

Good Manufacturing Practices for Food



Presentation Materials

California Department of Public Health
Food and Drug Branch
Industry Education and Training Unit

Phone – (916) 650 – 6500

Email – FDBtraining@cdph.ca.gov

Resource 1

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

**PART 117 -- CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS,
AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD**

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Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

Subpart B—Current Good Manufacturing Practice

Sec. 117.10 Personnel.

The management of the establishment must take 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, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g., by an impermeable cover). Personnel must 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 must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include:
 - (1) Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and 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.
 - (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 allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).

Sec. 117.20 Plant and grounds.

- (a) Grounds. The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:
 - (1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant 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.
 - (5) If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (a)(1) through (4) of this section, care must 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. The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:
 - (1) Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.

- (2) Permit the taking of adequate precautions to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.
- (3) Permit the taking of adequate precautions to protect food in installed outdoor bulk 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 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, food-contact surfaces, or food-packaging materials 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, manufactured, processed, packed, or held and where equipment or utensils are cleaned; and provide shatter-resistant 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 dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.
- (7) Provide, where necessary, adequate screening or other protection against pests.

Sec. 117.35 Sanitary operations.

- (a) General maintenance. Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and 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 must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a letter of 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 must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.
- (c) Pest control. Pests must not be allowed in any area of a food plant. Guard, guide, or pest-detecting 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 must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant 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, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food.

- (1) Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food must be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.
- (2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food-contact surfaces must 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 must be cleaned and sanitized as necessary.
- (3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.
- (e) Sanitation of non-food-contact surfaces. Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.
- (f) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.

Sec. 117.37 Sanitary facilities and controls.

Each plant must be equipped with adequate sanitary facilities and accommodations including:

- (a) Water supply. The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must 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 must be of adequate size and design and adequately installed and maintained to:
 - (1) Carry adequate 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 must be disposed of into an adequate sewerage system or disposed of through other adequate means.
- (d) Toilet facilities. Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.
- (e) Hand-washing facilities. Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.
- (f) Rubbish and offal disposal. Rubbish and any offal must 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, food-packaging materials, water supplies, and ground surfaces.

Sec. 117.40 Equipment and utensils.

- (a)
 - (1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.
 - (2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with

lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

- (3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.
 - (4) Food-contact surfaces must be corrosion-resistant when in contact with food.
 - (5) Food-contact surfaces must 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, sanitizing agents, and cleaning procedures.
 - (6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.
- (b) Seams on food-contact surfaces must 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 and allergen cross contact.
 - (c) Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.
 - (d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.
 - (e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.
 - (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 must be accurate and precise 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 must be treated in such a way that food is not contaminated with unlawful indirect food additives.

Sec. 117.80 Processes and controls.

- (a) General.
 - (1) All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.
 - (2) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.
 - (3) Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.
 - (4) Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross contact and to contamination from any source.
 - (5) Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.
 - (6) All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.
- (b) Raw materials and other ingredients.
 - (1) Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food.
 - (2) Raw materials and other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.
 - (3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with FDA regulations for poisonous or deleterious substances before these raw materials or other ingredients are incorporated into finished food.

- (4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.
 - (5) Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.
 - (6) Frozen raw materials and other ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.
 - (7) Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination.
 - (8) Raw materials and other ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.
- (c) Manufacturing operations.
- (1) Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.
 - (2) All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.
 - (3) Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.
 - (4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.
 - (5) Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.
 - (6) Effective measures must be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross contact or contaminated food. Food transported by conveyor must be protected against allergen cross-contact and against contamination as necessary.
 - (7) Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.
 - (8) Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.
 - (9) Food, raw materials, and other ingredients that are adulterated:
 - (i) Must be disposed of in a manner that protects against the contamination of other food; or
 - (ii) If the adulterated food is capable of being reconditioned, it must be:
 - (A) Reconditioned (if appropriate) using a method that has been proven to be effective; or
 - (B) Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act before being incorporated into other food.
 - (10) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against allergen cross-contact and against contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food.
 - (11) Heat blanching, when required in the preparation of food capable of supporting microbial growth, must 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. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.
 - (12) Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must be treated or maintained in such a manner that they are protected against allergen cross

- contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms.
- (13) Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.
 - (14) Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of aw for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.
 - (15) Food, such as acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.
 - (16) When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality in accordance with §117.37(a), and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

Sec. 117.93 Warehousing and distribution.

Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

Sec. 117.95 Holding and distribution of human food by-products for use as animal food.

- (a) Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor, as identified in §507.12 of this chapter, must be held under conditions that will protect against contamination, including the following:
 - (1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;
 - (2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and
 - (3) During holding, human food by-products for use as animal food must be accurately identified.
- (b) Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.
- (c) Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

Sec. 117.110 Defect action levels.

- (a) The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.
- (b) The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook, which is accessible at <http://www.fda.gov/pchfrule> and at <http://www.fda.gov>.

Resource 2



Current Good Manufacturing Practices

Checklist for Title 21, CFR Part 117, Subpart B*



Facilities and Grounds			Y	N
1	Are the grounds under your control around your plant kept in a condition that will protect against the contamination of food?	§117.20(a)		
2	Are areas within the vicinity of the plant kept free from litter and waste with grass and weeds trimmed to prevent constituting an attractant, breeding place or harborage for pests?	§117.20(a)(1)		
3	Are roads, yards and parking lots maintained to prevent sources of contamination?	§117.20(a)(2)		
4	Is there adequate drainage of outside areas to prevent contamination of food by seepage, foot-borne filth, or providing a breeding place for pests?	§117.20(a)(3)		
5	Are systems for waste treatment and disposal operated in a manner to protect against contamination?	§117.20(a)(4)		
6	Are steps taken (e.g. increased inspection frequency, extermination, or other means) to prevent sources of food contamination from bordering grounds not under the control of the facility?	§117.20(a)(5)		
7	Are the plant buildings and structures of suitable size, construction, and design to maintain sanitary operations and to produce safe food?	§117.20(b)		
8	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?	§117.20(b)(1)		
9	Does the design of the plant permit the adequate separation of operations to reduce the likelihood of contamination or allergen cross-contact which may include a separation of operations by location, time, space, partition, air flow, dust control systems, or other effective means?	§117.20(b)(2)		
10	Are there proper precautions (e.g. protective coverings, controlling and checking areas above and around for pests, and skimming as necessary) to protect food in outdoor bulk fermentation vessels?	§117.20(b)(3)		
11	Are floors, walls and ceilings constructed to facilitate adequate cleaning and repair?	§117.20(b)(4)		
12	Is drip or condensate from fixtures, ducts and pipes prevented from causing or potentially causing contamination of food, food contact surfaces or food packaging materials?	§117.20(b)(4)		
13	Are aisles and working spaces unobstructed and of adequate width to permit employees to perform their jobs and protect against contamination?	§117.20(b)(4)		
14	Is there adequate lighting in all hand-washing, dressing and locker rooms and toilet areas?	§117.20(b)(5)		
15	Is there adequate lighting in all areas where food is processed, packed, or stored and where utensils and equipment are cleaned?	§117.20(b)(5)		
16	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?	§117.20(b)(5)		

* This document is intended for use as an instructional guide only. The official regulations can be found in Title 21, CFR Part 117.



Current Good Manufacturing Practices

Checklist for Title 21, CFR Part 117, Subpart B*



17	Is there adequate screening or other protection against pests?	§117.20(b)(7)		
18	Are buildings, physical facilities, fixtures, etc. maintained in a good state of repair adequate to prevent food from becoming contaminated?	§117.35(a)		
19	Are pests excluded with effective measures from processing areas?	§117.35(c)		
20	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?	§117.35(c)		
21	Is the facility's water supply sufficient for the intended operations and from an adequate source?	§117.37(a)		
22	Is water used in processing food or cleaning equipment safe and of adequate sanitary quality? Is running water at suitable temperature and under pressure?	§117.37(a)		
23	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?	§117.37(b)		
24	Is sewage disposal made into an adequate sewage system or disposed of by other adequate means?	§117.37(c)		
25	Are there adequate, reasonably accessible toilet facilities present?	§117.37(d)		
26	Are toilet facilities maintained in a sanitary condition and in good repair as to not be a potential source of contamination of food, food contact surfaces or food packaging materials?	§117.37(d)		
27	Are hand-washing facilities adequate, convenient, and furnished with running water at a suitable temperature?	§117.37(e)		
28	Are rubbish and offal conveyed, stored, and disposed of in a proper manner?	§117.37(f)		
	Personnel			
29	Does management take all reasonable measures and precautions to ensure disease control through medical exam, observation, exclusion, and reporting?	§117.10(a)		
30	Are employees instructed to report health conditions that might contaminate food, food contact surfaces or food packaging materials to their supervisor?	§117.10(a)		
31	Are employees with an illness or an open lesion (e.g. boil, sore, wound) excluded from any operation which may result in the contamination of any food, food-contact surface, or food-packaging materials until the condition is corrected?	§117.10(a)		
32	Does management take all reasonable measures and precautions to ensure cleanliness and allergen cross-contact prevention through hygienic practices?	§117.10(b)		
33	Do employees wear outer garments suitable to the operation which protects	§117.10(b)(1)		

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	against allergen cross contact and the contamination of food, food-contact surfaces and food-packaging materials?			
34	Do employees maintain adequate personal cleanliness?	§117.10(b)(2)		
35	Do employees wash hands thoroughly (and sanitize if necessary to protect against the contamination with undesirable microorganisms) before work, after each absence from their work stations and at any time their hands may have become soiled or contaminated?	§117.10(b)(3)		
36	Do employees remove unsecured jewelry and other objects that might fall into food, equipment or containers?	§117.10(b)(4)		
37	Do employees cover jewelry which cannot be removed with material which can be maintained in an intact, clean, and sanitary condition and that effectively protects against the contamination by the objects of the food, food-packaging and food-contact surfaces?	§117.10(b)(4)		
38	Are gloves used for food handling made of an impermeable material and maintained in a clean sanitary condition?	§117.10(b)(5)		
39	Where appropriate, do employees use hair nets, headbands, caps, beard covers or other effective hair restraints?	§117.10(b)(6)		
40	Do employees store clothing or other personal belongings away from areas where food is exposed or where equipment or utensils are washed?	§117.10(b)(7)		
41	Do employees confine eating, drinking, gum chewing, and the use of tobacco to areas where food is not exposed or equipment and utensils are not washed?	§117.10(b)(8)		
42	Are other necessary precautions taken to protect against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin)?	§117.10(b)(9)		
43	Does management ensure all individuals who manufacture, pack, or hold food subject to subparts B and F of this part are qualified to perform their assigned duties? (Subpart A)	§117.4(a)(1)		
44	Does the owner, operator, or agent in charge of the facility ensure all individuals who manufacture, process, pack, or hold food subject to parts C, D, E, F, or G of this part are qualified to perform their assigned duties? (Subpart A)	§117.4(a)(2)		
45	Is the overall sanitation of the plant under the supervision of one or more competent individuals assigned to this function?	§117.80(a)(3)		
46	Do all individuals (including temporary and seasonal employees) have the necessary education, training, or experience to manufacture, process, pack, or hold clean and safe food as appropriate to their assigned duties? (Subpart A)	§117.4(b)(1)		
47	Do all individuals (including temporary and seasonal employees) receive training in the principles of food safety, employee health, and personal	§117.4(b)(2)		

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Current Good Manufacturing Practices

Checklist for Title 21, CFR Part 117, Subpart B*



	hygiene as appropriate to the food, the facility, and the individual's assigned responsibilities? (Subpart A)			
48	Is the responsibility for ensuring compliance by individuals with the training and education requirements clearly assigned to supervisory personnel who have the education, training, or experience (or combination thereof) necessary to supervise the production of clean and safe food? (Subpart A)	§117.4(c)		
49	Are records maintained for food safety, employee health, and personal hygiene training employees receive? (Subpart A)	§117.4(d)		
50	Are employee training records kept for at least two years after they were created? (Subpart F)	§117.315(a)(1)		
	Equipment			
51	Is there adequate ventilation or control equipment to minimize dust, odors, and vapors where they may cause allergen cross contact or food contamination?	§117.20(b)(6)		
52	Are fans and other air blowing equipment located and operated in a manner to minimize the potential for allergen cross contact or contamination of food, food contact surfaces and food packaging materials?	§117.20(b)(6)		
53	Are cleaning and sanitizing of utensils and equipment performed in a manner to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials?	§117.35(a)		
54	Are cleaning compounds and sanitizing agents free from microorganisms and safe for use and verified with a letter of guarantee or other effective means?	§117.35(b)(1)		
55	Are only those toxic chemicals required to clean the plant, used in laboratory testing procedures, used in maintenance, and necessary for plant operations used or stored in in the plant where food is processed or exposed?	§117.35(b)(1)(i-iv)		
56	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?	§117.35(b)(2)		
57	Are food contact surfaces including utensils and equipment cleaned frequently enough to protect against allergen cross-contact and contamination?	§117.35(d)		
58	Are food contact surfaces used for manufacturing or holding low-moisture foods clean, dry, and in a sanitary condition at the time of use?	§117.35(d)(1)		
59	In wet processing, are food contact surfaces cleaned and sanitized before use and after any interruption during which contamination could occur?	§117.35(d)(2)		
60	Are single-service items (paper cups, towels, etc.) stored, handled, and dispensed in a manner that protects against allergen cross-contact and against the contamination of food, food contact surfaces or food packaging materials?	§117.35(d)(3)		
61	Are non-food-contact surfaces cleaned as often as necessary to protect	§117.35(e)		

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Current Good Manufacturing Practices

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	against allergen cross-contact and the contamination of food, food contact surfaces, and food-packaging?			
62	Are cleaned and sanitized portable equipment with food contact surfaces and utensils stored in a location and manner that protects the food contact surfaces from allergen cross-contact and contamination?	§117.35(f)		
63	Are all plant equipment and utensils designed to be adequately cleanable and properly maintained to protect against allergen cross-contact and contamination?	§117.40(a)(1)		
64	Is equipment designed and constructed to preclude adulteration of food with lubricants, fuel, metal fragments, contaminated water or any other contaminants?	§117.40(a)(2)		
65	Has equipment been installed in a way that facilitates cleaning of equipment and adjacent spaces?	§117.40(a)(3)		
66	Are food contact surfaces corrosion resistant when in contact with food?	§117.40(a)(4)		
67	Are food contact surfaces made of non-toxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures?	§117.40(a)(5)		
68	Are food contact surfaces maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives?	§117.40(a)(6)		
69	Are seams on food contact surfaces smoothly bonded or maintained to minimize the accumulation of food particles and organic matter and minimize the opportunity for growth of microorganisms and allergen cross-contact?	§117.40(b)		
70	Are the non-food contact surfaces of equipment in the food handling areas constructed that it can be kept in a clean and sanitary condition?	§117.40(c)		
71	Are holding, conveying and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems designed and constructed in a way to be maintained in a sanitary condition?	§117.40(d)		
72	Are freezers and cold storage compartments used to store and hold food capable of supporting the growth of microorganisms fitted with an indicating thermometer, temperature measuring device, or temperature recording device installed to show the temperature accurately within the compartment?	§117.40(e)		
73	Are instruments and controls for measuring, regulating, or recording temperatures, pH, water activity, acidity, etc. accurate (i.e. calibrated), precise, adequately maintained and adequate in number for their designated uses?	§117.40(f)		
74	Are compressed air or other gases mechanically introduced into food or used to clean food contact surfaces or equipment treated to ensure that food is not contaminated with unlawful food additives?	§117.40(g)		

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Current Good Manufacturing Practices

Checklist for Title 21, CFR Part 117, Subpart B*



75	Are utensils and equipment taken apart for thorough cleaning as necessary?	§117.80(c)(1)		
76	Are equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients constructed, handled, and maintained in a manner that protects against allergen cross-contact and from contamination?	§117.80(c)(7)		
Processes and Controls				
77	Are all operations in the manufacturing, processing, packing, and holding food conducted in accordance with adequate sanitation principles?	§117.80(a)(1)		
78	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?	§117.80(a)(2)		
79	Are adequate precautions taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source?	§117.80(a)(4)		
80	Are chemical, microbial, or extraneous material testing procedures used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination?	§117.80(a)(5)		
81	Is all food which has become adulterated (within the meaning of the FD&C Act) either rejected or treated/processed to eliminate contamination?	§117.80(a)(6)		
82	If water is reused does it prevent allergen cross-contact and the increase of the level of contamination of the food?	§117.80(b)(1)		
83	When water is used for washing, rinsing or conveying is it of safe and sanitary quality?	§117.80(b)(1)		
84	Are raw materials inspected, segregated or otherwise handled as necessary to ascertain that they are clean and ready for use?	§117.80(b)(1)		
85	Are raw materials or other ingredients which contain levels of microorganisms that may produce food poisoning or other disease excluded?	§117.80(b)(2)		
86	Are ingredients that contain microorganisms that may cause disease pasteurized or otherwise treated?	§117.80(b)(2)		
87	Do raw materials and other ingredients comply with FDA regulations, guidelines, and action levels for poisonous or deleterious substances?	§117.80(b)(3)		
88	Do raw materials and other ingredients comply with FDA regulations, guidelines, and defect action levels for natural or unavoidable defects?	§117.80(b)(4)		
89	Are raw materials and other ingredients, including rework, held in bulk or in labeled containers designed to protect against allergen cross-contact and against contamination?	§117.80(b)(5)		
90	Are raw materials held at temperature and humidity levels that prevent food from being adulterated?	§117.80(b)(5)		
91	Are raw materials scheduled for rework identified as such?	§117.80(b)(5)		

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92	Are frozen raw materials and other ingredients kept frozen?	§117.80(b)(6)		
93	If thawing of raw materials is necessary, is it done in a manner that prevents the raw materials and other ingredients from becoming adulterated?	§117.80(b)(6)		
94	Are liquid and dry raw materials and other ingredients received and stored in BULK held in a manner that protects against allergen cross-contact and against contamination?	§117.80(b)(7)		
95	Are liquid and dry materials and other ingredients received and stored in bulk held in a manner to protect against contamination?	§117.80(b)(7)		
96	Are raw materials, other ingredients, and rework containing food allergens clearly identified and held in a manner that prevents allergen cross-contact?	§117.80(b)(8)		
97	Are mechanical manufacturing steps (e.g. washing, cutting, sorting, cooling, forming, etc.) performed so as to protect food against allergen cross-contact and contamination?	§117.80(c) (10)		
98	Is heat blanching, when required in the preparation of food capable of supporting microbial growth, performed in an effective manner and then either rapidly cooled or passed to subsequent manufacturing without delay?	§117.80(c) (11)		
99	Are batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time treated or maintained in a manner that protects against contamination and minimizes the potential for growth of undesirable microorganisms?	§117.80(c) (12)		
100	Are filling, assembling, and packaging operations protected against allergen cross-contact, contamination, and the growth of undesirable microorganisms?	§117.80(c) (13)		
101	Are foods that rely on the control of water activity preventing the growth of undesirable microorganisms (e.g. dry mixes, nuts, dehydrated food, etc.) processed and maintained at a safe moisture level?	§117.80(c) (14)		
102	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?	§117.80(c) (15)		
103	Has ice in contact with food been made from water that is safe and of adequate sanitary quality and manufactured in accordance with GMPs?	§117.80(c) (16)		
104	Is all food manufacturing, processing, packing, and holding done under such conditions and controls to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination, and deterioration of food?	§117.80(c) (2)		
105	Are foods that can support the rapid growth of microorganisms held at a temperature that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding?	§117.80(c)(3)		
106	Are measures (e.g. sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a _w) taken to destroy or prevent the growth of undesirable microorganisms adequate to prevent the food from	§117.80(c)(4)		

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Checklist for Title 21, CFR Part 117, Subpart B*



	becoming adulterated?			
107	Is work-in-progress and rework handled in a manner that protects against allergen cross-contact, contamination, and the growth of undesirable microorganisms?	§117.80(c)(5)		
108	Are effective measures taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients or refuse?	§117.80(c)(6)		
109	Is food transported by conveyor protected against allergen cross-contact and from contamination?	§117.80(c)(6)		
110	Are adequate measures taken to protect against the inclusion of metal or other extraneous material in food?	§117.80(c)(8)		
111	Are food, raw materials and other ingredients that are adulterated disposed of in a manner to protect other food from contamination?	§117.80(c)(9)(i)		
112	When reconditioning of adulterated food is done, is a proven effective method used?	§117.80(c)(9)(ii)		
113	Is reconditioned food examined and found free of contamination before being incorporated with other food?	§117.80(c)(9)(ii)		
114	Is the storage and transportation of finished food under conditions that protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against the deterioration of the food and the container?	§117.93		
115	Are human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor held under conditions that will protect against contamination?	§117.95(a)		
116	Are containers and equipment used to convey or hold human food by-products for use as animal food before distribution designed, constructed, cleaned as necessary, and maintained to protect against the contamination?	§117.95(a)(1)		
117	Are human food by-products for use as animal food held for distribution held in a way to protect against contamination from sources such as trash?	§117.95(a)(2)		
118	Are human food by-products for use as animal food accurately identified and labeled while being held and throughout distribution?	§117.95(a)(3), (b)		
119	Are shipping containers (e.g. totes, drums, tubs, etc.) and bulk vehicles used to distribute human food by-products for animal food examined/inspected prior to use?	§117.95(c)		
120	Are quality control operations utilized that reduce natural or unavoidable defects to the lowest level currently feasible?	§117.110(a)		
121	Are foods or ingredients, containing defects at levels which render it adulterated, prohibited from being mixed with other lots of unadulterated foods or ingredients?	§117.110(b)		

Resource 3



Key Facts about Preventive Controls for Human Food

Preventive controls are steps that you, a domestic or foreign food facility, must take to reduce or eliminate food safety hazards. The rule on Preventive Controls for Human Food is mandated by the 2011 FDA Food Safety Modernization Act. The rule also incorporates the Current Good Manufacturing Practice (CGMP) requirements, which have been updated.

- **DO THE REQUIREMENTS FOR PREVENTIVE CONTROLS FOR HUMAN FOOD APPLY TO ME?**
- **DO THE REQUIREMENTS FOR CURRENT GOOD MANUFACTURING PRACTICES (CGMPs) APPLY TO ME?**
- **WHEN DO I HAVE TO BE IN COMPLIANCE WITH THE RULE?**
- **WHAT CURRENT GOOD MANUFACTURING PRACTICES WERE UPDATED UNDER THIS RULE?**
- **WHAT ARE THE REQUIREMENTS REGARDING FOOD SAFETY PLANS?**
- **WHAT DO I DO IF A HAZARD COULD FIT UNDER DIFFERENT PREVENTIVE CONTROLS?**
- **WHAT IS THE FOOD SAFETY PLAN BUILDER? HOW DO I USE IT?**
- **ARE THERE ANY OTHER RESOURCES TO HELP ME FOLLOW THIS RULE?**

■ **DO THE REQUIREMENTS FOR PREVENTIVE CONTROLS FOR HUMAN FOOD APPLY TO ME?**

In general, the requirements apply to you if you manufacture, process, pack, or hold human food for consumption in the United States, whether your facility is domestic or foreign. The requirements apply to you if you are required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic (FD&C) Act. Entities defined as “farms,” retail food establishments, and restaurants are some of the entities that are not subject to the preventive control requirements because they are not required to register. In addition, there are several exemptions or modified requirements that may apply.

■ **DO THE REQUIREMENTS FOR CURRENT GOOD MANUFACTURING PRACTICES (CGMPs) APPLY TO ME?**

In general, the requirements apply to you if you manufacture, process, pack or hold human food. As with the preventive controls requirements, there are exemptions and modified requirements, but they are not identical.

■ **WHEN DO I HAVE TO BE IN COMPLIANCE WITH THE RULE?**

September 18, 2017: Small businesses (businesses with fewer than 500 full-time equivalent employees)

September 17, 2018: Very small businesses (averaging less than \$1 million per year (adjusted for inflation) in annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale)

September 17, 2018: Facilities subject to the Pasteurized Milk Ordinance (PMO) (for their Grade “A” milk and milk products); compliance date was extended to allow time for changes to the PMO to incorporate the requirements of this preventive controls rule)

* *All other businesses (also known as “large” businesses) were required to be in compliance on September 19, 2016. Note that compliance dates for some facilities and activities have been extended.*

SEE ALL FSMA COMPLIANCE DATES
<https://www.fda.gov/food/guidanceregulation/fsma/ucm540944.htm>

■ WHAT CURRENT GOOD MANUFACTURING PRACTICES (CGMPs) WERE UPDATED UNDER THIS RULE?

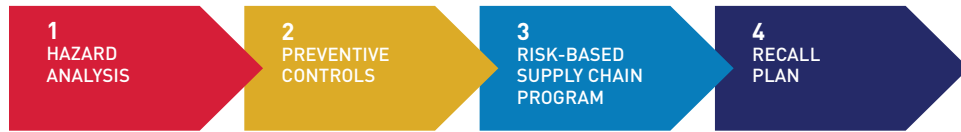
Now you are required to be in compliance with some provisions that were optional before.

- **Training:** Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties. The employees must be trained in the principles of food hygiene and food safety, including the importance of employee health and hygiene as appropriate to the food, the facility, and the individual’s assigned duties. Records of training must be maintained.
- **Allergen cross-contact:** FDA’s longstanding position that CGMPs address allergen cross-contact is now explicit in the regulatory text. You are required to employ practices and procedures to control allergen cross-contact.
- **Human food by-products used for animal foods:** The updated CGMPs contain provisions for holding and distributing human food by-products that are used for animal food.

**Human Food By-Products for Use as Animal Food
(Guidance for Industry - Draft)**

■ WHAT ARE THE REQUIREMENTS REGARDING FOOD SAFETY PLANS?

You, a domestic or foreign food facility, must (1) have and implement a written food safety plan that identifies food safety hazards that require a preventive control and (2) implement preventive controls to significantly minimize or prevent the hazard. The plan is required to include the following:



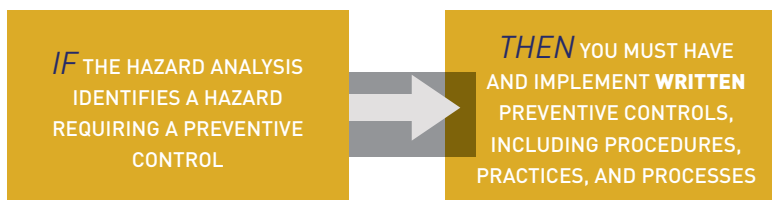
1 HAZARD ANALYSIS: You are required to identify any known or reasonably foreseeable (i.e., potential) biological, chemical, and physical hazards, and determine if any of those hazards require a preventive control.

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

Hazard Analysis and Risk-Based Preventive Controls for Human Food

Hazard analysis and risk-based preventive controls for human food [Draft Guidance for Industry]

PREVENTIVE CONTROLS: If the hazard analysis identifies a hazard that requires a preventive control, you are required to develop and implement a control to significantly minimize or prevent the hazard.



The rule outlines preventive controls and associated requirements that could include:

- process controls
- food allergen controls
- sanitation controls
- other controls

- **Process controls:** procedures, practices, and processes to control parameters during operations. Examples of process controls are cooking and refrigeration, and product formulation.
 - Associated requirements for process controls include, as appropriate, parameters (and minimum or maximum values) associated with the control of the hazard, monitoring, corrective actions, verification including validation as necessary, records
- **Food allergen controls:** procedures, practices, and processes to control allergen cross-contact within a facility and procedures to ensure all food allergens are correctly labeled.
 - Associated requirements for food allergen controls include, as appropriate, monitoring, corrective actions, verification, and records
- **Sanitation Controls:** procedures, practices, and processes to make sure the facility is maintained in a sanitary manner to control hazards such as environmental pathogens. Environmental monitoring is required if contamination of a ready-to-eat food with an environmental pathogen such as *Listeria monocytogenes* is a hazard requiring a preventive control.
 - Associated requirements for sanitation controls include, as appropriate, monitoring, corrective actions, verification (including environmental monitoring for an environmental pathogen or appropriate indicator organism as necessary), and records

[See Control of *Listeria monocytogenes* in Ready-to-Eat Foods \(Draft Guidance for Industry\)](#)

- **Other Controls:** preventive control procedures that are not process, food allergen, or sanitation controls, but are necessary to ensure that a hazard requiring a preventive control will be significantly minimized or prevented.
 - Associated requirements for other controls include, as appropriate, monitoring, corrective actions, verification, and records

Explaining the Oversight and Management of Preventive

Controls: Once a facility has identified a preventive control for a hazard, the facility must make sure that the controls are being met using the following actions:

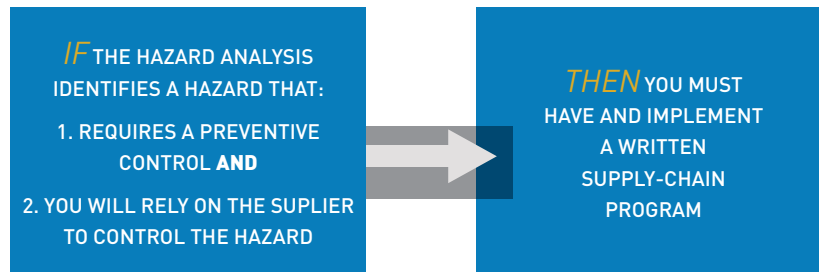
- **MONITORING:** These procedures are designed to provide assurance that preventive controls are consistently performed. Monitoring is conducted as appropriate to the preventive control. For example, monitoring of a heat process to kill pathogens would include recording temperature values. Monitoring must be documented.
- **CORRECTIONS:** These are steps taken, in a timely manner, to identify and correct a minor, isolated problem that occurs during food production.

(continued)

(continued)

- **CORRECTIVE ACTIONS:** These include actions to identify and correct a problem implementing a preventive control, reduce the likelihood the problem will recur, evaluate affected food for safety, and prevent that food from entering commerce if you cannot ensure that the affected food is not adulterated. Corrective actions must be documented with records.
- **VERIFICATION:** These activities are required to ensure that preventive controls are consistently implemented and effective in minimizing hazards. Examples of verification activities include scientifically validating process preventive controls to ensure that the control measure is capable of effectively controlling an identified hazard and calibrating (or checking the accuracy of) process monitoring and verification instruments such as thermometers. Verification activities also include reviewing records to ensure that monitoring and corrective actions (if necessary) are being conducted. Verification activities must be documented.
- Product testing and environmental monitoring are also possible verification activities, 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 is required if the contamination of a ready-to-eat food with an environmental pathogen is a hazard the facility identified as requiring a preventive control.

3 Risk-Based Supply Chain Program: If you are a manufacturer and identify a hazard related to ingredients you receive from a supplier and will depend on the supplier to control that hazard, you must have and implement a supply-chain program with appropriate verification activities.



Supply chain program must include:

- Using approved suppliers
- Determining appropriate supplier verification activities and frequency of those activities. They may include:
 - On-site audit
 - Sampling and testing of raw material
 - Review of suppliers' relevant food safety records
 - Other appropriate verification activities
- Conducting supplier verification activities
- Documenting supplier verification activities

When do I NOT need a supply-chain program?

- If you control the hazard at your own facility OR
- If the hazard will be controlled by a subsequent entity (such as another processor). Certain requirements are specific to this situation.

4 **Recall Plan:** If the hazard analysis identifies a hazard that requires a preventive control, you must have a written recall plan that includes the procedures that describe the steps to perform the recall and at minimum assigns responsibility for:

- Notifying the direct consignees of the food being recalled, including how to return or dispose of the affected food;
- Notifying the public about hazards in the food;
- Conducting effectiveness checks; and
- Appropriately disposing of the recalled product.

■ WHAT IS THE FOOD SAFETY PLAN BUILDER? HOW DO I USE IT?

The Food Safety Plan Builder is a software program that can help you develop a customized food safety plan for your facility. The program can be downloaded for free.

■ Food Safety Plan Builder Resources:

Download the [Food Safety Plan Builder](#)

Read the [User Guide](#)

How to use the Food Safety Plan Builder ([videos](#))

■ ARE THERE ANY OTHER RESOURCES TO HELP ME FOLLOW THIS RULE?

The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies.

You can also use the [FSMA TAN Popular Topics](#)

[FSMA Rules & Guidance for Industry](#)

[Training & Materials on Preventive Controls for Human Food \(FSPCA\)](#)

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



cGMP Resources



California Department of Public Health

[CDPH – Food and Drug Branch \(FDB\)](http://www.cdph.ca.gov/FDB)
(www.cdph.ca.gov/FDB)

[Industry Education and Training Unit](http://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/FoodIndustryTraining.aspx)
(www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/FoodIndustryTraining.aspx)

[FDB Labeling Guide](http://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/GeneralFoodLabelingRequirements.pdf)
(www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/GeneralFoodLabelingRequirements.pdf)

[Health and Safety Code \(Sherman Law\)](http://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/SFDCL.pdf)
(www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/SFDCL.pdf)

[California Retail Food Code \(CRFC\)](http://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/RetailFood/CRFC.pdf)
(www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/RetailFood/CRFC.pdf)

Academic Resources

[University of California Food Safety Extension](http://ucfoodsafety.ucdavis.edu/)
(<http://ucfoodsafety.ucdavis.edu/>)

[Cornell University Institute for Food Safety](https://instituteforfoodsafety.cornell.edu/)
(<https://instituteforfoodsafety.cornell.edu/>)

[North Carolina State University](https://fbns.ncsu.edu/)
(<https://fbns.ncsu.edu/>)

U.S. Food and Drug Administration (FDA)

[Main Page](http://www.fda.gov)
(www.fda.gov)

[Title 21 Code of Federal Regulations Part 117](http://www.ecfr.gov/cgi-bin/text-idx?SID=24fd382fb2c262f67a95dac0fe471b8f&mc=true&node=pt21.2.117&rgn=div5)
(www.ecfr.gov/cgi-bin/text-idx?SID=24fd382fb2c262f67a95dac0fe471b8f&mc=true&node=pt21.2.117&rgn=div5)

[Food Safety Plan Builder](http://www.fda.gov/food/guidanceregulation/fsma/ucm539791.htm)
(www.fda.gov/food/guidanceregulation/fsma/ucm539791.htm)

[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)
(www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/chemicalcontaminantsmetalsnaturaltoxinspesticides/ucm077969.htm)

[Defect Levels Handbook \(natural or unavoidable defects in foods that present no health hazards for humans\)](http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/sanitationtransportation/ucm056174.htm)
(www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/sanitationtransportation/ucm056174.htm)

[Food Safety Modernization Act FAQ's](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm)
(www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm)

[District Recall Coordinators](http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm)
(www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm)

[Reportable Food Registry](http://www.fda.gov/ReportableFoodRegistry)
(www.fda.gov/ReportableFoodRegistry)