

# Good Manufacturing Practices for Food



## Presentation Materials

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# Resource 1



**Code of Federal Regulations**  
TITLE 21--FOOD AND DRUGS  
CHAPTER I—FOOD AND DRUG ADMINISTRATION

**PART 110 -- CURRENT GOOD MANUFACTURING PRACTICE IN  
MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD**

Subpart A—General Provisions

- 110.3 Definitions.
- 110.5 Current good manufacturing practice.
- 110.10 Personnel.
- 110.19 Exclusions.

Subpart B—Buildings and Facilities

- 110.20 Plant and grounds.
- 110.35 Sanitary operations.
- 110.37 Sanitary facilities and controls.

Subpart C—Equipment

- 110.40 Equipment and utensils.

Subpart D [Reserved]

Subpart E—Production and Process Controls

- 110.80 Processes and controls.
- 110.93 Warehousing and distribution.

Subpart F [Reserved]

Subpart G—Defect Action Levels

- 110.110 Natural or unavoidable defects in food for human use that present no health hazard.

Authority: Secs. 402, 701, 704 of the Federal Food, Drug, & Cosmetic Act (21 U.S.C. 342, 371, 374); sec. 361 of the Public Health Service Act (42 U.S.C. 264).

**Subpart A —General Provisions**

Sec. 110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

- (a) Acid foods or acidified foods means foods that have an equilibrium pH of 4.6 or below.
- (b) Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.
- (c) Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.
- (d) Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.
- (e) Critical control point means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.
- (f) Food means food as defined in section 201(f) of the act and includes raw materials and ingredients.
- (g) Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food-contact surfaces” includes utensils and food-contact surfaces of equipment.
- (h) Lot means the food produced during a period of time indicated by a specific code.
- (i) Microorganisms means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term “undesirable microorganisms” includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective “microbial” instead of using an adjectival phrase containing the word microorganism.
- (j) Pest refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

- (k) Plant means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.
- (l) Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.
- (m) Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.
- (n) Safe-moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity ( $a_w$ ). An  $a_w$  will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given  $a_w$  will not support the growth of undesirable microorganisms.
- (o) Sanitize means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.
- (p) Shall is used to state mandatory requirements.
- (q) Should is used to state recommended or advisory procedures or identify recommended equipment.
- (r) Water activity ( $a_w$ ) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

#### Sec. 110.5 Current good manufacturing practice.

- (a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).
- (b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

#### Sec. 110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

- (a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.
- (b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:
  - (1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.
  - (2) Maintaining adequate personal cleanliness.
  - (3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
  - (4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.
  - (5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.
  - (6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.
  - (7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
  - (8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

- (9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.
- (c) Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.
- (d) Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

#### Sec. 110.19 Exclusions.

- (a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more “raw agricultural commodities,” as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.
- (b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

### Subpart B—Buildings and Facilities

#### Sec. 110.20 Plant and grounds.

- (a) Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:
  - (1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
  - (2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
  - (3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
  - (4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

If the plant grounds are bordered by grounds not under the operator’s control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

- (b) Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:
  - (1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.
  - (2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.
  - (3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:
    - (i) Using protective coverings.
    - (ii) Controlling areas over and around the vessels to eliminate harborage for pests.
    - (iii) Checking on a regular basis for pests and pest infestation.
    - (iv) Skimming the fermentation vessels, as necessary.
  - (4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.
  - (5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.
  - (6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.

- (7) Provide, where necessary, adequate screening or other protection against pests.

Sec. 110.35 Sanitary operations.

- (a) General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.
- (b) Substances used in cleaning and sanitizing; storage of toxic materials. (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:
- (i) Those required to maintain clean and sanitary conditions;
  - (ii) Those necessary for use in laboratory testing procedures;
  - (iii) Those necessary for plant and equipment maintenance and operation; and
  - (iv) Those necessary for use in the plant's operations.
- (2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.
- (c) Pest control. No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.
- (d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.
- (1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.
  - (2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.
  - (3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.
  - (4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.
  - (5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.
- (e) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

Sec. 110.37 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

- (a) Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.
- (b) Plumbing. Plumbing shall be of adequate size and design and adequately installed and maintained to:
  - (1) Carry sufficient quantities of water to required locations throughout the plant.
  - (2) Properly convey sewage and liquid disposable waste from the plant.

- (3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.
- (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
- (5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.
- (c) Sewage disposal. Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.
- (d) Toilet facilities. Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:
  - (1) Maintaining the facilities in a sanitary condition.
  - (2) Keeping the facilities in good repair at all times.
  - (3) Providing self-closing doors.
  - (4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).
- (e) Hand-washing facilities. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:
  - (1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.
  - (2) Effective hand-cleaning and sanitizing preparations.
  - (3) Sanitary towel service or suitable drying devices.
  - (4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.
  - (5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.
  - (6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.
- (f) Rubbish and offal disposal. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

### Subpart C—Equipment

#### Sec. 110.40 Equipment and utensils.

- (a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.
- (b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.
- (c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.
- (d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.
- (e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.
- (f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

- (g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

### Subpart E—Production and Process Controls

#### Sec. 110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

- (a) Raw materials and other ingredients. (1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.
- (2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.
- (3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.
- (4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.
- (5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.
- (6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.
- (7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.
- (b) Manufacturing operations. (1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.
- (2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity,  $a_w$ , pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.
- (3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

- (i) Maintaining refrigerated foods at 45 deg.F (7.2 deg.C) or below as appropriate for the particular food involved.
  - (ii) Maintaining frozen foods in a frozen state.
  - (iii) Maintaining hot foods at 140 deg.F (60 deg.C) or above.
  - (iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.
- (4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.
- (5) Work-in-process shall be handled in a manner that protects against contamination.
- (6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.
- (7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.
- (8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.
- (9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.
- (10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.
- (11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.
- (12) Batters, breadings, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:
- (i) Using ingredients free of contamination.
  - (ii) Employing adequate heat processes where applicable.
  - (iii) Using adequate time and temperature controls.
  - (iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.
  - (v) Cooling to an adequate temperature during manufacturing.
  - (vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.
- (13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:
- (i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.
  - (ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.
  - (iii) Using materials for food containers and food- packaging materials that are safe and suitable, as defined in Sec. 130.3(d) of this chapter.
  - (iv) Providing physical protection from contamination, particularly airborne contamination.
  - (v) Using sanitary handling procedures.
- (14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of  $a_w$  for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

- (i) Monitoring the  $a_w$  of food.
  - (ii) Controlling the soluble solids-water ratio in finished food.
  - (iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the  $a_w$  of the food does not increase to an unsafe level.
- (15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:
- (i) Monitoring the pH of raw materials, food in process, and finished food.
  - (ii) Controlling the amount of acid or acidified food added to low-acid food.
- (16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.
- (17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

Sec. 110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

### Subpart G—Defect Action Levels

Sec. 110.110 Natural or unavoidable defects in food for human use that present no health hazard.

- (a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.
- (b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.
- (c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.
- (d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.
- (e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Center for Food Safety and Applied Nutrition (HFS-565), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

[51 FR 24475, June 19, 1986, as amended at 61 FR 14480, Apr. 2, 1996]

# Resource 2





# GMPs Checklist \*

## (21 CFR Part 110)



<b>Current Good Manufacturing Practice</b>			Y / N
1.	Has the food been manufactured under such conditions that it is fit for food?	§110.5(a)(1)	<input type="checkbox"/> <input type="checkbox"/>
2.	Has the food been prepared, packed, or held under sanitary conditions whereby it may not have become contaminated with filth, or whereby it may not have been rendered injurious to health?	§110.5(a)(2)	<input type="checkbox"/> <input type="checkbox"/>
<b>Facility and Grounds</b>			
3.	Are the grounds about your plant under your control kept in a condition that will protect against the contamination of food?	§110.20(a)	<input type="checkbox"/> <input type="checkbox"/>
4.	Are areas within the vicinity of the plant kept free from litter and waste with grass and weeds trimmed?	§110.20(a)(1)	<input type="checkbox"/> <input type="checkbox"/>
5.	Are roads, yards and parking lots maintained to prevent sources of contamination?	§110.20(a)(2)	<input type="checkbox"/> <input type="checkbox"/>
6.	Is there adequate drainage of outside areas that may contribute to contamination?	§110.20(a)(3)	<input type="checkbox"/> <input type="checkbox"/>
7.	Are systems for waste treatment and disposal operated in a manner to protect against contamination?	§110.20(a)(4)	<input type="checkbox"/> <input type="checkbox"/>
8.	Are steps taken to prevent sources of food contamination from bordering grounds not under the control of the facility?	§110.20(a)(4)(a)	<input type="checkbox"/> <input type="checkbox"/>
9.	Is there adequate lighting in all dressing and locker rooms and toilet areas?	§110.20(b)(5)	<input type="checkbox"/> <input type="checkbox"/>
10.	Is there adequate lighting in all areas where food is processed, packed, or stored and where utensils and equipment are cleaned?	§110.20(b)(5)	<input type="checkbox"/> <input type="checkbox"/>
11.	Are there safety-type light bulbs, fixtures, skylights, or other glass suspended over areas where food is exposed provided to protect against food contamination in case of glass breakage?	§110.20(b)(5)	<input type="checkbox"/> <input type="checkbox"/>
12.	Are the plant buildings and structures of suitable size, construction, and design to maintain sanitary operations and to produce safe food?	§110.20(b)	<input type="checkbox"/> <input type="checkbox"/>
13.	Does the plant building(s) provide sufficient space for placement of equipment and storage of materials to permit maintenance of sanitary operations and production of safe food?	§110.20(b)(1)	<input type="checkbox"/> <input type="checkbox"/>
14.	Does the design of the plant permit the separation of operations in which contamination is likely to occur which may include a separation of operations by location, time, space, partition, air flow, or other effective means?	§110.20(b)(2)	<input type="checkbox"/> <input type="checkbox"/>
15.	Are there proper precautions to protect food in outdoor bulk fermentation vessels?	§110.20(b)(3)	<input type="checkbox"/> <input type="checkbox"/>
16.	Are floors, walls and ceilings constructed to facilitate adequate cleaning and repair?	§110.20(b)(4)	<input type="checkbox"/> <input type="checkbox"/>
17.	Does drip or condensate from fixtures, ducts and pipes cause or potentially cause contamination of food, food contact surfaces or food packaging materials?	§110.20(b)(4)	<input type="checkbox"/> <input type="checkbox"/>
18.	Are aisles and working spaces unobstructed and of adequate width to permit employees to perform their jobs and protect against contamination?	§110.20(b)(4)	<input type="checkbox"/> <input type="checkbox"/>
19.	Are buildings, physical facilities, fixtures, etc. maintained in a good state of repair?	§110.35(a)	<input type="checkbox"/> <input type="checkbox"/>
20.	Is plumbing of adequate size and design to: carry sufficient quantities of water to required locations; properly convey sewage and liquid disposable waste from the plant; provide adequate floor drainage; and prevent backflow or cross connections between piping systems carrying fresh and waste water or sewage?	§110.37(b)	<input type="checkbox"/> <input type="checkbox"/>
21.	Is sewage disposal made into an adequate sewage system or disposed of by other adequate means?	§110.37(c)	<input type="checkbox"/> <input type="checkbox"/>
22.	Are rubbish and offal conveyed, stored, and disposed of in a proper manner?	§110.37(f)	<input type="checkbox"/> <input type="checkbox"/>

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# GMPs Checklist \*

## (21 CFR Part 110)



23.	Is the facility's water supply sufficient for the intended operations and from an adequate source?	§110.37(a)	<input type="checkbox"/>	<input type="checkbox"/>
24.	Is water used in processing food or cleaning equipment safe and of adequate sanitary quality? Is running water at suitable temperature and under pressure?	§110.37(a)	<input type="checkbox"/>	<input type="checkbox"/>
25.	Is reused water maintained to prevent the increase of contamination of food?	§110.80(a)(1)	<input type="checkbox"/>	<input type="checkbox"/>
26.	Are there adequate, reasonably accessible toilet facilities?	§110.37(d)	<input type="checkbox"/>	<input type="checkbox"/>
27.	Are toilet facilities maintained in a sanitary condition and in good repair?	§110.37(d)(1)(2)	<input type="checkbox"/>	<input type="checkbox"/>
28.	Do toilet facilities have self closing doors?	§110.37(d)(3)	<input type="checkbox"/>	<input type="checkbox"/>
29.	Are doors to the toilet facilities designed not to open into areas where food is exposed to airborne contamination or have double doors or positive airflow systems?	§110.37(d)(4)	<input type="checkbox"/>	<input type="checkbox"/>
30.	Are hand-washing facilities adequate, convenient, and furnished with running water at a suitable temperature?	§110.37(e)(1)	<input type="checkbox"/>	<input type="checkbox"/>
31.	Are hand-washing facilities furnished with adequate hand cleaning and sanitizing preparations?	§110.37(e)(2)	<input type="checkbox"/>	<input type="checkbox"/>
32.	Are hand-washing stations equipped with sanitary towel service or suitable drying service?	§110.37(e)(3)	<input type="checkbox"/>	<input type="checkbox"/>
33.	Are devices and fixtures in toilet facilities designed to protect against recontamination of clean, sanitized hands?	§110.37(e)(4)	<input type="checkbox"/>	<input type="checkbox"/>
34.	Are there readily understandable signs directing employees to wash and, where appropriate, sanitize their hands?	§110.37(e)(5)	<input type="checkbox"/>	<input type="checkbox"/>
35.	Are refuse receptacles constructed and maintained to protect against contamination of food?	§110.37(e)(6)	<input type="checkbox"/>	<input type="checkbox"/>
36.	Is there adequate screening or other protection against pests?	§110.20(b)(7)	<input type="checkbox"/>	<input type="checkbox"/>
37.	Are pests excluded from all areas of the food plant?	§110.35(c)	<input type="checkbox"/>	<input type="checkbox"/>
38.	Are effective measures taken to exclude pests from processing areas?	§110.35(c)	<input type="checkbox"/>	<input type="checkbox"/>
39.	Are there restrictions and precautions to insure that the use of insecticides and pesticides will not contaminate food, food product surfaces and food packaging material?	§110.35(c)	<input type="checkbox"/>	<input type="checkbox"/>
<b>Personnel</b>				
40.	Does management take all reasonable measures and precautions to ensure disease control through medical exam, observation, exclusion, and reporting?	§110.10(a)	<input type="checkbox"/>	<input type="checkbox"/>
41.	Are employees instructed to report health conditions that might contaminate food, food product surfaces or food packaging materials to their supervisor?	§110.10(a)	<input type="checkbox"/>	<input type="checkbox"/>
42.	Does management take all reasonable measures and precautions to ensure cleanliness through hygienic practices?	§110.10(b)	<input type="checkbox"/>	<input type="checkbox"/>
43.	Are employees trained to protect against contamination of food by properly wearing suitable outer garments, hair nets, beard coverings, etc.?	§110.10(b)(1) & (6)	<input type="checkbox"/>	<input type="checkbox"/>
44.	Are employees trained to maintain adequate personal cleanliness?	§110.10(b)(2)	<input type="checkbox"/>	<input type="checkbox"/>
45.	Are employees trained to wash hands thoroughly before work and after each absence from their work station?	§110.10(b)(3)	<input type="checkbox"/>	<input type="checkbox"/>
46.	Are employees trained to remove unsecured jewelry and other objects that might fall into food?	§110.10(b)(4)	<input type="checkbox"/>	<input type="checkbox"/>
47.	Are gloves used for food handling made of an impermeable material and	§110.10(b)(5)	<input type="checkbox"/>	<input type="checkbox"/>

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# GMPs Checklist \*

## (21 CFR Part 110)



	maintained in a clean sanitary condition?		
48.	Are employees trained to store clothing or other personal belongings away from areas where food is exposed or where equipment or utensils are washed?	§110.10(b)(7)	<input type="checkbox"/>
49.	Are employees trained to confine eating, drinking, gum chewing, and use of tobacco to areas where food is not exposed or equipment and utensils are not washed?	§110.10(b)(8)	<input type="checkbox"/>
50.	Are employees trained to protect against contamination of food, food contact surfaces, or food packaging materials from microorganisms or other foreign substances?	§110.10(b)(9)	<input type="checkbox"/>
51.	Do personnel responsible for identifying plant sanitation failures or food contamination have the combination of education and experience to produce clean, safe food?	§110.10(c)	<input type="checkbox"/>
52.	Do food handlers and supervisors have appropriate training in proper food handling techniques and food protection principles?	§110.10(c)	<input type="checkbox"/>
53.	Is the responsibility for assuring compliance by all personnel with the requirements of the GMP regulation clearly assigned to competent supervisory personnel?	§110.10(d) & 110.80	<input type="checkbox"/>
<b>Equipment</b>			
54.	Are all plant equipment and utensils designed to be adequately cleanable and properly maintained?	§110.40(a)	<input type="checkbox"/>
55.	Is equipment designed and constructed to preclude adulteration of food with: lubricants, fuel, metal fragments, and contaminated water?	§110.40(a)	<input type="checkbox"/>
56.	Has equipment been installed in a way that facilitates cleaning of equipment and adjacent spaces?	§110.40(a)	<input type="checkbox"/>
57.	Are food contact surfaces made of corrosion resistant and non-toxic material?	§110.40(a)	<input type="checkbox"/>
58.	Are all equipment and utensils properly maintained?	§110.40(a)	<input type="checkbox"/>
59.	Are holding, conveying and manufacturing systems designed in a way to be maintained in a sanitary condition?	§110.40(d)	<input type="checkbox"/>
60.	Are seams on food contact surfaces smoothly bonded or otherwise maintained to minimize growth of microorganisms or accumulation of dirt, food particles, etc.?	§110.40(b)	<input type="checkbox"/>
61.	Is equipment taken apart for thorough cleaning as necessary?	§110.80(b)(1)	<input type="checkbox"/>
62.	Are the non-food contact surfaces of equipment in the food handling area constructed that it can be kept in a clean condition?	§110.40(c)	<input type="checkbox"/>
63.	Are non-food-contact surfaces cleaned as often as necessary to protect against the contamination of food?	§110.35(d)(3)	<input type="checkbox"/>
64.	Are freezers and cold storage compartments fitted with appropriate temperature measuring and/or recording devices to accurately show the compartment temperature?	§110.40(e)	<input type="checkbox"/>
65.	Are freezers and cold storage compartments fitted with automatic controls for regulating temperature or, in the case of manual operations, with an automatic alarm system to indicate a significant temperature change?	§110.40(e)	<input type="checkbox"/>
66.	Are instruments and controls for measuring, regulating, or recording temperature, pH, water activity, acidity, etc. accurate (i.e. calibrated)?	§110.40(f)	<input type="checkbox"/>
67.	Are compressed air or other gases mechanically introduced into food or used to clean food contact surfaces or equipment treated to insure that food is not contaminated with unlawful food additives?	§110.40(g)	<input type="checkbox"/>
68.	Are cleaning and sanitizing of utensils and equipment performed in a manner to	§110.35(a)	<input type="checkbox"/>

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# GMPs Checklist \*

## (21 CFR Part 110)



	protect against contamination?		
69.	Are cleaning compounds and sanitizing agents free from microorganisms and safe for use?	§110.35(b)(1)	<input type="checkbox"/>
70.	Are toxic cleaning compounds, sanitizing agents, and pesticide chemicals used, identified, held, and stored in a manner to protect against contamination of food, food contact surfaces, and food packaging materials?	§110.35(b)(2)	<input type="checkbox"/>
71.	Are food contact surfaces including utensils and equipment surfaces cleaned frequently to protect against contamination?	§110.35(d)	<input type="checkbox"/>
72.	Are food contact surfaces used for manufacturing or holding low-moisture food dry and in a sanitary condition at the time of use?	§110.35(d)(1)	<input type="checkbox"/>
73.	In wet processing, are food contact surfaces cleaned and sanitized before use and after any interruption during which contamination could occur?	§110.35(d)(2)	<input type="checkbox"/>
74.	Are single-service items (paper cups, towels, etc.) stored, handled, and dispensed in an appropriate manner?	§110.35(d)(4)	<input type="checkbox"/>
75.	Are sanitizing agents safe and adequate under conditions of use?	§110.35(d)(5)	<input type="checkbox"/>
76.	Are cleaned and sanitized portable equipment with food contact surfaces and utensils stored in a manner that protects them from contamination?	§110.35(e)	<input type="checkbox"/>
77.	Is there adequate ventilation or control equipment to minimize odors and vapors?	§110.20(b)(6)	<input type="checkbox"/>
78.	Are fans and other air blowing equipment located in a manner to prevent contamination of food, food contact surfaces and food packaging materials?	§110.20(b)(6)	<input type="checkbox"/>
<b>Processes and Controls</b>			
79.	Are operations conducted in accordance with adequate sanitation principles?	§110.80	<input type="checkbox"/>
80.	Is there an appropriate quality control operation employed to ensure that food is suitable for human consumption and that food packaging material is safe and suitable?	§110.80	<input type="checkbox"/>
81.	Are all reasonable precautions taken to ensure that production procedures protect from contamination from any source?	§110.80	<input type="checkbox"/>
82.	Do raw materials or other ingredients contain levels of microorganisms that may produce food poisoning or other disease?	§110.80(a)(2)	<input type="checkbox"/>
83.	Are ingredients that contain microorganisms that may cause disease pasteurized or otherwise treated?	§110.80(a)(2)	<input type="checkbox"/>
84.	Are raw materials inspected, segregated or otherwise handled as necessary to ascertain that they are clean and ready for use?	§110.80(a)(1)	<input type="checkbox"/>
85.	Is all adulterated food (within the meaning of the FD&C Act) either rejected or treated/processed to eliminate contamination?	§110.80	<input type="checkbox"/>
86.	Is appropriate chemical, microbial, or extraneous material testing conducted to identify sanitation failures or possible food contamination?	§110.80	<input type="checkbox"/>
87.	Are containers inspected to ensure they do not contribute to contamination?	§110.80(a)(1)	<input type="checkbox"/>
88.	Do raw materials and other ingredients comply with FDA regulations, guidelines, and action levels for poisonous or deleterious substances?	§110.80(a)(3) & (4)	<input type="checkbox"/>
89.	Are raw materials and other ingredients, including rework, held in bulk or in containers designed to protect against contamination?	§110.80(a)(5)	<input type="checkbox"/>
90.	Are raw materials held at temperature and humidity levels that prevent food from being adulterated?	§110.80(a)(5)	<input type="checkbox"/>
91.	Are raw materials scheduled for rework identified as such?	§110.80(a)(5)	<input type="checkbox"/>

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# GMPs Checklist \*

## (21 CFR Part 110)



92.	Are frozen raw materials and other ingredients kept frozen?	§110.80(a)(6)	<input type="checkbox"/>	<input type="checkbox"/>
93.	Is there careful monitoring of physical factors such as time, temperature, humidity, pH, pressure, and manufacturing operations such as freezing, dehydration, heat processing, etc.?	§110.80(b)(2)	<input type="checkbox"/>	<input type="checkbox"/>
94.	Are foods that can support the rapid growth of microorganisms held in a manner to prevent adulteration?	§110.80(b)(3)	<input type="checkbox"/>	<input type="checkbox"/>
95.	Are refrigerated foods kept at 45°F (7.2°C) or below as appropriate?	§110.80(b)(3)	<input type="checkbox"/>	<input type="checkbox"/>
96.	Are hot foods maintained at 140°F (60°C) or above?	§110.80(b)(3)	<input type="checkbox"/>	<input type="checkbox"/>
97.	Are acid or acidified foods held in hermetically sealed containers at ambient temperatures heat treated?	§110.80(b)(3)	<input type="checkbox"/>	<input type="checkbox"/>
98.	Are measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, control of pH or water activity adequate to prevent the growth of undesirable microorganisms?	§110.80(b)(4)	<input type="checkbox"/>	<input type="checkbox"/>
99.	Is work in progress handled in a manner that protects against contamination?	§110.80(b)(5)	<input type="checkbox"/>	<input type="checkbox"/>
100.	Are effective measures taken to protect finished food from contamination by raw materials, other ingredients or refuse?	§110.80(b)(6)	<input type="checkbox"/>	<input type="checkbox"/>
101.	Are equipment, containers, and utensils used to process food constructed, handled, and maintained in a manner that protects against food contamination?	§110.80(b)(7)	<input type="checkbox"/>	<input type="checkbox"/>
102.	Are liquid or dry materials and other ingredients received and stored in bulk held in a manner to protect against contamination?	§110.80(a)(7)	<input type="checkbox"/>	<input type="checkbox"/>
103.	Are traps, sieves, metal detectors, magnets, etc. used to detect the inclusion of metal or other extraneous material?	§110.80(b)(8)	<input type="checkbox"/>	<input type="checkbox"/>
104.	Are food, raw materials and other ingredients that are adulterated disposed of in a manner to protect other food from contamination?	§110.80(b)(9)	<input type="checkbox"/>	<input type="checkbox"/>
105.	When reconditioning of adulterated food is done, is a proven effective method used?	§110.80(b)(9)	<input type="checkbox"/>	<input type="checkbox"/>
106.	Is reconditioned food examined and found free of contamination before being incorporated with other food?	§110.80(b)(9)	<input type="checkbox"/>	<input type="checkbox"/>
107.	Are mechanical manufacturing steps performed so as to protect food from contamination?	§110.80(b)(10)	<input type="checkbox"/>	<input type="checkbox"/>
108.	Is heat blanching, when required, performed in an effective manner and washed, when required, with water of safe and adequate sanitary quality?	§110.80(b)(11)	<input type="checkbox"/>	<input type="checkbox"/>
109.	Are batters, breading, and other similar preparations treated or maintained in a manner that protects against contamination?	§110.80(b)(12)	<input type="checkbox"/>	<input type="checkbox"/>
110.	Are filling, assembling, and packaging operations protected against contamination by use of safe and suitable material for food containers and packaging materials?	§110.80(b)(13)	<input type="checkbox"/>	<input type="checkbox"/>
111.	Are critical control points identified and controlled for filling, assembling, and packaging operations?	§110.80(b)(13)	<input type="checkbox"/>	<input type="checkbox"/>
112.	Are foods that rely on the control of water activity preventing the growth of undesirable microorganisms processed and maintained at a safe moisture level?	§110.80(b)(14)	<input type="checkbox"/>	<input type="checkbox"/>
113.	Are foods that rely principally on the control of pH for preventing the growth of undesirable microorganisms monitored and maintained at pH 4.6 or below?	§110.80(b)(15)	<input type="checkbox"/>	<input type="checkbox"/>
114.	Has ice in contact with food been made from water that is safe and of adequate sanitary quality and manufactured in accordance with GMPs?	§110.80(b)(16)	<input type="checkbox"/>	<input type="checkbox"/>
115.	Are human food manufacturing areas or equipment not used for manufacturing nonhuman food-grade animal feed or inedible products unless contamination of the	§110.80(b)(17)	<input type="checkbox"/>	<input type="checkbox"/>

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# GMPs Checklist \*

## (21 CFR Part 110)



	human food is not reasonably possible?		
116.	Is the storage and transportation of finished food under conditions that protect against physical, chemical, or microbial contamination?	§110.93	<input type="checkbox"/>
117.	Is food containing defects above current defect action levels mixed with other lots of food?	§110.110(d)	<input type="checkbox"/>
118.	Does the finished product contain natural or unavoidable defects at low, non-hazardous levels?	§110.110(a)	<input type="checkbox"/>
119.	Have Good Manufacturing Practices been followed in producing the food?	§110.110(c)	<input type="checkbox"/>
120.	Has food containing defects above the current defect action level been mixed with another lot of food?	§110.110(d)	<input type="checkbox"/>

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# Resource 3



# FSMA FACTS

## Final Rule on Preventive Controls for Human Food

### Summary

The FDA Food Safety Modernization Act (FSMA) Preventive Controls for Human Food rule is now final, and compliance dates for some businesses begin in September 2016.

This final rule is the product of an unprecedented level of outreach by the FDA to industry, consumer groups, the agency's federal, state, local and tribal regulatory counterparts, academia and other stakeholders. This outreach began before the rule was proposed in January 2013.

In response to input received during the comment period and during hundreds of engagements that included public meetings, webinars, listening sessions, and visits to farms and food facilities across the country, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions were designed to make the originally proposed rule more practical, flexible, and effective for industry, while still advancing the FDA's food safety goals.

The final rule has elements of both the original and supplemental proposals, in addition to new requirements that are the outgrowth of public input received during the comment period for both proposals. For example, flexibility has been built into key requirements, including

control of the supply chain, and the definition of farms— which are exempt from these regulations— has significantly changed to reflect modern farming practices.

Below are the key requirements and compliance dates.

1. **Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. The rule sets requirements for a written food safety plan that includes:**
  - **Hazard analysis:** The first step is hazard identification, which must consider known or reasonably foreseeable biological, chemical, and physical hazards. These hazards could be present because they occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain (if they affect the safety of the food).
  - **Preventive controls:** These measures are required to ensure that hazards requiring a preventive control will be minimized or prevented. They include process, food allergen, and sanitation controls, as well as supply-chain controls and a recall plan.

# Final Rule on Preventive Controls for Human Food

- **Oversight and management of preventive controls.** The final rule provides flexibility in the steps needed to ensure that preventive controls are effective and to correct problems that may arise.
    - **Monitoring:** These procedures are designed to provide assurance that preventive controls are consistently performed.

Monitoring is conducted as appropriate to the preventive control. For example, monitoring of a heat process to kill pathogens would include actual temperature values and be more frequent than monitoring preventive maintenance activities used to minimize metal hazards, which could be a simple record of the date on which the activity took place.
    - **Corrective actions and corrections:** Corrections are steps taken to timely identify and correct a minor, isolated problem that occurs during food production. Corrective actions include actions to identify a problem with preventive control implementation, to reduce the likelihood the problem will recur, evaluate affected food for safety, and prevent it from entering commerce. Corrective actions must be documented with records.
    - **Verification:** These activities are required to ensure that preventive controls are consistently implemented and effective. They include validating with scientific evidence that a preventive control is capable of effectively controlling an identified hazard; calibration (or accuracy checks) of process monitoring and verification instruments such as thermometers, and reviewing records to verify that monitoring and corrective actions (if necessary) are being conducted.

Product testing and environmental monitoring are possible verification activities but are only required as appropriate to the food, facility, nature of the preventive control, and the role of that control in the facility's food safety system. Environmental monitoring generally would be required if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control.
- 2. The definition of a 'farm' is clarified to cover two types of farm operations. Operations defined as farms are not subject to the preventive controls rule.**
- **Primary Production Farm:** This is an operation under one management in one general, but not necessarily contiguous, location devoted to the growing of crops, the harvesting of

# Final Rule on Preventive Controls for Human Food

crops, the raising of animals (including seafood), or any combination of these activities. This kind of farm can pack or hold raw agricultural commodities such as fresh produce and may conduct certain manufacturing/processing activities, such as dehydrating grapes to produce raisins and packaging and labeling raisins.

The supplemental rule proposed, and the final rule includes, a change to expand the definition of “farm” to include packing or holding raw agricultural commodities (such as fresh produce) that are grown on a farm under a different ownership. The final rule also includes within the “farm” definition companies that solely harvest crops from farms.

- **Secondary Activities Farm:** This is an operation not located on the Primary Production Farm that is devoted to harvesting, packing and/or holding raw agricultural commodities. It must be majority owned by the Primary Production Farm that supplies the majority of the raw agricultural commodities harvested, packed, or held by the Secondary Activities Farm.

This definition for a Secondary Activities Farm was provided, in part, so that farmers involved in certain formerly off-farm packing now fit under the definition of “farm,” as the packing is still part of the farming operation. In

addition to off-farm produce packing operations, another example of a Secondary Activities Farm could be an operation in which nuts are hulled and dehydrated by an operation not located at the orchard before going to a processing plant. If the farmer that owns the orchards and supplies the majority of the nuts is a majority owner of the hulling/dehydrating facility, that operation is a Secondary Activities Farm.

- Primary Production and Secondary Activities Farms conducting activities on produce covered by the Produce Safety Rule will be required to comply with that rule.

### **3. Supply-chain program is more flexible, with separate compliance dates established.**

- The rule mandates that a manufacturing/processing facility have a risk-based supply chain program for those raw material and other ingredients for which it has identified a hazard requiring a supply-chain applied control. Manufacturing/processing facilities that control a hazard using preventive controls, or who follow requirements applicable when relying on a customer to control hazards, do not need to have a supply-chain program for that hazard.

# Final Rule on Preventive Controls for Human Food

- Covered food facilities are responsible for ensuring that these foods are received only from approved suppliers, or on a temporary basis from unapproved suppliers whose materials are subject to verification activities before being accepted for use. (Approved suppliers are those approved by the facility after a consideration of factors that include a hazard analysis of the food, the entity that will be controlling that hazard, and supplier performance.)
  - A facility will not be required to implement a preventive control when an identified hazard will be controlled by a subsequent entity such as a customer or other processor. The facility will have to disclose that the food is “not processed to control (identified hazard)” and obtain written assurance from its customer regarding certain actions the customer agrees to take.
  - Another entity in the supply chain, such as a broker or distributor, can conduct supplier verification activities, but the receiving facility must review and assess that entity’s documentation of the verification of control of the hazard.
  - Separate compliance dates have been established for the supply-chain program provisions so that a food facility will not be required to comply with the supply-chain program provisions before its supplier is required to comply with the preventive controls for human food rule or the produce safety rule.
- 4. Current Good Manufacturing Practices (CGMPs) are updated and clarified.**
- The final rule does not include nonbinding provisions, which are more appropriate for guidance.
  - Some of the previously nonbinding provisions, such as education and training, are now binding.
    - Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties.
    - Such employees must have the necessary combination of education, training, and/or experience necessary to manufacture, process, pack, or hold clean and safe food. Individuals must receive training in the principles of food hygiene and food safety, including the importance of employee health and hygiene.
    - Note that there are similar requirements related to preventive controls.

# Final Rule on Preventive Controls for Human Food

- The FDA’s longstanding position that CGMPs address allergen cross-contact is now explicit in the regulatory text.

## Compliance Dates

Compliance dates for businesses are staggered over several years after publication of the final rule.

- **Very small businesses** (averaging less than \$1 million per year (adjusted for inflation) in both annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale): Three years, except for records to support its status as a very small business (January 1, 2016).
- **Businesses subject to the Pasteurized Milk Ordinance** (compliance dates extended to allow time for changes to the PMO safety standards that incorporate the requirements of this preventive controls rule): Three years
- **Small businesses** (a business with fewer than 500 full-time equivalent employees): Two years
- **All other businesses**: One year

Compliance dates after publication of the final rule for the requirements of the supply chain program:

- **Receiving facility is a small business and its supplier will not be subject to**

**the human preventive controls rule or the produce safety rule**: Two years

- **Receiving facility is a small business and its supplier will be subject to the human preventive controls rule or the produce safety rule**: Two years or six months after the supplier is required to comply with the applicable rule, whichever is later
- **Receiving facility is not a small or very small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule**: 18 months
- **Receiving facility is not a small or very small business and its supplier will be subject to the human preventive controls rule or the produce safety rule**: Six months after the supplier is required to comply with the applicable rule

## Assistance to Industry

The FDA is developing several guidance documents on subjects that include:

- Hazard analysis and preventive controls,
- Environmental monitoring,
- Food allergen controls,
- Validation of process controls,

# Final Rule on Preventive Controls for Human Food

- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule.

Plans for training and technical assistance are well under way. They include:

- Establishing a Food Safety Technical Assistance Network within the agency to provide a central source of information to support industry understanding and implementation of FSMA.
- Collaborating with the Food Safety Preventive Controls Alliance (<http://www.iit.edu/ifsh/alliance/>) to establish training and technical assistance programs.
- Partnering with the National Institute of Food and Agriculture in the U.S. Department of Agriculture to administer a grant program to provide technical assistance to small and mid-size farms and small food processors.

## More Information

Federal Register

[www.regulations.gov](http://www.regulations.gov)

FDA Food Safety Modernization Act

[www.fda.gov/fsma](http://www.fda.gov/fsma)

FDA's FSMA Technical Assistance Network

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>

# Resource 4



# Employees must wash their hands and portions of their arms exposed directly to food

## Hand Washing Steps:



1) Wet hands with warm water



2) Lather hands with soap for at least 20 seconds



3) Scrub backs of hands, wrists, between fingers and under fingernails



4) Rinse hands with warm water



5) Dry hands with single use paper towels or by use of a forced air hand drying device



6) Turn off faucet with paper towel

## Remember to wash your hands...

*Before:* Starting work

*After:* Using the restroom  
Switching between raw and ready to eat food  
Eating or drinking  
Taking out the garbage  
Handling animals

Sneezing or coughing  
Smoking  
Touching body, face or hair  
Mopping the floor  
Handling soiled equipment or utensils

Any other activities that contaminate the hands



# Resource 5





## GMP Additional Resources

1. California Food and Drug Branch – **Industry Education and Training Unit**  
<http://www.cdph.ca.gov/services/Pages/fdbETU.aspx>
2. California Food and Drug Branch  
<http://www.cdph.ca.gov/FDB>
3. California Food and Drug Branch – Food Industry Training Information  
<http://www.cdph.ca.gov/CAFoodTraining>
4. US Food and Drug Administration  
<http://www.fda.gov/>
5. FDA District Recall Coordinators  
<http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm>
6. FDA's Reportable Food Registry  
<http://www.fda.gov/ReportableFoodRegistry>
7. USDA (FSIS)  
<http://www.fsis.usda.gov/>
8. Center for Disease Control  
<http://www.cdc.gov/>
9. Industry Guidance: Information on Recalls of FDA Regulated Products  
<http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm>
10. Recall policy – 21 CFR Recall Regulations Sec. 7.40  
[http://edocket.access.gpo.gov/cfr\\_2004/aprqtr/21cfr7.40.htm](http://edocket.access.gpo.gov/cfr_2004/aprqtr/21cfr7.40.htm)
11. FDA – Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed  
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/chemicalcontaminantsmetalsnaturaltoxinspesticides/ucm077969.htm>
12. FDA – Defect Levels Handbook (natural or unavoidable defects in foods that present no health hazards for humans)  
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/sanitatio ntransportation/ucm056174.htm>
13. FDA – Model Food Code  
<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm>