable defects of the food must be monitored, controlled, and reduced to acceptable levels. Combining food that contains a high level of defects with food of better quality to decrease the final defect level is not permitted. The [Food Defect Levels Handbook](#) (FDA 2005) provides examples of defect action levels that may result in food adulteration.

Training Requirements

Inadequate training and education are one of the main causes of food recalls. Therefore, it is crucial that employees receive appropriate food safety and CGMP training.

The Food Safety Modernization Act Preventive Controls for Human Food rule obligates all employees (including temporary and seasonal workers) to receive adequate food safety training as necessary for their job duties ([CFR 2020b, subpart A](#)). Training should be conducted with sufficient frequency to guarantee that employees remain familiar with the CGMPs. The required training must be *documented* and the *records maintained*.

Summary

Protecting human health by providing safe food products is very important. The CGMPs were developed and mandated by the FDA to regulate food production and ensure that finished products are safe and wholesome for the consumers. The CGMPs require the development of proactive food safety systems. Properly developed and implemented, these systems can be successful in mitigating and controlling numerous food safety hazards, thus effectively decreasing the number of incidents of food contamination and mislabeling.

Acknowledgements

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References

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By
Ewa Pietrysiak, Postdoctoral Research Associate, School of Food Science,
Washington State University
Girish M. Ganjyal, Interim Director, Associate Professor & Extension Food Processing Specialist,
School of Food Science, Washington State University



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