FF9. Food facility and farm mixed-type facility requirements

When performed on food crops, activities such as size reduction, extraction, and sometimes dehydration[[1]](#footnote-1) are regulated by FDA as food processing[[2]](#footnote-2) that is subject to good manufacturing practice (GMP) regulations, even if they occur on a farm (in which case the farm is defined by FDA as a “farm mixed-type facility” that is generally required to register with FDA). The regulations in 21 CFR Part 117 form the foundation of U.S. food safety regulations; reproduced below are the requirements established in Part 117 for facilities, equipment, and personnel.

FF9.1 Regulations

i. Food facilities and farm mixed-type facilities that process conventional foods and/or dietary supplements for distribution in the U.S. are required to comply with 21 CFR Part 117 and/or Part 111, as well as other FDA regulations as applicable, even if the facilities are located outside the US.[[3]](#footnote-3)

ii. The following sections outline the minimum requirements for facilities, equipment, and personnel required under Part 117 for processors of conventional foods and dietary supplements. Operators of food facilities and farm mixed-type facilities must consult the full text of Part 117 and Part 111, as well as other FDA regulations as applicable, to determine the appropriate additional requirements for their operations.

FF9.2 Personnel

i. The management of the establishment must take reasonable measures and precautions to ensure the following:

1.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.

2. 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:

* 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.
* Maintaining adequate personal cleanliness.
* 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.
* 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.
* Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.
* Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.
* Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
* 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.
* 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).

FF9.3 Plant and grounds

i. 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.

ii. 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:

* Using protective coverings.
* Controlling areas over and around the vessels to eliminate harborages for pests.
* Checking on a regular basis for pests and pest infestation.
* 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.

FF9.4 Sanitary operations

i. 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.

ii. 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:

* Those required to maintain clean and sanitary conditions;
* Those necessary for use in laboratory testing procedures;
* Those necessary for plant and equipment maintenance and operation; and
* 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.

iii. 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.

iv. 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.

v. 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.

vi. 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.

FF9.5 Sanitary facilities and controls

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

1. 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.

2. Plumbing*.* Plumbing must be of adequate size and design and adequately installed and maintained to:

* Carry adequate quantities of water to required locations throughout the plant.
* Properly convey sewage and liquid disposable waste from the plant.
* Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.
* 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.
* 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.

3. Sewage disposal*.* Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.

4. 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.

5. 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.

6. 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.

FF9.6 Equipment and utensils

i. General requirements.

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.

ii. 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.

iii. 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.

iv. 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.

v. 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.

vi. 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.

vii. 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.

1. See the definitions of “farm,” “raw agricultural commodity,” and “processed food.” [↑](#footnote-ref-1)
2. “Processing” in this context includes “manufacturing,” because U.S. food regulations generally do not distinguish between “processing” and “manufacturing”; see the definition of “manufacturing/processing.” However, there is a subtle but important distinction between “manufacturing/processing” (as used in FDA food regulations) and “processing” (as used in U.S. law). (See the definition of “processed food” for more information.) [↑](#footnote-ref-2)
3. In addition to the requirements of U.S. food regulations, food manufacturers may also consider certification models such as from the Global Food Safety Initiative (GFSI). [↑](#footnote-ref-3)