PH7. Post-harvest handling

Post-harvest activities are critical to ensuring the botanical material meets appropriate quality specifications. Temporary storage, sorting and inspection, washing and cleaning, and dehydration are steps commonly applied to the harvested material; these require proper attention in order to prevent degradation and contamination.

This section recommends basic practices to be used on farms of all types; it does not include any specialized requirements established in 21 CFR 112 for covered produce farms.

In most cases, these activities when applied to food crops on a farm are regulated by FDA as farm activities, rather than food processing activities; however, in some cases FDA may consider certain routine farm activities to be food processing subject to food GMPs. Some of these circumstances will be noted in the section below.

PH7.1 Handling immediately after harvest

i. The harvested crop should be handled, stored, and consolidated in a manner that ensures that the harvested material does not degrade.

ii. Avoidance of compaction. In general, do not fill or stack sacks or other harvest containers to levels that will result in compacting of harvested materials, as this may cause physical damage as well as temperature build-up and overheating.

iii. Protection from external sources of contamination. Protect the harvested material from contact with birds, rodents, insects, and other animals, as well as dirt, dung, smoke, and exhaust.

iv. Protection from the elements. Protect the harvested material from exposure to the elements as appropriate. In most cases the material should be protected from direct sunlight, rainfall, freezing, etc., except where such exposure is required for a specific purpose such as sun-drying or bletting.

v. Timing. Where applicable, minimize the transit time from the point of harvest to the location used for consolidation and cleaning. (However, this may not apply where additional steps are required to prepare the crop for use, such as sun-drying.) Plant materials should be promptly unloaded and unpacked upon arrival.

vi. Examination. If harvested materials are brought from diverse locations or collectors to one location for consolidation and cleaning, examine the harvested material upon arrival to determine whether the material appears to be generally uniform and acceptable.

vii. Consolidation. If multiple harvest lots are consolidated together, assign a new lot number to the combined harvest. Maintain records of the individual lot numbers and quantities combined together.

viii. Temperature and moisture control. Ensure that both the temperature and moisture of the harvested material are controlled throughout post-harvest handling as appropriate to prevent degradation. Use of refrigeration, packing in dry ice, or other cooling steps may be used when needed and appropriate.

PH7.2 Separating the desired plant part

i. For certain materials, additional steps are required to separate the target plant part. For example, in some species the outer bark of the trunk, branches, or roots is removed (referred to as “rossing”).

ii. Such steps that serve to isolate the desired plant part are generally defined by U.S. regulation as farm activities (rather than food processing activities).[[1]](#footnote-1)

PH7.3 Washing and cleaning

Many harvested materials, especially roots, need to be washed after harvest to remove dirt and soil. Cleaning is also needed to remove any foreign matter that may have been inadvertently mixed in with the harvest.

i. Washing may be performed under running water, with spray nozzles (where this will not damage the plant material), or by soaking. It may be advantageous to use separate containers for different stages of washing and rinsing.

ii. The following recommendations apply to washing and cleaning operations on a farm.[[2]](#footnote-2)

1. Water quality. Use only potable water for washing the harvested plant material.[[3]](#footnote-3)

2. Building design. Carry out washing operations in a building or room designed to prevent build-up of mud and other possible sources of contamination. Washing areas should be isolated from areas where other steps are performed.

3. Drainage. Provide adequate drainage from the washing site, sufficient to dispose of peak water usage. The drainage system should be designed to avoid contamination of potable water supplies.

4. Drying. Arrange and handle washed crop material in a manner that ensures wash water is adequately removed from the cleaned material.

5. Removal of foreign matter. Either before or after washing, inspect for and remove all visible foreign matter and sub-standard material. Ensure the botanical material is sufficiently well displayed for ready visibility (e.g., on a conveyor, or spread out on tables, screens, or tarps). Foreign matter includes plant material from other species or from other parts of the harvested species; soil and rocks; insects and other animals; and wire, glass, paper, tools or tool parts, and other man-made objects. Sub-standard material includes, for example, discolored leaves or flowers; immature, overripe, or badly bruised fruits; or any other material that would cause the botanical material not to meet its specifications.

iii. Records.

1. Records should be kept of the washing and cleaning performed, including the identity, lot number, and the quantity of botanical material before and after cleaning; the location, date, and person(s) involved; the equipment used; and other information as appropriate.

2. Records should be kept of the water source and water quality used for washing and cleaning.

3. Records should be kept of general cleaning procedures and also any crop-specific cleaning procedures.

4. Maintain these records for at least several years, or as required by regulation.

PH7.4 Dehydration

Many of the plants that are grown or collected for use in food must be properly dried prior to use, and drying of plant materials is often performed by the same individuals and companies that harvest the plants. Drying conditions can either preserve or degrade naturally occurring botanical constituents and can greatly affect the quality of the material. Insufficient drying can result in microbial or mold growth, while either insufficient or excessive drying can result in degradation of organoleptic characteristics and botanical constituents. Adherence to proper dehydration conditions is therefore essential when drying is performed.

i. Where the botanical crop will be distributed in the U.S. and is intended for use in food (as opposed to non-food uses such as for biofuels, pharmaceuticals, clothing, household products, cosmetics, etc.), FDA regulations may apply to the drying process.

ii. Under current FDA regulations, the drying of botanical food crops on a farm (including those used for conventional foods and for dietary supplements) may be, but is not always, considered an activity that falls within the definition of a “farm.”

1. Dehydration of a raw agricultural commodity that results in creation of a distinct food commodity is considered “manufacturing/processing.”[[4]](#footnote-4) For example, drying grapes into raisins, apricots into dried apricots, fresh peas into dried peas, and fresh chilis into dried chilis are all manufacturing/processing operations.[[5]](#footnote-5)

2. Dehydration accompanied by another activity that is itself defined as a manufacturing/processing operation and is not part of “harvesting,” “holding,” or “packing,” such as slicing or chopping, is a food processing operation rather than a farm activity. For example, if echinacea root is sliced and then dried, the drying is considered a food processing operation rather than a farm activity because slicing is defined as manufacturing/processing and the echinacea turns into a “processed food” as soon as it is sliced.

3. Dehydration of a raw agricultural commodity on a farm that does not result in the creation of a distinct food commodity and does not involve other manufacturing/processing operations is considered a farm activity.[[6]](#footnote-6) For example, the drying of hay, cinnamon bark quills, or ginkgo leaf on a farm is a farm activity.

iii. Under current FDA regulations, a farm that conducts dehydration of crops for distribution in the U.S. as food may be considered either a “farm” or a “farm mixed-type facility” depending on the nature of the activities performed.

1. If the farm performs only dehydration that is within the definition of a farm activity in the definition of “primary production farm,” then FDA considers it a “farm.” As such, the drying performed on the farm is not subject to FDA food processing regulations such as 21 CFR Part 111 or 21 CFR Part 117, except that (as per 21 CFR § 117.5 (k)(2)), if a “farm” or “farm mixed-type facility” dehydrates raw agricultural commodities that are “produce”[[7]](#footnote-7) 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; and 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.[[8]](#footnote-8)

2. If the farm performs dehydration that is outside the definition of a farm activity, then FDA considers it a “farm mixed-type facility.” Such a facility is generally (subject to certain exemptions) required to register with FDA as a food processing facility, and is generally (subject to certain exemptions) required to comply with the Good Manufacturing Practices (GMPs) established in 21 CFR Part 117 and/or 21 CFR Part 111[[9]](#footnote-9) as well as other relevant FDA regulations, at least for those activities that are outside the farm definition.

iv. Irrespective of its regulatory status and whether the material being dried will be used for food or for a non-food purpose, drying processes should meet the following guidelines.

1. Timing. Conduct the dehydration process as quickly as possible after the harvested crop is ready for drying. This is often immediately after harvest, but in some cases, such as where bletting is required, a delay may be necessary.

2. Sunlight and shade. As a general rule, flowers and leaves in which color preservation is important should be dried in the shade, unless otherwise specified. Direct sunlight may be utilized for drying when appropriate.

3. Temperature control. The optimal drying temperature differs for various plants and plant parts; however, an air temperature of 110° F or 45° C is appropriate for a wide range of botanical materials. Drying should be completed quickly enough to minimize growth of spoilage organisms or (where relevant) pathogens. Some plants, however, are particularly susceptible to excessive temperatures and may require use of a lower temperature. Establish and maintain a temperature that is appropriate for the specific crop and do not allow the temperature in the drying facility or in the botanical material itself to exceed the range at which damage to the quality of the crop may occur.

4. Cutting before drying. When the harvested crop consists of items that are large or contain a high level of moisture (e.g., fruit), slice, chop or split these into relatively uniform pieces to ensure they dry quickly, thoroughly, and consistently.[[10]](#footnote-10)

v. Air drying. Many operations conduct drying processes in open air, either outdoors or in enclosed areas. On farms drying may be performed in the field or in barns or sheds, while food drying that is outside the “farm” definition must occur in a building that meets the requirements of the applicable food processing regulations. Drying may rely entirely on ambient heat or may also use artificial heat. The following practices are essential to all such operations.

1. Design outdoor drying operations with sufficient covering over the dehydrating botanical material (e.g., a net, tarp or roof) to protect against contamination from birds and other flying animals. Also, establish procedures to rapidly provide cover in case of rain or other events that could interrupt the drying process or contaminate the in-process material.

2. Design indoor drying operations to ensure that there is sufficient ventilation for airborne moisture to escape.

3. In both outdoor and indoor settings, provide adequate air circulation throughout the drying area, for example by installing fans as needed or by monitoring natural air circulation.

4. Place material to be dried in thin layers on clean surfaces that afford adequate air circulation. Use food-grade surfaces if the crop is a food crop.

5. Carefully turn the dehydrating material as needed to facilitate rapid and complete drying.

6. If heaters or other sources of artificially generated heat are used in the drying operation, provide adequate ventilation of the heating equipment, and use only fuels that will not result in smoke or other combustion products coming into contact with the crop and thereby contaminating the material.[[11]](#footnote-11)

vi. Mechanical drying. If using mechanical drying equipment, such as belt, drum, rotary, or oven-tray dryers, follow all manufacturer instructions and established operating procedures to ensure that quality of the botanical material is maintained.

vii. Finished moisture content. Ensure that the moisture content of the material after drying conforms to any established specifications. If a moisture specification is expressed quantitatively (e.g., 12 percent), use adequate analytical tests to accurately measure moisture content.

viii. Records.

1. Records should be kept of the drying performed, including the identity, lot number, and quantities of botanical raw material and dried product; the location where drying occurs; the dates (and where applicable the times) when drying begins and ends; the person(s) involved; the equipment used; the temperature used, especially if a controlled temperature is specified; and other information as appropriate. The moisture content of the dried material should also be recorded if a quantitative moisture limit has been established.

2. Records should be kept of general drying procedures and any crop-specific drying procedures.

3. Maintain these records for at least several years, or as required by regulation.

ix. Keep a retention sample of each lot of dehydrated material.

1. Label the retention sample with the botanical identity, lot number, and any other relevant information.

2. Store the sample in a manner to protect against insects, microbial growth, moisture, excessive heat, and other sources of degradation.

x. Maintain the retention sample in storage for several years or as long as the records associated with the lot are retained.

1. In the preamble to the proposed rule (78 FR 3540, 2013, Table 1), FDA designates “Activities designed only to isolate or separate the commodity from…other parts of the plant” as activities that do not transform a raw agricultural commodity into a processed food. When performed on a farm or farm mixed-type facility, these activities are part of “harvesting” rather than “manufacturing/processing.” [deleted because slightly inaccurate; and also redundant so not needed] (See also the 1998 Joint EPA/ FDA Policy Interpretation ([63 FR 54532](https://www.gpo.gov/fdsys/pkg/FR-1998-10-09/pdf/98-27261.pdf), 1998) and the 1999 FDA [Guidance for Industry: Antimicrobial Food Additives](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-antimicrobial-food-additives), July 1999.) [↑](#footnote-ref-1)
2. For washing and cleaning performed in a registered food facility, additional requirements apply; see section FF9. [↑](#footnote-ref-2)
3. EPA’s primary drinking water standards can be found at <https://www.epa.gov/ground-water-and-drinking-water/table-regulated-drinking-water-contaminants>. [↑](#footnote-ref-3)
4. Dehydration that does not create a distinct food commodity is considered part of “holding” (see the definition of “holding”). [↑](#footnote-ref-4)
5. Although such dehydration to create a new commodity is considered “manufacturing/processing,” it does not create a requirement for the farm to register as a “farm mixed-type facility” unless other manufacturing/processing is performed that is outside the farm definition. Dehydration by itself remains fully within the definition of “farm” whether or not a new commodity is created by the drying. See the definition of “primary production farm.” [↑](#footnote-ref-5)
6. Specifically, such dehydration is defined as “holding” by the farm, because the dehydration is necessary for proper storage of the food. See the definition of “holding.” [↑](#footnote-ref-6)
7. Note that this establishes a requirement applicable to all produce, not just “covered produce” as defined in Part 112. [↑](#footnote-ref-7)
8. If the farm dries and sells botanicals that are simply packaged and marketed as dietary supplements, without any other manufacturing/processing steps performed by the farm’s customers, FDA may consider the farm to be a manufacturer of dietary supplements and therefore subject to 21 CFR Part 111. See section DI10 of this document for further information. [↑](#footnote-ref-8)
9. See Sections FF9 and DI10 regarding the applicability of 21 CFR Part 117 and Part 111. [↑](#footnote-ref-9)
10. Note that FDA considers cutting, chopping, etc. to be food processing operations, so farms that perform these activities will be subject to the food GMPs in 21 CFR Part 117 and elsewhere, at least with respect to the cutting operations and subsequent drying and processing operations. [↑](#footnote-ref-10)
11. As mentioned previously, smoke may contaminate the material with hazardous PAHs, which are often an undesirable contaminant in botanical materials. Many governments have established limits for PAHs in food and other products. [↑](#footnote-ref-11)