



Good agricultural and collection practices and good manufacturing practices for botanical materials

Company Information

Company name			
Street Address			
City/State		Country	
Contact name		Contact phone	
Contact email		Company website	
Botanical material operation	<Describe the scope of the botanical material operation addressed by this form>		

This form is for use in conjunction with Section 9 Food Facility and Farm Mixed-Type Facility Requirements. Supporting information for specific elements can be attached to this form.

When performed on food crops, activities such as size reduction, extraction, and sometimes dehydration are regulated by FDA as food processing¹ 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.

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.

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.

¹ “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.)

Section 9 Food Facility and Farm Mixed-Type Facility Requirements

FF9 Food Facility and Farm Mixed-Type Facility Requirements		Assessment ¹	
Element	Description	Comply	N/A
FF9.1 Regulations			
FF9.1	The operation has registered as a food facility as applicable.		
Comments:			
FF9.2 Personnel			
FF9.2 i.1)	The management of the establishment takes reasonable measures and precautions to exclude persons with health conditions from any operations which may be expected to result in contamination of food until the condition is resolved.		
Comments:			
FF9.2 i.2)	All persons working in direct contact with food, food-contact surfaces, and food-packaging materials wear 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.		
Comments:			
FF9.2 i.2)	All persons working in direct contact with food, food-contact surfaces, and food-packaging materials maintain adequate personal cleanliness.		
Comments:			
FF9.2 i.2)	All persons working in direct contact with food, food-contact surfaces, and food-packaging materials wash hands thoroughly at appropriate times during work.		
Comments:			
FF9.2 i.2)	All persons working in direct contact with food, food-contact surfaces, and food-packaging materials remove or cover all unsecured jewelry and other objects that might fall into food, equipment, or containers, and remove hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand.		
Comments:			
FF9.2 i.2)	All persons working in direct contact with food, food-contact surfaces, and food-packaging materials maintain gloves, if they are used in food handling, in an intact, clean, and sanitary condition.		
Comments:			
FF9.2 i.2)	All persons working in direct contact with food, food-contact surfaces, and food-packaging materials wear hair restraints, where appropriate, in an effective manner.		
Comments:			

Section 9 Food Facility and Farm Mixed-Type Facility Requirements

FF9 Food Facility and Farm Mixed-Type Facility Requirements		Assessment¹	
Element	Description	Comply	N/A
FF9.2 i.2)	All persons working in direct contact with food, food-contact surfaces, and food-packaging materials store clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.		
Comments:			
FF9.2 i.2)	All persons working in direct contact with food, food-contact surfaces, and food-packaging materials do not eat food, chew gum, drink beverages, or use tobacco in areas where food may be exposed or where equipment or utensils are washed.		
Comments:			
FF9.2 i.2)	All persons working in direct contact with food, food-contact surfaces, and food-packaging materials take 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.		
Comments:			
FF9.3 Plant and grounds			
FF9.3 i.1)	Within the immediate vicinity of the plant, equipment is properly stored, litter and waste are removed, and weeds or grass are cut.		
Comments:			
FF9.3 i.2)	Roads, yards, and parking lots are maintained so that they do not constitute a source of contamination.		
Comments:			
FF9.3 i.3)	Areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests are adequately drained.		
Comments:			
FF9.3 i.4)	Systems for waste treatment and disposal are operated in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.		
Comments:			
FF9.3 i.5)	If the plant grounds are bordered by grounds not under the operator's control are not kept in a condition that will protect against the contamination of food, care is exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.		
Comments:			

Section 9 Food Facility and Farm Mixed-Type Facility Requirements

FF9 Food Facility and Farm Mixed-Type Facility Requirements		Assessment¹	
Element	Description	Comply	N/A
FF9.3 ii.1)	The plant construction and design provides adequate space for placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.		
Comments:			
FF9.3 ii.2)	The plant construction and design 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.		
Comments:			
FF9.3 ii.3)	The plant construction and design permit the taking of adequate precautions to protect food in installed outdoor bulk vessels by any effective means.		
Comments:			
FF9.3 ii.4)	The plant is constructed such that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair.		
Comments:			
FF9.3 ii.4)	The plant is constructed such that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials.		
Comments:			
FF9.3 ii.4)	The plant is constructed such 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.		
Comments:			
FF9.3 ii.5)	The plant is constructed to 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.		
Comments:			
FF9.3 ii.5)	The plant is constructed to 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.		
Comments:			
FF9.3 ii.6)	The plant is constructed to provide adequate ventilation or control equipment to minimize dust, odors and vapors in areas where they may cause allergen cross-contact or contaminate food.		

Section 9 Food Facility and Farm Mixed-Type Facility Requirements

FF9 Food Facility and Farm Mixed-Type Facility Requirements		Assessment¹	
Element	Description	Comply	N/A
Comments:			
FF9.3 ii.6)	Ventilation and other air-blowing systems are located and operated in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.		
Comments:			
FF9.3 ii.7)	Where necessary, adequate screening or other protection against pests is provided.		
Comments:			
FF9.4 Sanitary operations			
FF9.4 i)	Buildings, fixtures, and other physical facilities of the plant are maintained in a clean and sanitary condition and are kept in repair adequate to prevent food from becoming adulterated.		
Comments:			
FF9.4 i)	Cleaning and sanitizing of utensils and equipment is conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.		
Comments:			
FF9.4 ii.1)	Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures are free from undesirable microorganisms and are safe and adequate under the conditions of use. Compliance with this requirement is verified by an effective means.		
Comments:			
FF9.4 ii.2)	Toxic cleaning compounds, sanitizing agents, and pesticide chemicals are identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.		
Comments:			
FF9.4 iii)	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.		
Comments:			
FF9.4 iii)	The use of pesticides to control pests in the plant is performed only under precautions and restrictions that protect against the contamination of food, food-contact surfaces, and food-packaging materials.		
Comments:			
FF9.4 iv.1)	Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food are in a clean, dry, sanitary condition before use.		

Section 9 Food Facility and Farm Mixed-Type Facility Requirements

FF9 Food Facility and Farm Mixed-Type Facility Requirements		Assessment¹	
Element	Description	Comply	N/A
Comments:			
FF9.4 iv.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 are cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated.		
Comments:			
FF9.4 iv.2)	Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment are cleaned and sanitized as necessary.		
Comments:			
FF9.4 iv.3)	Single-service articles are 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.		
Comments:			
FF9.4 v)	Non-food-contact surfaces of equipment used in the operation of a food plant are 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.		
Comments:			
FF9.4 vi)	Cleaned and sanitized portable equipment with food-contact surfaces and utensils are stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.		
Comments:			
FF9.5 Sanitary facilities and controls			
FF9.5 i.1)	The water supply is adequate for the operations intended and is derived from an adequate source. Water that contacts food, food-contact surfaces, or food-packaging materials is safe and of adequate sanitary quality.		
Comments:			
FF9.5 i.1)	Running water at a suitable temperature, and under pressure as needed, is provided for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, and for employee sanitary facilities.		
Comments:			
FF9.5 i.2)	The plumbing system is of adequate size and design and is adequately installed and maintained.		
Comments:			

Section 9 Food Facility and Farm Mixed-Type Facility Requirements

FF9 Food Facility and Farm Mixed-Type Facility Requirements		Assessment¹	
Element	Description	Comply	N/A
FF9.5 i.3)	Sewage is disposed of into an adequate sewerage system or disposed of through other adequate means.		
Comments:			
FF9.5 i.4)	Employees are provided with adequate, readily accessible toilet facilities. Toilet facilities are kept clean and are not a potential source of contamination of food, food-contact surfaces, or food-packaging materials.		
Comments:			
FF9.5 i.5)	Hand-washing facilities are designed to ensure that an employee's hands are not a source of contamination.		
Comments:			
FF9.5 i.6)	Rubbish and any offal is conveyed, stored, and disposed of to protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.		
Comments:			
FF9.6 Equipment and utensils			
FF9.6 i.1)	All plant equipment and utensils used in manufacturing, processing, packing, or holding food are designed and of such material and workmanship as to be adequately cleanable, and are adequately maintained to protect against allergen cross-contact and contamination.		
Comments:			
FF9.6 i.2)	Equipment and utensils is designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.		
Comments:			
FF9.6 i.3)	Equipment is installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.		
Comments:			
FF9.6 i.4)	Food-contact surfaces are corrosion-resistant.		
Comments:			
FF9.6 i.5)	Food-contact surfaces are constructed 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.		
Comments:			

Section 9 Food Facility and Farm Mixed-Type Facility Requirements

FF9 Food Facility and Farm Mixed-Type Facility Requirements		Assessment¹	
Element	Description	Comply	N/A
FF9.6 i.6)	Food-contact surfaces are maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.		
Comments:			
FF9.6 ii)	Seams on food-contact surfaces are smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter.		
Comments:			
FF9.6 iii)	Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food is constructed so that it can be kept in a clean and sanitary condition.		
Comments:			
FF9.6 iv)	Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, are of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.		
Comments:			
FF9.6 v)	Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms is fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.		
Comments:			
FF9.6 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 are accurate and precise and adequately maintained, and adequate in number for their designated uses.		
Comments:			
FF9.6 vii)	Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment is treated in such a way that food is not contaminated with unlawful indirect food additives.		
Comments:			
¹ Assessments are used to indicate the compliance to or relevance of the specific element. Comply = Fully compliant or adherent to the element N/A = Not applicable to the operation			

Section 9 Food Facility and Farm Mixed-Type Facility Requirements

I attest that all the information contained in this form is correct to the best of my knowledge.

Signature: _____

Date: _____