GF5. General farm standards

Operations that grow and/or harvest crops are defined under U.S. regulations as “farms,” at least if the crop is a food crop. This includes wild collection operations. Farmers and wild collectors of fresh produce such as lettuce or blueberries are usually (depending on certain exemptions) subject to specific agricultural practice requirements established in 21 CFR Part 112. Irrespective of whether Part 112 applies to the farm, this section outlines recommended practices to ensure the quality and freedom from contamination of the crops produced.

GF5.1 General considerations

i. Farms (including wild collectors) that grow and/or harvest “covered produce” are required to comply with 21 CFR Part 112, unless the farm qualifies for one of the exemptions in Part 112.[[1]](#footnote-1) In general terms, “covered produce” refers to food that is:

1. A fruit (e.g., apples, bananas, blueberries, etc.).

2. A vegetable that is not always cooked prior to consumption (e.g., kale, mushrooms, radishes, etc.).

3. A culinary herb (e.g., mint, oregano, cilantro, etc.).

4. Other herbaceous plants from which parts other than the fruit are harvested for food use. [[2]](#footnote-2)

5. Sprouts, mushrooms, and nuts.

ii. The distinction between covered produce and other crops is based on food safety considerations.

1. Special regulations apply to the growing and harvesting of covered produce because these crops may be consumed raw and without further processing. In the absence of proper agricultural standards, a significant public health risk may exist due to potential contamination of the produce with pathogenic microorganisms. The agricultural standards in 21 CFR Part 112 are intended to prevent such contamination.

2. Crops other than covered produce are either not used for food, or almost exclusively are used for further processing or cooked by the consumer prior to consumption. Cooking destroys microorganisms, and food processors are required to implement procedures to mitigate the risk of microbial contamination. As a result, crops that are not covered produce do not require the same strict growing, harvesting, and handling practices to prevent microbial contamination that produce crops do.

iii. The guidelines in this section are intended to apply to farms (including wild collectors) that are *not* subject to Part 112. These guidelines are less strict and less extensive than those required in Part 112. Even so, it will not be possible for each of these recommendations to be implemented by every farm, especially those in remote locations or non-industrialized countries. Buyers of botanical materials used for food must evaluate any food safety hazards that may be present and take appropriate steps to mitigate the risks they present.

iv. Farms that are subject to Part 112 must consult the full text of Part 112 to determine the applicable requirements for their operations.

v. Food farms must note that certain activities commonly performed on farms, such as cutting or chopping the harvested crop, are regulated by the U.S. Food and Drug Administration (FDA) as food processing operations rather than as farm activities.

1. Farms that perform these activities are called “farm mixed-type facilities.”

2. If the food produced by a farm mixed-type facility is harvested in, or imported to, the U.S. then the facility is required to register with FDA as a food facility, and is required to comply with food processing Good Manufacturing Practices (GMPs).

3. Food processing operations are discussed further in Sections FP8 and FF9 of this document.

4. In addition, if a farm or farm mixed-type facility dehydrates raw agricultural commodities that are “produce”[[3]](#footnote-3) as defined in Part 112 to create a distinct commodity, then Part 117 Subpart B applies to the packaging, packing, and holding of the dried commodities. Compliance with this requirement may be achieved by complying with Part 117 Subpart B or with the applicable requirements for packing and holding in Part 112.

GF5.2 Farm buildings

Buildings used for farm activities that do not require food facility registration as defined in 21 CFR Part 117[[4]](#footnote-4) and that do not require compliance with Part 117 Subpart B should meet the following standards at a minimum.

i. Farm buildings should be of suitable design and sound construction, and should be maintained in good repair.

ii. Location. Farm buildings should preferably be located in areas that are not subject to flooding and that are away from objectionable odors, smoke, dust, pests, or other contaminants.

iii. Light. Farm buildings should provide sufficient space and light to accomplish the activities performed in the building.

iv. Pest control. Design, manage, and monitor farm buildings to keep out pests, including insects, rodents, and other animals. Maintain records of pest control, including any chemical pest control measures used, for at least several years. Where the harvested crop is intended for food use, ensure all pest control chemicals used inside the buildings or in proximity to the harvested materials are permitted for use around food, and use them strictly in accordance with the label instructions.[[5]](#footnote-5)

v. Order and cleanliness. Design and maintain farm buildings with sufficient order and cleanliness to prevent contamination of crops handled in these locations, including cross-contact with allergens where applicable. Consider segregating the storage of organic from non-organic materials, and GMO from non-GMO materials. Maintain records of building cleaning for at least several years.

vii. Grounds. Minimize the presence of trash, landscape plants, pooling water, and other harborage for pests around the exterior of farm buildings.

viii. Waste. Provide adequate storage for waste, recycling, and unusable materials prior to removal from the premises. Ensure waste is stored and removed properly to avoid attracting animals, releasing mold spores, or otherwise creating contamination.

GF5.3 Farm equipment

Equipment (including utensils) used for farm activities that do not require facility registration as defined in 21 CFR Part 117[[6]](#footnote-6) should meet the following standards.

i. Equipment should be suitable for its purpose and properly functioning. This includes mechanical equipment, wagons, buckets and other containers, tarps, hand tools, brooms and brushes, etc.

ii. Design and installation. Design and install farm equipment in a manner that permits easy access for cleaning and maintenance.

iii. Construction. Use only equipment made of non-toxic and non-corrosive materials, especially for those parts that come in contact with the botanical material. Avoid equipment having parts that contact the crop that are difficult to easily and thoroughly clean, such as parts made of absorbent materials or parts that are not physically accessible. If absorbent materials are used (e.g., wood), ensure such use does not present a risk of unacceptable contamination. Avoid use of glass, brittle plastic, and other such materials that may introduce physical contaminants.

iv. Maintenance. Examine all farm equipment and maintain in proper working order; repair as necessary. Maintain records of equipment maintenance for at least several years.

v. Cleanliness. Maintain all equipment in clean condition. Pay particular attention to ensuring that those parts of equipment that come in direct contact with the crop are clean and free of potential contaminants (e.g., chipping paint, lubricants, insects or other pests, etc.). Store clean equipment away from sources of contamination, and keep equipment properly labeled as to cleaning status (clean vs. dirty). Maintain records of equipment cleaning for at least several years.

vi. Absence of cross-contamination. Remove remnants of any prior botanical material from equipment to prevent cross-contamination. Where cross-contact with allergens is possible (e.g., where equipment has been used with a gluten-containing grain), ensure the equipment is thoroughly cleaned prior to use for the next crop; or consider use of dedicated equipment for the allergen-containing crop.

vii. Storage containers. Do not use botanical material containers to hold or contain non-plant materials, such as tools or chemicals. Where cross-contact with allergens is possible, consider using separate containers that are dedicated to the allergen-containing crop. Ensure containers provide adequate protection for the plant material during storage, and are labeled appropriately as to the contents (e.g., with identity of the crop; lot number; grade such as organic or non-GMO, especially when needed to distinguish between similar crops on the same farm; presence of any allergens; etc.).

viii. Field press. Consider having a field press available to take vouchers of harvested plants.

ix. Toilets. Provide appropriate toilet facilities in farm buildings and provide portable toilets at field locations.[[7]](#footnote-7) Ensure toilet facilities comply in number, location, installation, and function (including effluence, drainage, and sewage functions) with applicable local, state, and federal regulations. Ensure toilets are stocked with toilet paper and single-use paper towels and are maintained in clean and functioning condition.

x. Hand wash facilities. Provide hand washing facilities with soap and running water (preferably hot water) in farm buildings and at field locations.

xi. Safety equipment. Provide personal protective equipment or other safety equipment as appropriate.

xii. First aid kit. Have a first aid kit available to workers, including bandages, hydrogen peroxide, antibiotic ointment, gloves, and other wound protecting material.

xiii. Transport equipment. Provide suitable conveyances to transport tools and other equipment, supplies, personnel, and the botanical material.

xiv. Training. Ensure that all personnel are properly trained in the use of the equipment, especially mechanized equipment, and that equipment is operated in a manner that ensures the safety of the operators and avoids or minimizes damage to the botanical material.

GF5.4 Farm personnel

i. Ensure that all personnel have the appropriate training and/or experience to perform their duties properly.

1. At a minimum, personnel should be familiar with appropriate handling practices for botanicals, safety procedures, hygienic procedures (e.g., handwashing, basic first aid to cover minor cuts in the field, etc.), equipment operation, and any tasks relevant to their job function.

2. For wild harvesting, ensure collectors are familiar with sustainable harvest practices and are able to properly identify the target botanical and distinguish it from any local species that may be confused with the target species.

3. Maintain records of training and other qualifications for at least as long as the employee or collector performs work for the farm.

ii. Ensure personnel wear appropriate work clothing and shoes. Provide additional garments as needed, such as water-proof boots or raingear.

iii. Protect personnel from adverse environmental exposures to the extent possible, such as extreme heat or cold, noxious plants, harmful insects or animals, excessive noise or dust, etc.

iv. Establish hand washing requirements for personnel working in post-harvest handling operations. Personnel should wash their hands before work, after using the bathroom, after meals, and any other time their hands are soiled.

v. Do not allow personnel to work handling botanical material if they are sick or if they have open wounds, sores, or skin infections.

GF5.5 Records

i. In addition to specific records mentioned elsewhere in this document, accurate records should be prepared for each stage of site selection, planting, cultivation, harvest, and post-harvest handling as applicable.

ii. All records with relevance to a particular cycle of crop cultivation and/or harvest should preferably be retained past the time when the harvested crop is no longer in the marketplace, which may be several years or more.[[8]](#footnote-8)

1. See Appendix 2 for more information. [↑](#footnote-ref-1)
2. According to a strict reading of the definition of “produce,” many crops that are not actually used as fresh fruits and vegetables are covered by Part 112, such as orris, goldenseal, and marshmallow. It is unclear to what extent FDA will prioritize enforcement of Part 112 for these crops. [↑](#footnote-ref-2)
3. Note that this establishes a requirement applicable to all produce, not just “covered produce” as defined in Part 112. [↑](#footnote-ref-3)
4. See Appendix 3. [↑](#footnote-ref-4)
5. Any pest control chemicals applied directly to the harvested crop must be explicitly permitted for use on the specific crop in question, as discussed in Sections D1 and BQ2. [↑](#footnote-ref-5)
6. See Appendix 3. [↑](#footnote-ref-6)
7. Note that depending on the harvest location it may not be possible to provide toilet and/or hand-wash facilities. [↑](#footnote-ref-7)
8. Even when the harvested crop is sold in fresh form (i.e., a perishable form that might be expected to leave the marketplace quickly), downstream companies may process (e.g., by drying or extracting) the material into a shelf stable form that remains in the marketplace for years. [↑](#footnote-ref-8)