FP8. Further processing and handling

After being cleaned and often dried, the botanical material may be packed and held for distribution, or it may first be subject to additional processing such as size reduction or extraction. As with other activities, these steps should be optimized appropriately in order to prevent degradation or contamination.

FP8.1 Special preparation

i. Certain botanical materials may require specialized preparation, as by roasting, frying, steaming, etc. These are particularly common traditional preparations for Ayurvedic and Asian botanical materials.

ii. Such preparations are outside the scope of this document, but should be done in a manner that ensures the prepared material meets established specifications, and should be done by appropriately trained personnel, using appropriate procedures and equipment. Appropriate records should be kept for at least several years.

FP8.2 Size reduction

i. Plant material can be traded in a number of forms, including whole, chopped, cut and sifted, teabag cut, shredded, and powder. Cutting or chopping of plant materials can occur either before or after dehydration, while milling to powder is normally performed after drying. Size reduction operations should be conducted with practices that ensure that the material’s quality and purity are maintained.

ii. Where the botanical crop is intended for use in food (as opposed to non-food uses such as for biofuels, pharmaceuticals, clothing, household products, cosmetics, etc.), cutting (other than cutting that serves to separate the desired plant part from the rest of the plant), milling, and other size reduction steps are defined by FDA as food processing operations. Therefore, any farm (including wild harvest operations) that performs these activities on a food crop is a “farm mixed-type facility” under FDA regulations, and is generally (subject to certain exemptions) required to register with FDA as a food processing facility and to comply with 21 CFR Part 117 and/or Part 111 as well as other relevant FDA regulations, if the material will be distributed in the US. This applies even if the farm is located outside the US.

iii. Timing. Where possible, size reduction operations are preferably performed as close to the time of manufacture of finished products as possible, in order to reduce quality degradation that may be associated with storage of cut or powdered forms.

iv. Advance cleaning and preparation. Before size reduction, perform any necessary cleaning and screening steps. These may include, for example, use of a de-stoner, a gravity separator, or a metal detector. The material should also be inspected as appropriate to remove foreign or otherwise unacceptable material, such as foreign plant parts, foreign species, foreign objects, moldy pieces, etc.

v. Protection of operators. Provide adequate ventilation in the size reduction facility to protect operators’ health. Also provide any needed protective gear, such as dust masks or respirators, eye protection, and ear plugs.

vi. Dust control. Ensure milling facilities are equipped with suitable dust control equipment to minimize the chance of explosion (airborne botanical dust is highly combustible) and to minimize the spread of cross-contamination and allergens. Milling should be performed in a separate room or building from other process steps.

vii. Temperature control. Do not allow the temperature in milling equipment to rise above the temperature at which damage to the quality of the botanical material may occur.

viii. Size requirements. Ensure that the material after size reduction meets all established specifications with regard to particle size, length, and/or density requirements.

ix. Metal detection. After size reduction, it may be prudent to pass the material through a magnet bank or metal detector to ensure that any metal fragments from the equipment or screens are removed.[[1]](#footnote-1)

x. Records.

1. Records should be kept of the size reduction performed, including the identity, lot number, and quantities of botanical raw material and cut or milled product; the identity, lot number, and quantity of any processing aids or excipients used; the location, date, and person(s) involved; the equipment used; the size after processing; and other information as appropriate.

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

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

xi. Keep a retention sample of each lot of material after size reduction.[[2]](#footnote-2)

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. If the sample consists of fresh plant material, store the samples in a frozen or dried state.

3. Maintain the retention sample in storage for several years, or as long as the records associated with the lot are retained, or as required by regulation.

FP8.3 Extraction

i. Plant material may be extracted using various solvents and various extraction technologies.[[3]](#footnote-3)

ii. Extracting a botanical material for food use (as opposed to a non-food use such as for biofuels, pharmaceuticals, clothing, household products, cosmetics, etc.) is considered a food processing operation by FDA. Facilities that perform food extraction are generally (subject to certain exemptions) required to register with FDA as a food processing facility and to comply with 21 CFR Part 117 and/or Part 111 as well as other relevant FDA regulations, if the extracted material will be distributed in the US. This applies even if the facility is located outside the US.

iii. The extraction process and conditions should be chosen based on the desired characteristics of the final product (e.g., flavor, content of marker substances, etc.).

iv. Preparatory steps. Prior to extraction, perform any necessary cleaning and screening and, if necessary, cut, chop, or mill the cleaned material to a defined particle size. Perform other preparatory steps as appropriate.

v. Extraction. Extract the prepared material using a specified extraction technology (e.g., maceration, percolation, steam distillation, etc.) and a defined solvent or mixture of solvents (e.g., water, 30% ethanol in water, supercritical carbon dioxide, etc.). Extraction conditions should be defined to the extent necessary for the applicable technology; these may include temperature, pressure, agitation, extraction time, ratio of solvent to crude botanical, number of repeated extractions of the same crude botanical, etc.

vi. Post-extraction processing. After extraction, separate the liquid extract from the spent botanical material through decanting, filtering, pressing, or centrifuging, then concentrate the liquid to remove the solvent as appropriate. Perform any additional processing appropriate for the extract, such as:

1. Concentration of desirable constituents.

2. Removal of undesirable constituents.

3. Pasteurization.

4. Addition of excipients.

5. Drying.

6. Milling to a powder.

7. Metal detection.

vii. Protection of operators. Provide adequate ventilation in the extraction facility to protect operators’ health and prevent the buildup of combustible vapors. Also provide any needed personal protective equipment, and provide hazardous material training for any solvents or other chemicals used.

viii. Records.

1. Appropriate records should be kept of the extraction performed, including the identity, lot number, and quantity of botanical raw material extracted; the identity, lot number, and quantity of any processing aids or excipients used; the identity, batch number, and quantity of final extract; the location, dates, and person(s) involved; the equipment used; the equipment settings used and actual readings obtained; and other information as appropriate.

2. Records should be kept of general procedures for each manufacturing process and any crop-specific manufacturing procedures.

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

ix. Keep a retention sample of each lot of material after extraction.

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. If the sample consists of liquid extract that is not shelf stable, store the samples in a frozen state.

3. Maintain the retention sample in storage for several years, or as long as the records associated with the lot are retained, or as required by regulation.

FP8.4 Packing, packaging, and storage

i. The use of adequate packing or packaging equipment and materials will affect the quality of packed or packaged botanical materials, as will storage conditions.

ii. The following practices are relevant to packing, packaging, and storage operations for botanical materials in bulk.

iii. Packing and packaging materials. Drums, boxes, bags, liners, etc. should be constructed of appropriate materials that pose no risk of introducing contamination to the botanical material.

1. Packing/packing materials that directly contact a botanical material intended for food use should be made of materials that are suitable for contact with foods and/or drugs.

2. Do not reuse packing/packaging materials that cannot be properly cleaned (and sanitized where appropriate).

3. Packing/packaging material that includes recycled material is acceptable so long as the recycling process results in material that poses no risk of contamination.

4. Where the botanical material will eventually be distributed into the State of California, avoid the use of packing/packaging materials that contain bisphenol A (BPA), which is regulated under California Proposition 65.[[4]](#footnote-4)

iv. Tamper evidence. Where appropriate, ensure packing/packaging is equipped with tamper-evident features. This is particularly important if the botanical material is for food use.

v. Suitability. Use only packing/packaging material that is appropriate for its intended use.

1. Plant materials to be shipped in fresh form (e.g., fresh fruits or herbs) require proper packing to prevent bruising, compaction, spoilage, and other damage. Containers for fresh plant material should be designed to allow adequate air circulation.

2. Dried botanical materials should be protected from excessive humidity. Use of packing/packaging materials that form an adequate moisture barrier may be necessary, especially if the finished material is hygroscopic (e.g., powdered botanical extracts). Use of desiccants inside the containers may also be appropriate.

3. Some botanical materials may require protection from light. Such materials should be packed or packaged in amber-colored or opaque containers.

4. Some botanical materials may require protection from oxygen. Such materials should be packed or packaged with an appropriate oxygen barrier, such as glass or foil containers. Use of oxygen-absorbers inside the containers may also be appropriate.

5. Botanical materials that contain a high level of essential (volatile) oils should be stored in non-plastic containers.

vi. Labeling. Labels must be clearly printed, permanently affixed, and conform to any labeling regulations in the country in which the material was produced and in any countries to which it is intended to be shipped. Labels or labeling of bulk botanical materials should include the following information:

1. Plant name (including scientific name, common English name, and other identifying information where applicable, such as variety, cultivar, hybrid, patent number, etc.);

2. The part of the plant;

3. The form of the material (e.g., whole, teabag cut, powder, extract, etc.);

4. The grade or certification, where applicable (e.g., organic, biodynamic, Kosher, USP, etc.);

5. Other descriptive information, where applicable (e.g., wildcrafted, steamed, etc.);

6. The lot number;

7. The fact that a material has been sterilized using ionizing radiation, if applicable;[[5]](#footnote-5)

8. The name and contact information of the grower, manufacturer, and/or distributor;

9. The country of harvest, collection, and/or manufacture;

10. The date of harvest, collection, production, and/or expiration;

11. The net quantity by weight or volume;

12. The seller’s and/or buyer’s item number, if any;

13. The identity of substances added to the material, if any (e.g., anticaking or flow agents used in a milling operation, excipients or other ingredients added to extracts, etc.).

vii. Storage. Store botanical materials in cool, dry areas away from direct sunlight and off the ground. Storage facilities should be dry, well ventilated, and have sufficient insulation or other temperature-control features to avoid extreme temperature fluctuations. Storage facilities should be appropriately designed and maintained to exclude insects and other pests from the facility. Ensure storage facilities are not inappropriately fumigated with chemicals that may contaminate the botanical material.

viii. Separation from non-food storage. Segregate storage of botanical materials from storage of chemicals and other non-food items.

ix. Control of odor absorption. Where necessary, segregate botanical materials that are high in essential oils so that other herbs do not inadvertently absorb their odors. For example, peppermint leaf should not be stored in close proximity to black tea leaf unless it is in well-sealed, airtight containers.

x. Records.

1. Appropriate records should be kept of the packing or packaging performed, including the identity, lot number, and quantity of botanical material; the packing or packaging materials used, including any associated lot numbers; a sample of the label used; the location, date(s), and person(s) involved; any equipment used; and other information as appropriate.

2. Records should be kept of general procedures for packing or packaging and any crop-specific packing or packaging procedures.

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

xi. If the botanical material is packaged in retail form, keep a retention sample of each packaged lot.

1. Label the retention sample with the product name, 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. If the product is not shelf stable, store the samples in a frozen state.

3. Maintain the retention sample in storage for several years, or as long as the records associated with the lot are retained, or as required by regulation.

FP8.5 Shipping

i. The quality of botanical materials must be maintained through the shipping procedures, and these should be designed and carried out to minimize damage and degradation.

ii. Botanical materials that are represented as conforming to various certifications (e.g., organic, biodynamic, or Kosher) must bear clearly stated shipping and handling instructions to prevent cross-contamination and invalidation of the certification. The details of such instructions are not addressed here and are the responsibility of companies shipping any such certified goods.

iii. Secondary shipping containers and pallets. Ensure that the secondary shipping containers into which packed or packaged botanical materials are placed are suitable for transporting food products, where applicable, and are designed to meet any special needs of the material. Ensure secondary containers and pallets are clean and dry and are not inappropriately fumigated with chemicals that may contaminate the botanical material.

iv. Carriers. Ship botanical materials via carriers that are suitable for transportation of food products, if applicable. Special emphasis should be placed on temperature control and ventilation where necessary, such as for shipments of fresh materials. Ensure botanical materials intended for food use (including both conventional foods and dietary supplements) are not shipped in the same conveyance with hazardous materials or poisons. Ensure conveyances are clean and free of insects and other pests. Ensure conveyances are not inappropriately fumigated with chemicals that may contaminate the botanical material.

v. Classification. Specify on bills of lading the accurate freight classifications or, for international shipments, the appropriate Harmonized Tariff System code. Ensure botanical materials intended for food use (including both conventional foods and dietary supplements) are designated as “food.”

vi. Regulations. Ensure botanical materials used for food that originate in, or will be distributed within, the U.S. are shipped in accordance with 21 CFR Part 1 Subpart O (regulations on the Sanitary Transportation of Human and Animal Food).

vii. Records.

1. Appropriate records should be kept of the shipping performed, including the identity, lot number, and quantity of botanical material shipped; the carrier used; the date; tracking number if used; the destination company and address; and other information as appropriate.

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

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

1. If additional processing will be performed, it may be appropriate to delay the final metal detection step until after all other processing is complete. [↑](#footnote-ref-1)
2. If the size reduction is a preliminary step for further processing such as extraction, it may be preferable to take the retention sample at a later point it the process. [↑](#footnote-ref-2)
3. Refer to AHPA’s “Guidance for the Manufacture and Sale of Bulk Botanical Extracts” for a more extensive discussion. [↑](#footnote-ref-3)
4. See California Office of Environmental Health Hazard Assessment (OEHHA) website <https://www.p65warnings.ca.gov/fact-sheets/bisphenol-bpa> for more information regarding bisphenol A and Proposition 65. [↑](#footnote-ref-4)
5. Use of ionizing radiation is permitted for certain food ingredients under U.S. regulations. Where used, regulations require labels to disclose this fact in compliance with 21 CFR 179.26(c). [↑](#footnote-ref-5)