

# GOOD AGRICULTURAL AND COLLECTION PRACTICES AND GOOD MANUFACTURING PRACTICES FOR BOTANICAL MATERIALS

CONTAINS NONBINDING RECOMMENDATIONS

March 2017

Prepared by the American Herbal Products Association



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## Acknowledgements

This update to the AHPA-AHP Good Agricultural and Collection Practices (2006) was initiated under the auspices of the Botanical Raw Materials Committee of the American Herbal Products Association (AHPA) and numerous additional volunteers. This committee was chartered by AHPA to facilitate the quality and supply of raw materials to ensure sufficient production and stable markets for botanical ingredients. It also has the goal of providing protection for wild plant communities. The original 2006 version of this document was a cooperative effort between AHPA and the American Herbal Pharmacopoeia (AHP). A significant part of AHP's mission is to develop quality control standards for the manufacture of herbal supplements and botanical medicines.

Special thanks are due to Edward Fletcher (Herbal Ingenuity), the committee's chair. Appreciation is also due to Staci Eisner for drafting and editing the revisions to the document, to numerous AHPA members who reviewed the document and offered comments, and to Wendy Applequist, Ph.D. (Missouri Botanical Garden) for contributing an appendix with instructions on preparing voucher specimens.

AHPA and AHP are not the first organizations to produce texts discussing good agricultural and collection practices for herbs. Several earlier published works that address these topics have been valuable resources in the production of the present document. Some of the concepts and language found herein originate in public documents related to agricultural practices published by numerous other international organizations. Acknowledgement and access to these prior works is found in Appendix 6 of this document.

## Preface

Organizations involved in a trade that produces and markets consumer goods must recognize from time to time their obligations to provide guidance on issues that will ensure that those goods are produced to high standards. This may be especially true when those products are intended for human consumption and are used as aids in promoting health.

Botanical products such as teas, dietary supplements, cosmetics, perfumes, and potpourri are widely available in the United States and internationally. The botanical ingredients for these products come from all over the world and are obtained from both cultivated and wild-harvested plants. Some manufacturers produce all or part of their own herbal ingredients, while some buy them directly from farmers and collectors. Others obtain their herbal ingredients through distribution channels that can include several stages between the harvest



of a plant and the manufacture of the finished product. Regardless of these trade variables, agricultural and collection practices have product quality, cultural, and environmental implications.

The idea that good agricultural practices (GAPs) needs to be clearly described and documented is a fairly recent development. For example, it was only in 2003 that the Committee on Agriculture of the Food and Agriculture Organization (FAO) of the United Nations began to consider the process of developing an international approach to GAPs.<sup>1</sup> Similarly, the interest in publishing meaningful and well-designed good collection practices (GCPs) guidelines has only recently come into focus.

For most botanical crops there are no formal good agricultural and collection practices (GACPs) prescribed by either the United States Department of Agriculture (USDA) or the U.S. Food and Drug Administration (FDA). Only for “produce” crops grown in or imported to the U.S. have minimum GACPs been promulgated by FDA; found in 21 CFR Part 112,<sup>2</sup> these regulations focus primarily on microbiological safety concerns rather than general quality or environmental issues.

Similarly, in many cases there are no formal good manufacturing practices (GMPs) that apply to the processing of botanicals. However, botanicals intended for food use must be processed in compliance with food GMPs established by FDA.<sup>3</sup> Botanical food ingredients and conventional food products must be manufactured in compliance with 21 CFR 117, while dietary supplements must be manufactured in compliance with 21 CFR 111.

## Introduction

This document provides guidance to growers, collectors, and processors of botanical crops. Its goals are to ensure that the herbal raw materials used in consumer products are accurately identified, are not adulterated with contaminants that may present a public health risk, and are in full conformity with all of the quality characteristics for which they are represented. In many countries, standards of identity, quality, and purity for herbal ingredients used in medicines are codified in national pharmacopeias and are mandatory standards. In the United States, standards are established by buyers, either to their own specifications or to those set by an

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<sup>1</sup> FAO. *Development of a Good Agricultural Practice Approach*. November 5, 2003. This document is online at [http://www.fao.org/prods/GAP/archive/GAPCONCEPT12\\_en.pdf](http://www.fao.org/prods/GAP/archive/GAPCONCEPT12_en.pdf).

<sup>2</sup> 21 CFR Part 112 refers to Title 21, Part 112 of the U.S. Code of Federal Regulations.

<sup>3</sup> In addition, drug GMPs apply to various stages of processing for botanically-derived drug ingredients and products; these are outside the scope of this document.



authoritative body, such as the American Herbal Pharmacopoeia or the United States Pharmacopeia.

The AHPA GACP-GMP has relevance to the growing, collecting, and processing of botanical crops for a wide variety of purposes, including use as foods, drugs, cosmetics, perfumes, propagative material, etc., but with particular focus on use for food and supplement ingredients. The definitions (section 1), quality characteristics (section 2), GACPs (sections 3 to 7), and subsequent processing and handling provisions (section 8) of the document apply to all herbal crops whether cultivated or wild harvested, conventional or organic, for food or non-food purposes. Section 9 of the document summarizes basic U.S. food GMP provisions applicable to processing of botanicals for use as or in food in the US. Section 10 sets forth additional recommended practices for processing of botanical materials for use as dietary ingredients (i.e., for use as ingredients in dietary supplements in the U.S. or equivalent types of products in other markets).

While this document may be useful in any country, with respect to specific regulations it is limited to those applicable to crops grown, collected, and/or processed in the U.S. or imported to the US. However, in no case does the document include the full text of any regulations; for that, readers must consult the applicable sections of the US Code of Federal Regulations.<sup>4</sup>

This guidance serves as a template that growers, harvesters, and processors can adapt to their own businesses and is designed to have relevance for both small and large producers. By establishing standard operating procedures that follow the practices presented here, firms at every level in the supply chain will better ensure the production of good quality herbal raw materials.

However, this document does not serve as a substitute for the empirical knowledge that has been passed down from preceding generations involved in the cultivation, wild collection, and processing of useful plants. Readers are encouraged to give due consideration to long-established practices in growing, harvesting and processing herbs. For example, the experience that has already been gained in understanding optimal harvest seasons for herbs continues to be applicable today. Traditionally, roots have been collected in the spring and fall, flowers on a sunny day when fully open, and fruits and seeds when they are fully ripe or mature, unless otherwise specified. Though modern harvest protocols can emphasize seasonal variations in constituent profiles, many of the older practices have been found to correlate with contemporary standards. Also, many traditional cleaning and processing techniques—garbling, scraping of barks (rossing), winnowing, etc.—are still relevant, as are such specific practices as aging of some herbal materials and the numerous processing steps that are sometimes applied

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<sup>4</sup> The Code of Federal Regulations is available at <http://www.ecfr.gov/cgi-bin/ECFR?page=browse>.





to Chinese herbal materials prior to use. Today's herbal industry can benefit through awareness of these and other traditional techniques.

Furthermore, it must not be assumed that every firm should implement every applicable provision of this document. Rather, after identifying which sections of the document are relevant to its operations, firms should carefully review those provisions in light of their own circumstances and needs, and after due consideration should implement whichever recommendations are useful and practical for their situation. Except where U.S. regulations or the firm's certification organizations (e.g., for organic, Kosher, or non-GMO standards) establish actual requirements, firms should ignore suggestions that are too expensive, too burdensome, or are simply not useful. The document must not be viewed as a list of required prescriptions but rather as a menu of options.

Comments on the document, especially by growers, collectors, and processors who use the guidance in their facilities and operations, are welcome and should be submitted to AHPA at the email or physical address listed below. Revisions may be made to this guidance as additional insights are gained through this practical use.

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Silver Spring, Maryland USA 20910  
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All hyperlinks provided throughout this document were last accessed as of the date of publication.

Finally, the AHPA Botanical Raw Materials Committee and other reviewers have already identified the need to develop additional appendices to this work, by providing worksheets and checklists that will assist growers and collectors in implementing the guidance provided here.<sup>5</sup> Readers of this document who have ideas to contribute to this future project are invited to contact the AHPA office.

## Disclaimers

The information presented here is provided for guidance purposes only. Producers of herbal ingredients and of finished consumer products that contain herbs are responsible for knowing, understanding, and conforming to all state, local, and federal laws and regulations that are

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<sup>5</sup> With respect to templates for use by processors, many such documents are available from AHPA through the AHPA website.



relevant to their businesses, and for implementing practices that may go beyond those described here, as needed.

This document does not serve as a substitute for a grower's or collector's need to be knowledgeable about the plants which they produce. In addition, it does not address all of the needs of those who are producing crops that comply with organic agriculture or other specifically defined agricultural doctrines.

In preparing this document, every effort was made to identify current practices that might affect the quality and cleanliness of herbal ingredients. These guidelines may be revised periodically as new information and technology develops.

Please note that this document contains interpretations of Food and Drug Administration regulations. Application of FDA's regulations is fact specific and those using this document should consult with counsel or experienced consultants regarding their application to specific facts. FDA has established a portal for asking questions regarding the application of the Food Safety Modernization Act and its regulations.

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>



## DEFINITIONS

US laws and regulations establish specialized definitions for various words and phrases, which are key to proper understanding of the applicable legal and regulatory requirements; in addition, some terms are unique to the botanical industry and may be unfamiliar to most English speakers.

The entries below define what is meant by various terms used in the document. Where quotation marks are used within the definitions, these indicate other terms with specialized meanings whose definitions are also provided here and should be consulted.

### 1. D.1. Definitions

“Adulterated,” when used in reference to “food,” is defined by U.S. law<sup>6</sup> to mean the food meets one of the following conditions: (a) the food bears or contains any poisonous or deleterious substance which may render it injurious to health, except if the substance is not an added substance such food is not considered adulterated if the quantity of such substance in such food does not ordinarily render it injurious to health; (b) the food bears or contains any added poisonous or added deleterious substance that is unsafe; (c) the food consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; (d) the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (e) the food is a dietary supplement that has been prepared, packed, or held under conditions that do not comply with 21 CFR Part 111; or (f) the food meets various other technical provisions that U.S. law deems to be adulterated.<sup>7</sup>

“Botanical” as used in U.S. laws and regulations means any plant, fungus, or alga.<sup>8</sup>

“Botanical material” as used in this document refers to roots, rhizomes, leaves, stems, flowers, seeds, fruit, or other botanical structures or combinations of botanical structures that have been, or will be, harvested, handled, packed, stored, or processed.

“Covered activity” for purposes of 21 CFR Part 112 (i.e., the regulations applicable to growing and “harvesting” of “covered produce”) is defined by FDA as growing, harvesting, “packing,” or “holding” “covered produce” on a “farm.” Covered activities include “manufacturing/processing” of covered produce on a farm, but only to the extent that such activities are performed on “raw agricultural commodities” and only to the extent that such activities are within the meaning of farm as defined by FDA. For produce that is exempted from Part 112 under 21 CFR § 112.2(b) because it receives commercial processing that will

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<sup>6</sup> 21 U.S.C. § 342.

<sup>7</sup> See the full text of 21 U.S.C. § 342 for a complete list of the conditions that render food adulterated.

<sup>8</sup> For example, 21 CFR § 101.36(h) states in part, “The common or usual name of ingredients of dietary supplements that are botanicals (including fungi and algae) shall be...”



remove microbiological hazards, covered activities also include providing the written assurances required therein; acting consistently with those assurances; and documenting actions taken in compliance with those assurances.<sup>9</sup>

“Covered produce” is defined by FDA as “produce” that is subject to the requirements of 21 CFR Part 112 in accordance with §§112.1 and 112.2; the term refers to the harvestable or harvested part of the crop.<sup>10</sup> Basically, covered produce consists of fruits and vegetables or other produce, or mixtures thereof, that meet all of the following criteria: (a) they are intended for use as “food”; (b) they are “raw agricultural commodities”; (c) they are grown in the U.S. or will be imported to the US; and (d) FDA believes they are commonly eaten raw and therefore require special agricultural controls to ensure food safety (i.e., they are not excluded under 21 CFR § 112.2).<sup>11</sup> Covered produce does not include crops that meet any of the following criteria: They are (a) intended for non-food purposes (e.g., for biofuels, pharmaceuticals, clothing, household products, cosmetics, etc.); (b) grown outside the U.S. and will not be imported to the US; (c) in the FDA’s list at 21 CFR § 112.2(a)(1) of produce rarely eaten raw (e.g., asparagus, winter squash, potatoes); (d) not raw agricultural commodities (i.e., they have been processed beyond their raw or natural state); or (e) produced by an individual for personal consumption or consumption on the same “farm” where they are grown or another farm under the same management.<sup>12</sup>

“Dietary ingredient” is defined under U.S. law as an ingredient in a “dietary supplement” that is a vitamin; mineral; herb or other botanical; amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of these.<sup>13</sup>

“Dietary supplement” is defined under U.S. law as a “food” product (other than tobacco) intended to supplement the diet that bears or contains one or more “dietary ingredients”; is intended for ingestion typically in tablet, capsule, powder, softgel, gelcap, or liquid form; is not represented for use as a conventional food or as a sole item of a meal or the diet; and is labeled as a dietary supplement.<sup>14</sup>

“Facility” is defined under FDA regulations<sup>15</sup> as any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility,

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<sup>9</sup> The definition of “covered activity” under FDA regulations contains additional details. For the complete definition see 21 CFR § 112.3.

<sup>10</sup> 21 CFR § 112.3. See also Appendix 1 for more information.

<sup>11</sup> See additional details in 21 CFR § 112.1. In particular, it is to be noted that the list of examples of crops that are covered by Part 112 (i.e., that are not included on the list of “rarely consumed raw” crops that are exempt from Part 112) includes various crops that many people may assume are customarily cooked before eating, such as artichokes.

<sup>12</sup> See additional details in 21 CFR § 112.2, including the list of botanical crops that FDA considers to be “rarely consumed raw.”

<sup>13</sup> 21 U.S.C. § 321 (ff).

<sup>14</sup> The definition of “dietary supplement” under U.S. law contains additional details. For the complete definition see 21 U.S.C. § 321 (ff).

<sup>15</sup> 21 CFR § 1.227.



traveling to multiple locations, that “manufactures/processes,” “packs,” or “holds” “food” for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

(1) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(2) *Foreign facility* means a facility other than a “domestic facility” that manufactures/processes, packs, or holds food for consumption in the United States.

“Farm” is defined by FDA regulation as the two types of operations enumerated below.<sup>16</sup> Under these definitions, farm includes both operations that grow crops and operations that merely “harvest” crops (i.e., wild collecting operations).

(1) Primary production farm. A “primary production farm” is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term farm includes operations that, in addition to these activities:

(i) “Pack” or “hold” “raw agricultural commodities”;

(ii) Pack or hold “processed food,” provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and

(iii) “Manufacture/process” food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same management; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(1) Drying/dehydrating “raw agricultural commodities” to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and “packaging” and “labeling” such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

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<sup>16</sup> 21 CFR § 1.227 and 21 CFR § 112.3.



(2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation).

(2) Secondary activities farm. A “secondary activities farm” is an operation, not located on a “primary production farm,” devoted to harvesting (such as hulling or shelling), packing, and/or “holding” of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

“Farm mixed-type facility” is a “farm” that engages in both activities that are exempt from food facility registration<sup>17</sup> and activities that are outside the farm definition and therefore require the establishment to be registered with FDA.

“FDA” means the U.S. Food and Drug Administration.

“Food” is defined under U.S. law as (1) articles used for food or drink for man or other animals; (2) chewing gum; (3) articles used for components of any such article.<sup>18</sup> Under FDA regulations, food includes seeds and beans used to grow sprouts.<sup>19</sup> Examples of food include: Fruits, vegetables, fish, dairy products, eggs, “raw agricultural commodities” for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, “dietary supplements” and “dietary ingredients,” infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.<sup>20</sup>

“Food processing,” for purposes of this document, describes operations that are subject to FDA food regulations (e.g., 21 CFR Part 117) and that require the facility in which the operations occur to be registered with FDA as a food facility.<sup>21</sup>

“Garbling” means separating the target plant part from extraneous matter, such as dirt, other plant parts, etc.

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<sup>17</sup> See Appendix 3.

<sup>18</sup> 21 U.S.C. § 321 (f).

<sup>19</sup> 21 CFR § 112.3.

<sup>20</sup> 21 CFR § 1.227.

<sup>21</sup> See Appendix 3 for more information about facility registration.



“Harvesting” is defined under FDA regulations<sup>22</sup> as activities that are traditionally performed on “farms” for the purpose of removing “raw agricultural commodities” from the place they were grown or raised and preparing them for use as “food.” Harvesting is limited to activities performed on raw agricultural commodities, or on “processed foods” created by drying/dehydrating a raw agricultural commodity without additional “manufacturing/processing,” on a farm.<sup>23</sup> Harvesting does not include activities that transform a raw agricultural commodity into a “processed food.” Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

“Herbarium” means a collection of plant samples and associated data preserved for study over the long term.

“Holding” is defined under FDA regulations<sup>24</sup> as storage of “food,” and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating “raw agricultural commodities” when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a “processed food.” Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

“Label” (when used as a noun) is defined under U.S. laws and regulations as a display of written, printed, or graphic matter upon the immediate container of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity.<sup>25</sup>

“Labeling” (when used as a noun) is defined under U.S. laws and regulations as all “labels” and other written, printed, or graphic matter (1) upon any article or any of its containers or

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<sup>22</sup> 21 CFR § 1.227, 21 CFR § 112.3 and 21 CFR § 117.3.

<sup>23</sup> Activities that are considered “harvesting” when performed on the farm where the crop was grown, may constitute “manufacturing/processing” when performed at a different location by a different company. For example, if apples are washed on the same farm where they were grown, this is a harvesting activity; however, if the apples are sold to a different company which then washes them, this is a manufacturing/processing activity.

<sup>24</sup> 21 CFR § 1.227, 21 CFR § 112.3 and 21 CFR § 117.3.

<sup>25</sup> 21 U.S.C. § 321 (k); 21 CFR 1.3.



wrappers, or (2) accompanying such article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.<sup>26</sup>

“Labeling” (when used as a verb) means the activity of applying “labels” or “labeling” to an article or its immediate containers or wrappers.

“Manufacturing/processing” is defined under FDA regulations<sup>27</sup> as making “food” from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating “raw agricultural commodities” to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, “labeling,” milling, mixing, “packaging” (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For “farms” and “farm mixed-type” facilities, manufacturing/processing does not include activities that are part of “harvesting,” “packing,” or “holding.”

See also the definition of “processed food” below, for an important distinction between “processing” and “manufacturing/processing.”

“Packaging” (when used as a verb) is a “manufacturing/processing” activity in which food is placed into a container that directly contacts the food and that the consumer receives. Placing “raw agricultural commodities” into retail packages on a “farm” or “farm mixed-type facility” is exempt from the food processing regulations in Part 117 unless (a) additional manufacturing/processing that is outside the farm definition is also performed, or (b) raw agricultural commodities that are “produce” as defined in Part 112 are dehydrated to create a distinct commodity, in which case Part 117 Subpart B applies to the packaging, “packing,” and “holding” of the dried commodities.<sup>28</sup>

“Packing” is defined under FDA regulations<sup>29</sup> as placing “food” into a container other than “packaging” the food and also includes activities performed incidental to packing of a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a “raw agricultural commodity” into a “processed food.” Packing includes, for example, placing immediate packages of food (e.g., individual bottles labeled for retail sale) into secondary packages that will not be received by the consumer (such as cases, master packs, etc.).

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<sup>26</sup> 21 U.S.C. § 321 (m); 21 CFR 1.3.

<sup>27</sup> 21 CFR § 112.3 and 21 CFR § 117.3.

<sup>28</sup> Compliance with this last requirement may be achieved by complying with Part 117 Subpart B or with the applicable requirements for packing and holding in Part 112.

<sup>29</sup> 21 CFR § 1.227, 21 CFR § 112.3 and 21 CFR § 117.3.





“Pesticide” is defined under U.S. law as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest; any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant; and nitrogen stabilizers.<sup>30</sup> Pesticides include herbicides, fungicides, and insecticides as well as other substances.

“Processed food” is defined under U.S. law as any human or animal “food” other than a “raw agricultural commodity,” and (according to FDA’s interpretation of this legal definition) includes any raw agricultural commodity that has been subject to “manufacturing/processing” *that alters the general state of the commodity or creates a distinct commodity*, such as canning, cooking, freezing dehydration, or milling. In contrast, minor manufacturing/processing that does not alter the general state of the commodity or create a distinct commodity, such as coloring, washing, or waxing, does not (according to FDA’s interpretation) transform the raw agricultural commodity into a processed food.<sup>31</sup>

Under the FDA interpretation of this provision, dehydration transforms a raw agricultural commodity into a processed food only if the drying “creates a new commodity,” i.e. if the crop is normally traded in fresh form then dehydration of it constitutes manufacturing/processing. For example, fresh apples are a raw agricultural commodity while dried apples are a processed food. In contrast, dehydration of commodities normally traded in dried form does not transform the commodity into a processed food (e.g., dried allspice berries and dried cinnamon bark remain raw agricultural commodities even though they have been dehydrated).<sup>32</sup>

“Processed botanical” for purposes of this document means any (food or non-food) “raw agricultural commodity” that has been subject to “manufacturing/processing” that alters the general state of the commodity or creates a distinct commodity, such as size reduction or extraction, or dehydration if the commodity is not normally traded in dried form.

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<sup>30</sup> The definition of “pesticide” under U.S. law contains additional details. For the complete definition see 7 U.S.C. § 136 (u).

<sup>31</sup> The precise legal definition given in 21 U.S.C. § 321 (gg) is as follows: “The term ‘processed food’ means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.” This use of the term “processing” is different from the term “manufacturing/processing” as defined in FDA regulations. In the preamble to the proposed Produce Safety rule (78 FR 3540, 2013), FDA explains that manufacturing/processing includes nearly any type of food manipulation, even minor steps such as coloring, washing or waxing, but that a raw agricultural commodity is transformed into a processed food only if the manufacturing/processing alters the general state of the commodity or creates a new or distinct commodity.

<sup>32</sup> The distinction between (a) drying a harvested food crop and thereby creating a distinct commodity from the fresh material (e.g., drying grapes into raisins) versus (b) drying a harvested food crop without creating a distinct commodity (e.g., the drying of hay or grains) stems from the 1998 Joint EPA/ FDA Policy Interpretation (63 FR 54532, 1998). The U.S. Environmental Protection Agency (EPA) and FDA created this distinction for purposes of implementing the U.S. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1996. Under this interpretation, if the dried material is a distinct commodity from the fresh commodity then it is a processed food; if the dried material is not a distinct commodity from the fresh commodity then it remains a raw agricultural commodity. The distinction was carried forward into the FDA regulations implementing FSMA (see for example the definitions of “farm,” “harvesting,” and “holding” in 21 CFR Part 112 and 21 CFR Part 117, and the preambles at 80 FR 74385, 2015; 80 FR 74395-34398, 2015; and 78 FR 3540, 2013).



“Produce” is defined under FDA regulations<sup>33</sup> as any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant<sup>34</sup> (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as “food” and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).<sup>35</sup>

“Raw agricultural commodity” is defined under U.S. law as any human or animal “food” in its raw or natural state, including all fruits that are washed, colored, otherwise treated in their unpeeled natural form prior to marketing.<sup>36</sup> For purposes of this document, raw agricultural commodity also refers to non-food botanical crops in their raw or natural state. The natural state of a raw agricultural commodity may include being dried, but only if the commodity is normally traded in dried form (e.g., pinto beans). Dehydration of a raw agricultural commodity that is a food normally traded in fresh form (e.g., blueberries) transforms it into a “processed food.”

“Rossing” means separating the outer bark from the inner bark.

“Voucher specimen” means an individual specimen plant including the aboveground structures (e.g., leaves, stems, flowers, fruits) and belowground structures when possible,

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<sup>33</sup> 21 CFR § 112.3.

<sup>34</sup> The Merriam-Webster dictionary defines “herbaceous” as either “of, relating to, or having the characteristics of an herb”; or “of a stem: having little or no woody tissue and persisting usually for a single growing season; or “having the texture, color, or appearance of a leaf” (<https://www.merriam-webster.com/dictionary/herbaceous>, accessed 12/02/2016).

TheFreeDictionary.com defines “herbaceous plant” as “a plant lacking a permanent woody stem”

(<http://www.thefreedictionary.com/herbaceous+plant>, accessed 12/02/2016) and Wikipedia defines “herbaceous plants” as “plants that have no persistent woody stem above ground” ([https://en.wikipedia.org/wiki/Herbaceous\\_plant](https://en.wikipedia.org/wiki/Herbaceous_plant), accessed 12/02/2016). It is unclear which of these meanings FDA intends. “Of, relating to, or having the characteristics of an herb” and “having the texture, color, or appearance of a leaf” do not fit, since the examples given by FDA (cabbage, potatoes) are not “herbs” and potatoes are not leaves. It seems FDA intends to limit the definition of “vegetable” to non-woody plants, but this leads to additional contradictions because FDA lists “oregano” (a woody plant) in the definition of “covered produce.”

<sup>35</sup> Although it is not stated in the definition, FDA clarifies in the preamble to the rule that “algae” are excluded from the definition of produce. (80 FR 74385, November 27, 2015)

<sup>36</sup> 21 U.S.C. § 321 (r).



that is representative of the harvested crop and which is documented, expertly identified, pressed, dried, labeled, and maintained in storage for future reference.



## BOTANICAL IDENTITY AND QUALITY

Botanical identity and quality must be assured throughout the growing, harvesting, post-harvest handling, and further processing of botanical materials. Improper or careless practices at any stage may result in material that is misidentified, adulterated, or that fails to meet the necessary specifications.

### 2. BQ.1. Botanical identity and quality

#### BQ.1.1. General considerations

- i. All steps in the production of a botanical material must be performed properly to ensure the quality of the resulting finished material. This includes everything from site location and cultivation, to harvest, to post-harvest steps such as washing, cutting, dehydrating, packaging, storing, and transporting.
- ii. Written specifications. Appropriate written specifications should be established for botanical materials, either by the buyer, the seller, or both. Such specifications should address the various criteria set forth in the sections below with respect to identity, physical and chemical characteristics, and potential contaminants, to the extent applicable to the buyer's or seller's needs.
  1. Specifications for raw materials and ingredients to be used in manufacturing should be developed taking into account the effect of the processing on the characteristic in question. For example, an extraction process may serve to either concentrate or remove a contaminant, and the allowed level of the contaminant in the crude botanical should be adjusted accordingly. Similarly, a manufacturing process may serve to destroy microorganisms in the botanical material, which may obviate the need to control for pathogens in the raw material.
  2. Specifications for finished processed products should take into account the intended use of the product (e.g., whether it will be used for consumer products or rather will be used for agricultural or industrial purposes; whether it will be further processed by another company or whether it will be sold directly to consumers; etc.).
- iii. Sources of information. Recommended specifications and test methods for many botanical materials are provided in pharmacopoeial monographs and other compendia. See also Appendix 5.
- iv. Sampling. Tests and examinations for botanical materials must be performed on samples that are properly representative. Crude botanicals, in particular, must be sampled with



close attention to their inherent heterogeneity. Many pharmacopoeia provide guidelines for proper sampling of botanical materials.<sup>37</sup>

- v. Botanical materials must meet all representations made in labels and labeling, specification documents, certificates of analysis, guarantees, written agreements, and other documentation, not only with respect to test results but also with respect to identity, grade (e.g., organic, Kosher, or USP<sup>38</sup>), form (e.g., whole, powder, extract), locations of harvest and/or processing, dates of harvest and/or processing, and all other representations made regarding the material.

### BQ.1.2. Identity

- i. Any material offered as a particular genus, species, subspecies, variety, cultivar, hybrid, or other lesser division of a species must in fact be that exact taxon.
- ii. The botanical identity of each botanical material should be documented with as much specificity as appropriate.
  - 1. In general, the scientific name (genus, species (if applicable and relevant), subspecies/variety (if applicable and relevant), and author (if necessary for clarity) of each plant material should be documented.<sup>39</sup>
  - 2. In some cases, identification to the genus level is sufficient. For example, geranium species used to make geranium oil are commonly used interchangeably and are often labeled in commerce as “geranium,” so the scientific name for such materials need only be documented as “*Pelargonium* spp.”<sup>40</sup> Similarly, cinnamon species are often used interchangeably and are often labeled in commerce simply as “cinnamon,” in which case the scientific name need only be documented as “*Cinnamomum* spp.”<sup>41</sup>
  - 3. The local ethnic name and standard English common name (where available) may also be recorded.<sup>42</sup>

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<sup>37</sup> As an example, the U.S. Pharmacopoeia (USP) has sampling instructions for articles of botanical origin; see Second Supplement to USO 38 – NF 33, Chemical Tests <561> Articles of Botanical Origin.

<sup>38</sup> USP refers to the United States Pharmacopeia.

<sup>39</sup> The correct scientific names for botanicals are available from sources such as GRIN Taxonomy (<https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomyquery.aspx>). In general, names should be provided in accordance with the current International Code of Nomenclature for algae, fungi, and plants (<http://www.iapt-taxon.org/nomen/main.php>), unless there is reason to use outdated nomenclature (e.g., where conformity to a pharmacopoeial monograph is claimed and the monograph used outdated nomenclature).

<sup>40</sup> See 21 CFR § 582.10.

<sup>41</sup> For example, the American Spice Trade Association’s (ASTA’s) Spice List describes cinnamon merely as “*Cinnamomum* spp.” See <http://www.astaspice.org/government-relations-advocacy/complying-with-u-s-policy-regulations/spice-list/>.

<sup>42</sup> The standard English names for many botanicals are provided in AHPA’s *Herbs of Commerce* (McGuffin, M *et al.* 2000. *Herbs of Commerce*, 2<sup>nd</sup> ed. Silver Spring, MD: AHPA).



4. Other information, such as the cultivar or hybrid name, ecotype, chemotype or phenotype, may be recorded if applicable and relevant.
  5. In the case of materials represented as belonging to a landrace grown or collected in a specific region, records should be kept of the locally named line, including the source of the original seeds, plants or propagation materials if known.
- iii. The highest standard for identification of botanical species is examination by an expert (e.g., botanist, pharmacognosist, or other person with appropriate training) of the plant's morphologic characteristics.
1. Information regarding the morphologic features of various plant species is available in various pharmacopoeia, material medicas, floras, taxonomic keys, and other compendia and authoritative references.<sup>43</sup> Authenticated reference or herbarium samples may also be used for comparison. In some cases, authenticated live plants may be found growing at universities and public gardens, and it may be possible to obtain specimens for comparison from such sources.
  2. Morphologic identification may require examination of the flower or fruit morphology, in which case (if the flower or fruit is not the article of commerce) the plant should be properly identified by a person having access to the plant while in flower or fruit, either *in situ* at the harvest site or in the form of a voucher specimen or other reference specimen.
  3. The identification should be documented with detailed descriptions of the organoleptic, macroscopic, and microscopic characteristics observed, along with drawings, photographs, and/or photomicrographs for future reference.
  4. Where potential adulterating species are known, the presence or absence of features characteristic of the adulterant should be documented.
- iv. Additional evidence of identity may be developed by a number of other means.
1. Chemical fingerprinting may be performed using various kinds of chromatography (e.g., TLC, HPTLC, HPLC, GC<sup>44</sup>) to confirm the presence of peaks or bands that are diagnostic of the correct species and/or to confirm any

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<sup>43</sup> Several of these authoritative resources, such as the AHPA Botanical ID References Compendium, are listed in Appendix 5.

<sup>44</sup> TLC = Thin Layer Chromatography

HPTLC = High Performance Thin Layer Chromatography

HPLC = High Performance Liquid Chromatography

GC = Gas Chromatography



diagnostic relative intensities or ratios between peaks. The fingerprint of an authentic specimen may also be compared to that of the test sample.<sup>45,46</sup> Furthermore, fingerprints of the test sample may be used to demonstrate the absence of bands or peaks characteristic of an adulterant or substitute. A printout or photograph of the resulting fingerprint(s) should be maintained on file for future reference.

2. DNA analysis may be performed where applicable, such as DNA barcoding or other techniques.<sup>47</sup> A photograph of the resulting DNA barcode or fingerprint should be maintained on file for future reference; alternately, results may be printed from software that reduces the data to a number that quantifies the degree of similarity or difference from the reference material or expected sequences.
3. Quantitative testing may be performed for the presence of one or more botanical constituents that are consistent with the target botanical, or for the absence of botanical constituents indicative of a potentially adulterating species.<sup>48</sup> The results of the analysis should be maintained on file.
4. Infrared testing (e.g., FTIR or NIR<sup>49</sup>) may be performed on the material.<sup>50</sup> A printout of the resulting IR spectrum should be maintained on file; alternately, results may be printed from software that reduces the spectral data to a pass or fail result based on the degree of similarity or difference between the observed vs. the expected spectrum.

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<sup>45</sup> For materials purchased from another party, it may be preferable to look at a full fingerprint rather than just a few bands or peaks to avoid inadvertent purchase of a material to which exogenous plant constituents have been added but not disclosed.

<sup>46</sup> It is to be noted that legitimate differences may occur between the fingerprint of an authentic crude botanical sample vs. a sample of the same species that has been processed (as by heating, extracting, etc.). In addition, fingerprints may vary due to the natural chemical variation that occurs due to weather, season, soil chemistry, external stressors such as insects, etc. Thus, if the fingerprints of test sample and the authentic sample do not match exactly, this does not necessarily mean the test sample is improperly identified.

<sup>47</sup> Although the layperson might expect DNA to provide definitive identity results, in fact the use of DNA testing in botanical identification is not yet a fully developed science, and is known to produce false negatives and false positives. At the time of this writing it is often not sufficiently robust and reliable to provide definitive identification and is not generally accepted either by industry or by the scientific community as a replacement for morphologic examinations. Furthermore, usable DNA is not present in many botanical ingredients that have been processed as by heating, extraction, etc.

<sup>48</sup> The constituents used for this purpose should be characteristic of, and preferably unique to, the botanical in question, or to the potential adulterating botanical whose presence is to be excluded. However, it must be kept in mind that testing for individual constituents can be easily fooled by spiking the botanical material with those constituents obtained from an exogenous source.

<sup>49</sup> FTIR = Fourier Transform Infra-Red spectroscopy

NIR = Near Infra-Red spectroscopy

<sup>50</sup> Where infrared testing is used in conjunction with software that analyzes the spectrum to yield a “pass” or “fail” result, the software must be extensively trained with a sufficient number and diversity of authentic samples; otherwise, false negatives and false positives are likely to be obtained.



- v. Voucher specimens of the plant or other archival samples (e.g., of viable seeds or of the crude botanical prior to processing) may also provide evidence of botanical identity.<sup>51</sup>
1. Where voucher specimens are used, they should be prepared of the whole plant (if possible), preferably with flowers or fruit, collected from the harvest site, and should be assigned a unique identification code. Vouchers should be labeled with the botanical identity, date of preparation, person who prepared the voucher, and person who harvested the plant. Details such as the harvest/collection date, harvest/collection site (e.g., country and latitude/longitude), and general descriptions of the plant and habitat at the time of harvest should be annotated on the voucher or maintained in associated documentation. See Appendix 7 for additional details on the preparation of voucher specimens.
  2. Where samples of viable seed are kept as evidence of identity, the samples may be prepared by growers from the lot of seed used for planting, or may be prepared by growers or wild collectors from the plant population once the seed is mature.
  3. Archival samples of botanical raw materials for manufacturing should always be prepared prior to processing, especially before size reduction or extraction as these will destroy or remove important morphologic features.
- vi. The identity of processed botanicals, such as those that have been powdered, extracted, and/or blended with other botanicals, often cannot be definitively proven by testing the finished processed material. Microscopy, chemical testing, and/or DNA testing may be used where adequate and scientifically valid methods exist, but these at best provide evidence of identity rather than proof of identity.

### BQ.1.3. Physical characteristics

- i. A variety of physical characteristics may be relevant to the quality of a botanical material. These may include:
1. Moisture content. An appropriate specification should be set for the moisture content or loss on drying. Fresh materials will contain a much higher amount of water than dried. For dried materials, moisture content should be low enough to minimize microbial growth and prevent spoilage.
  2. Particle size. For cut, chopped, or milled materials, specifications for the size of the pieces or particles should be established where relevant. The piece or

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<sup>51</sup> Any such voucher or other archival sample is only useful, however, if it is an accurate and positively identified sample of the species; therefore, such samples cannot replace direct examination and/or testing of the actual botanical material itself.





particle size of manufacturing materials will affect operations such as steam sterilization, extraction, and encapsulation. In finished products, the particle size may affect mouthfeel, bioavailability, and stability.

3. Other relevant tests for powdered materials may include tapped density and bulk density.
  4. Other relevant tests for liquid materials may include pH, density or specific gravity, viscosity, and total dissolved solids.
- ii. For crude botanical materials, especially in whole form, additional tests may be relevant:
1. Soil content. It may be appropriate to set a quantitative limit for the amount of dirt and soil permitted in the material.
  2. Foreign organic material. It may be appropriate to set a quantitative limit for the amount of non-target plant parts, foreign species, insects, etc. permitted in the material.
  3. Unacceptable pieces. It may be appropriate to set a quantitative limit for the levels of discolored, damaged, broken, or moldy pieces permitted in the material.

#### **BQ.1.4. Chemical characteristics**

- i. A variety of chemical characteristics may be relevant to the quality of a botanical material. These may include:
  1. Extractives. In many cases it is desirable to establish a specification for the content of extractable material (“extractives”) in the botanical; this provides a measure of the chemical richness of the material.<sup>52</sup>
  2. Marker content. Specifications may be established for the levels of one or more botanical constituents in the material. Such tests may provide an indication that the material has been handled and stored properly to maintain freshness; for process control; to monitor shelf life; to limit the presence of toxic constituents; or, in those cases where a particular constituent or class of constituents is linked to the physiologic effect of the botanical, to control the physiologic activity.<sup>53</sup>

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<sup>52</sup> Measuring the content of extractives may be helpful in preventing the inadvertent purchase of material that has previously been extracted (i.e., spent extraction marc). In addition, use of materials containing a consistent level of extractives allows powdered extracts to be made with a reasonably consistent native extract ratio, and liquid extracts to be made with a reasonably consistent content of dissolved solids.

<sup>53</sup> For more complete information about the use of marker compounds, refer to the American Herbal Product Association’s (AHPA’s) “Use of Marker Compounds in Manufacturing and Labeling Botanically Derived Dietary Supplements” and “Standardization of Botanical Products: White Paper,” available at [www.ahpa.org](http://www.ahpa.org).



3. Other relevant tests may include the content of essential oils or fixed oils, total ash, acid-insoluble ash, water-soluble ash, crude fiber, etc. For finished formulated products, testing for preservative effectiveness and/or preservative content may also be appropriate.

### BQ.1.5. Contaminants

- i. Limits should be established for impurities and contaminants that may adulterate the material or adversely affect its quality, as follows.
- ii. Adulterating species. Specifications should be established to exclude the presence of known adulterants and substitutes. Depending on the form of the material and the nature of the adulterant, such testing may be performed using gross morphology or microscopy, or may involve chemical tests for constituents' characteristic of the adulterant (e.g., pyrrolizidine alkaloids).<sup>54</sup>
- iii. Microbiology. Specifications for the microbiological characteristics of the material (including indicator organisms, spoilage organisms, and/or potential pathogens) should be established where appropriate.<sup>55,56</sup> Microbiological specifications may not be relevant to raw agricultural commodities, materials intended for further processing, and those intended for use other than as a food or drug. However, microbial limits are often important for processed botanicals and finished consumer products (especially food products that will not be thoroughly cooked by the end-user prior to consumption).
- iv. Heavy metals. Specifications for the levels of heavy metals are often important in botanical materials intended for use as or in consumer products. If the material will eventually be sold as food in the State of California, due consideration should be given to the Proposition 65 safe-harbor levels for various metals.<sup>57</sup>

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<sup>54</sup> DNA testing might also be used, but since DNA testing cannot provide quantitative results, there is no way to know whether the presence of adulterant DNA indicates significant levels of adulteration or only an insignificant trace, especially when highly sensitive DNA technologies are used (e.g., PCR). Due to its extreme sensitivity, such testing commonly detects "adulterants" consisting merely of airborne pollen, or other stray plant or animal cells that are widespread both in the fields and in processing and laboratory environments.

<sup>55</sup> See AHPA's "Guidance Policy on Microbiology and Mycotoxins" (2012); last accessed on December 17, 2016 at [http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA\\_Microbiology\\_Mycotoxin\\_Guidance.pdf?ver=2016-04-26-121351-030](http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA_Microbiology_Mycotoxin_Guidance.pdf?ver=2016-04-26-121351-030).

<sup>56</sup> It should be noted that microbiological testing of a botanical material cannot, by itself, ensure the microbiological safety of the material, because low levels of pathogenic microorganisms may be missed during sampling and testing. To ensure microbiological safety, it is necessary to either (a) grow the botanical under strict conditions (such as those prescribed in 21 CFR Part 112) to preclude pathogenic contamination, or (b) formulate and/or process the botanical in a manner that destroys pathogens, as by combining with acid, heating, extracting, steam sterilizing, etc.

<sup>57</sup> See AHPA's "Background on California Proposition 65: Issues Related to Heavy Metals and Herbal Products" (2008) and AHPA's Guidance Policy on Heavy Metals (2012), last accessed on December 17, 2016 at [http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA\\_Heavy\\_Metals\\_Guidance.pdf?ver=2016-04-26-121351-157](http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA_Heavy_Metals_Guidance.pdf?ver=2016-04-26-121351-157).



- v. Pesticides. Establishment of pesticide specifications may be appropriate depending on the nature (e.g., cultivated vs. wild harvested) and intended use (e.g., food use vs. other uses) of the botanical. Tolerable pesticide levels in botanical crops vary from country to country. In the US, no detectable level of any pesticide is permitted on a food crop (or in food materials derived from that crop) unless a tolerance has been established for that specific pesticide on that specific crop (or for a defined Crop Group that includes the crop). As a result, the *de facto* tolerance for most pesticides and their breakdown products in most food botanicals is zero (or more accurately, “not detected” using a highly sensitive analytical test). However, as a practical matter, it is not possible to test a material for residues of every known pesticide; there are simply too many pesticides in use. Therefore, where pesticide specifications are established, consideration must be given to the range of pesticides that will be tested. Depending on the circumstances, it may be appropriate to use a standard pesticide panel (e.g., as per USP) or to create a customized panel to include pesticides employed during the cultivation or collection of the crop, those previously applied to the cultivation site, and/or those applied to neighboring fields.
- vi. Radioactivity. A specification for content of radioactivity may be important if the material is sourced from an area known to contaminate. For example, residues from the Chernobyl accident are still present in Eastern Europe.
- vii. Other relevant tests may include sulfur dioxide, ethylene oxide residue, polycyclic aromatic hydrocarbons (PAHs), aflatoxins and other mycotoxins, presence of genetically modified DNA, solvent residues, etc.



## CULTIVATION

Many factors must be considered and controlled in the cultivation of botanicals, from the choice of farm location through the applications of pesticides and fertilizer. These factors can significantly influence both the quality of the botanicals grown and the economics of the farming operation.

This section outlines recommended practices to ensure the quality and freedom from contamination of the crops produced. In addition, farmers of produce crops such as lettuce are usually (depending on certain exemptions) subject to the additional agricultural practice requirements established in 21 CFR Part 112.

### 3. C.1. Cultivation

#### C.1.1. Propagation material

- i. Seeds and other propagation material (roots, rhizomes, vegetative cuttings, tissue culture explants, spores, etc.) should be obtained from reliable sources such as reputable vendors, seed banks, or harvest from existing plants. Where possible, sourcing propagation material from governmental or other authoritative bodies such as international seed banks,<sup>58</sup> agricultural research stations, or universities may provide additional assurances of identity and quality; however, such sources may be limited in supply, and may be relatively expensive.
- ii. Propagation material should be clearly labeled and recorded with the identity, origin, date of collection or harvest, and other relevant descriptors where applicable (such as “organic,” “biodynamic,” “genetically modified,” or patent number).
- iii. Growers should take steps to ensure the correct botanical identity of seeds and other propagation material (e.g., through examination of documentation provided by the vendor and/or by morphologic examination of the crop once mature).
- iv. Growers should ensure that seed lots are of appropriate purity, health, and cleanliness, either by performing seed testing, by having an outside laboratory perform seed testing, or by requiring vendors to provide appropriate analytical reports for each lot of purchased seed. These tests should examine quality parameters such as:
  1. Percent viability.

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<sup>58</sup> For example, members of the International Seed Federation are required to meet special requirements such as recording the seed treatment rate used per line of seed. (This equals quantity of treatment material per quantity of seed). Accreditation is given to applicators based on certain criteria such as equipment calibration, record keeping, knowledge of factors affecting seed loadings, etc.



2. Presence of weed or other foreign seeds.
  3. Presence of insects.
  4. Presence of fungal contaminants.
- v. For each lot of propagation material used, records should be kept of the following:
1. Botanical identity of the lot, with as much specificity as appropriate. See section BQ.1.2. for detailed information on botanical identity.
  2. Other relevant information such as organic status, genetically modified status, or applicable patent number, if any.
  3. Source from which the lot was obtained (even if produced on-site).
  4. A copy of any guarantee, certification, analytical report, or other documentation provided by the vendor (where applicable).
  5. Results from any testing performed by the grower or an independent laboratory or consultant hired by the grower.
  6. Information regarding any treatments applied to seed by the vendor or grower to maximize germination, reduce pests or diseases, and improve yield.<sup>59</sup>
- vi. Growers may wish to maintain a retention sample of each lot of propagative material, for future reference if needed. Retention samples should be stored in a manner to protect against insects, microbial growth, moisture, excessive heat, and other sources of degradation. Where fresh plant material is used for propagation, samples should be stored in a frozen or dried state.

### C.1.2. Cultivation site

- i. The field or other setting in which a crop is to be planted should be evaluated to ensure it is suitable for cultivation of food (if applicable) and for the intended crop. Climatic conditions such as the length of day, sun intensity, rainfall (or irrigation) and humidity, air temperatures, and daily temperature cycles will significantly influence the physical, chemical and biological qualities of plants.

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<sup>59</sup> Seed treatments are used to initiate germination, promote good seedling establishment, minimize yield loss, maintain and improve quality, and avoid the spread of harmful organisms. Seed treatments may be chemical or physical.



- ii. Soil characteristics. Soil should be sampled in accordance with appropriate sampling plans,<sup>60</sup> and tested as appropriate; information regarding previous and neighboring land use may help identify relevant tests. Records should be maintained for at least several years of any soil testing performed. Tests to be considered should include:
  1. Soil pH. The pH may require adjustment to ensure the optimal range for the intended crop and/or to minimize weeds.
  2. Deficiencies in nutrients essential for growth of the intended crop (e.g., nitrogen, calcium, iron, etc.). Appropriate fertilizers may be necessary to provide nutrients at the optimal levels.
  3. Excessive levels of contaminants deleterious to either plant health (e.g., boron) or consumer health (e.g., heavy metals or radioactivity), or the presence and levels of any residual pesticides. Some crops will accumulate these contaminants to a greater degree than others. Contaminated soils may require appropriate remediation prior to planting the crop.<sup>61</sup>
  4. Other chemical characteristics as applicable, such as salinity, bicarbonate concentration, micronutrients, organic matter, etc.
  5. Soil texture (the relative amounts of sand, silt, and clay particles) and structure (the larger arrangements of particles). These characteristics strongly influence soil fertility and drainage, which in turn affect which crops can readily be grown at that location.
  6. Undesirable organisms. The presence of certain fungi, nematodes, etc. may affect which crops can be grown or may require appropriate control measures.
- iii. Water quality. Water should be tested as appropriate to evaluate its suitability for use in cultivation of food, its suitability for the target crop, and the extent to which it may require treatment prior to use.<sup>62</sup> Information regarding previous and neighboring land use, or (where municipal water is used) from annual municipal testing, may help identify

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<sup>60</sup> Information on soil sampling can be found from various organizations, such as <http://www.fao.org/docrep/003/t0234e/t0234e01.htm> and <http://animalrangeextension.montana.edu/forage/documents/soil%20sampling%20strategies.pdf>; an example plan is available at [http://www.waterboards.ca.gov/rwqcb4/water\\_issues/programs/401\\_water\\_quality\\_certification/Newhall/Workplan%20Soil%20Sampling%20for%20Pesticides%20March%202013.pdf](http://www.waterboards.ca.gov/rwqcb4/water_issues/programs/401_water_quality_certification/Newhall/Workplan%20Soil%20Sampling%20for%20Pesticides%20March%202013.pdf).

<sup>61</sup> If soil contaminants occur at levels high enough to be potentially problematic, a risk analysis, testing, or additional research should be performed to determine whether or not crops grown in the soil will meet established contaminant specifications. This also applies to contaminants found in water or air. The correlation between contaminants in the environment and their presence in the plant should be evaluated on a case by case basis.

<sup>62</sup> Procedures for various testing methods and parameters to test are available at <https://www.epa.gov/cwa-methods> and <http://www.fao.org/docrep/003/t0234e/t0234e01.htm>.



relevant tests. Maintain records for at least several years of any water testing performed.

Tests to be considered should include:

1. Water pH. Water that is too acidic or alkaline may interfere with cultivation of the target crop.
  2. Excessive levels of contaminants deleterious to either plant health (e.g., boron) or human health (e.g., heavy metals or radioactivity), or the presence and levels of any pesticides. Some crops will accumulate these contaminants to a greater degree than others.
  3. Other chemical characteristics as applicable, such as sodium absorption ratio, salinity, bicarbonate concentration, etc.
- iv. Site location and setting. Information relevant to either improving or damaging the crop or the site itself should be recorded and maintained for at least several years, if not permanently. Factors to consider may include:
1. Annual and seasonal rainfall at the specific location, or at least in the location's vicinity.
  2. Access to water, if the crop requires irrigation.
  3. Available sunlight and sun intensity, taking into account the site's facing in relation to cardinal direction (north, south, east, west), latitude, average annual sun days vs. overcast days, shading from trees or structures, etc.
  4. Annual climactic conditions such as USDA zone, average chill hours, humidity levels, etc.
  5. Slope, insofar as this affects drainage, the potential for water pooling or flooding, erosion and loss of topsoil, or runoff that may bring contaminants from neighboring properties.
  6. Geologic characteristics such as the presence of bedrock, hardpan, or a high water table that will affect water drainage or root growth.
  7. Identity (and genetic modification status, if relevant) of crops that will be grown on adjoining sites, if known, and any treatments that may be applied to those crops, if known.<sup>63</sup>

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<sup>63</sup> Information regarding adjoining fields may be difficult or impossible to obtain, and may not be relevant depending on the nature of the crops to be grown, the purpose for which the crops will be used, the application method of any pesticides used in neighboring property (e.g., spray by airplanes or fogging vs. more targeted application methods), the potential for airborne or waterborne drift from the neighboring property, etc. A risk assessment may be appropriate.



8. Location in relation to potential sources of air- or water-borne contamination, such as waterways, industrial facilities; mine tailings; parking lots; golf courses; underground storage tanks; feed lots; cities; etc. Pay special attention to potential sources of contamination that are upwind from the farm or upstream from the farm's water supply, where applicable.
- v. Site history. A thorough history of prior uses of the crop area should be prepared and maintained to the extent possible. Such records should be maintained for at least several years, if not permanently. Site characteristics to be considered may include:
1. Previous use of the site for housing, commercial, or industrial uses, and any physical or chemical contaminants that may have resulted therefrom.
  2. The most recent crop grown on the site, or if possible the crops grown in the past several (3-5) years.
  3. Crops recently grown on any adjoining sites, if possible.<sup>64</sup>
  4. Any recent (in the past 3-5 years if possible) use or detection of pesticides on the site, if known, including insecticides, herbicides and fungicides. If possible, information about the rates at which any such pesticides break down should be documented.
  5. Any recent use of the site as a feedlot, or for any other purpose for which domestic animals have had recent access to the site.
  6. Any corrective actions that have been taken to prepare a site where prior environmental contamination is known.
  7. Where organic status is desired for the crop, consider previous treatment of the site with pesticides or other disallowed substances that may interfere with organic certification.

### C.1.3. Fertilizer use

- i. Fertilizer use should generally be guided by soil sample analysis to determine what fertilizers may be needed, and what ratios of nutrients are required.
- ii. Consideration should be given to the value of fertilizer use in producing better and larger yields, as well as the effects such use may have in the environment.

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<sup>64</sup> As mentioned above, information regarding adjoining fields may be difficult to obtain and may not be relevant; a risk assessment may be appropriate.





- iii. Federal, state and local regulations may apply to some of the chemical fertilizers used on crops. Furthermore, organic growers must refrain from using chemical fertilizers; instead they should use naturally-sourced amendments when needed.
- iv. Fertilizer stocks should be kept away from water supplies and harvested crop materials.
- v. For chemical fertilizers:
  1. Apply in accordance with federal, state and local regulations that are applicable to the specific fertilizer, if any.
  2. Use in accordance with all label directions (e.g., application rates, safe handling, proper disposal, etc.).
  3. Store chemical fertilizers properly according to label instructions.
- vi. For manure- and/or compost-based fertilizers:
  1. Apply in accordance with organic and other regulations as applicable.
  2. Do not use manure- or compost-based fertilizers produced with sewage sludge or human feces; these present risks not only to downstream users or consumers of the crop, but also to farm personnel.
  3. Similarly, do not use untreated manure of any kind for crop fertilization. Use only fertilizers that have been adequately treated through an aerobic process.
  4. Monitor for undesirable microbial pathogens using appropriate test procedures. Testing may be performed periodically during composting or may be performed on finished batches of compost. Maintain records of such monitoring for several years.
  5. For manure- and/or compost-based fertilizers that are produced or openly stored on-farm:
    - Follow proper composting procedures (e.g., balanced carbon to nitrogen ratio; appropriate moisture levels; etc.).<sup>65</sup>
    - Monitor runoff from composting and storage sites. Maintain records of such monitoring for several years.
    - Do not include sewage sludge or human feces in compost.

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<sup>65</sup> Additional information on composting procedures can be found at <http://www.bae.ncsu.edu/extension/ext-publications/waste/composting/ag593-large-scale-composting.pdf>; <http://www.cwc.org/wood/wd973rpt.pdf>; <http://afsic.nal.usda.gov/soil-and-water-management/compost-and-composting>; and from organizations such as the Composting Council (<http://compostingcouncil.org/>).



- Where possible, avoid composting the seed heads of weedy plants unless the seeds will be killed by the heating of the compost pile.

vii. For all fertilizers:

1. Ensure that packaged fertilizers and containers of diluted or prepared fertilizer are properly labeled at all times.
2. Ensure that only properly trained personnel apply crop fertilizers.
3. Provide adequate safety protection for personnel.
4. Ensure that appropriately clean equipment and supplies are used. Ensure that fertilization equipment and supplies are appropriately decontaminated and/or disposed after use.
5. Apply fertilizers at a sufficiently early phase in the crop's cycle to optimally promote growth and to ensure the fertilizer has appropriately broken down before harvest.
6. Apply water-soluble foliar fertilizers within 24 hours of preparation. Prompt use optimizes the effectiveness of the application and prevents microbial contamination of the solution.
7. Ensure that water used for mixing any soluble fertilizer is potable or meets established criteria for agricultural irrigation water.
8. Apply fertilizers in a manner that does not contribute to contamination of water supplies.
9. When growing a crop on a contractual basis, use only fertilizers that have been authorized by the buyer, or provide the buyer with an opportunity for review and approval.
10. Maintain records of fertilizers used, including:
  - Fertilizer name or description.
  - Chemical name where applicable.
  - Vendor or other origin.
  - Date applied and by whom.
  - Quantity and/or concentration applied.



### C.1.4. Irrigation

Access to water of sufficient quantity and quality is essential to farm operations, and many crops rely on irrigation to supplement water received from normal rainfall.

- i. The following steps should be implemented to assure water quality and efficient use in farm operations.
  1. Water source. Identify the source of all water used in crop production (for example, on-farm well(s), open irrigation canal(s), reservoir(s), a municipal supply, or other sources).
  2. Water monitoring. Establish and follow testing procedures to monitor for contaminants of concern. This may include pathogenic microbes that may be present in water supplies (e.g., *E. coli* and other coliforms), heavy metals, pesticide residues or other contaminants.<sup>66</sup> The frequency of such procedures should take into account the water source(s) and results of previous tests. Analytical reports should be maintained on file for several years.
  3. Irrigation type. Choose the irrigation type (e.g., drip system, sprinkler, subsurface, overhead, etc.) based on considerations of cost, water conservation, plant health, and the risk of increased vector-borne diseases (e.g., from snails or mosquitoes).
  4. Irrigation systems. Do not use irrigation systems or equipment that may contaminate water or crops, such as those with lead pipes or fittings. Maintain irrigation systems in good working condition (i.e., no leaks or drips) to prevent water waste and to avoid high soil moisture levels that may contribute to mold and fungal problems.
  5. Application of irrigation. Apply irrigation according to the needs of the species and in a manner that adequately avoids runoff.
  6. Legal conformity. Conform to all rules that are applicable to the local or state water district.
- ii. Maintain irrigation-related records for at least several years, including:
  1. Records of water sources used in irrigation.
  2. Records of water quality testing.
  3. Records of irrigation system design, construction, maintenance, and repair.

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<sup>66</sup> Procedures for various testing methods and parameters to test are available at <https://www.epa.gov/cwa-methods> and <http://www.fao.org/docrep/003/t0234e/t0234e01.htm>



4. Any records needed to establish conformity with any applicable regulations.

### C.1.5. Crop maintenance and protection

The growth and development characteristics of individual plants, as well as the plant part destined for use, should guide field management practices. Various strategies can be implemented to protect and maintain the crop and to maximize the success of the harvest.

- i. Cultivation techniques. Adapt tilling, mulching, and other cultivation practices to the requirements of the specific crop and to minimize weeds. Consider use of no-till farming to reduce overhead costs (labor, equipment, and inputs such as fuel and irrigation), reduce soil erosion, and improve soil moisture and fertility which can improve yields.
- ii. Growth controls. The timely application of measures such as thinning, topping, bud nipping, pruning and shading may be used to control the growth and development of the plant, thereby improving the quality and/or quantity of the plant material being produced.
- iii. Crop rotation. Consider adjusting crop rotation plans to maintain soil fertility (e.g., through periodic planting with nitrogen-fixing crops) and to minimize pest and disease problems.
- iv. Companion plants. Consider companion planting strategies such as interplanting with crops that repel damaging insects or attract predatory insects; separately planting trap crops to attract insects away from the target crop; or interplanting to provide necessary shade, support, or humidity. Certain combinations of companion plants are reported to improve flavor and/or vigor. Conversely, some combinations of plants are known to stunt growth and should be avoided.
- v. Weeds. During crop growth and immediately prior to harvest, monitor fields for undesirable weeds and control them as appropriate. Any weeds containing tropane or pyrrolizidine alkaloids should be appropriately eliminated before harvesting.
- vi. Integrated pest management.<sup>67</sup> Minimize pest and disease infestations through appropriate selection of resistant varieties, appropriate choice of sowing time, appropriate seed treatments, removal of dead or diseased plants or tissues, applications of beneficial bacteria and fungi (e.g. mycorrhizae; compost tea), etc. Where insects reach unacceptable levels, evaluate alternatives to insecticides such as use of beneficial

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<sup>67</sup> Integrated pest management (IPM) involves the careful consideration of all available pest control techniques and the use of appropriate measures to discourage the development of pest populations and to reduce the use of pesticides to the extent possible. IPM emphasizes the growth of a healthy crop with the least possible disruption to ecosystems by encouraging the use of natural pest control mechanisms.



insects, physical insect barriers and traps, vacuuming, etc. Check with state agricultural agencies for guidance.

vii. Pesticide use. Pesticides (insecticides, herbicides, fungicides, etc.) from either natural or synthetic sources must be carefully controlled.

1. Pesticides should be applied to crops at the minimum effective rates, and only by properly trained personnel with the proper application equipment and personal protective equipment.
2. All pesticides must be approved for use on the specific crop by both local and U.S. federal governments. Application levels must ensure that established tolerance levels for the crop are not exceeded, except for pesticides for which no tolerance is required to be established by U.S. regulation,<sup>68</sup>.
3. Application and storage must be in accordance with label instructions and all regulations.
4. Keep pesticide stocks away from water supplies and harvested crop materials.
5. Pesticides must be applied sufficiently in advance of harvest to comply with label instructions and any relevant regulations.
6. Records of pesticide use should be kept for at least several years, including:
  - Pesticide name or description.
  - Chemical name where applicable.
  - Vendor or other origin.
  - Date applied and by whom.
  - Quantity and/or concentration applied.

viii. Records.

1. In addition to the pesticide-related records discussed above, maintain other records of crop planting, cultivation, maintenance, and protection as appropriate. Activities may be recorded in a Daily Farm Log that combines all this data into the same document, or in activity-specific documents such as a Fertilizer Application Log, Pesticide Application Log, etc.<sup>69</sup>

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<sup>68</sup> See for example 40 CFR 180.900-180.1325 and 180.2000-180.2020.

<sup>69</sup> An example of such a log is available at <https://www.ccof.org/documents/sample-farm-activity-log>. Alternately, software is available to manage and record farm activities.



2. All records with relevance to a particular cycle of cultivation and 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.<sup>70</sup>

### C.1.6. Other considerations

- i. Genetically modified materials. If genetically modified seeds or vegetative stock are used as propagation material, conform to all relevant federal and regional regulations, both at the agricultural location and in the countries in which the material may be sold. Also, disclose the use of genetically modified propagation material in records and crop labeling to ensure that downstream recipients of materials produced from these crops are informed of such use. If the crop is intended to receive non-GMO certification, follow the applicable requirements (e.g., with respect to seed sources, manure- or compost-based fertilizers, etc.).
- ii. Organic materials. If the crop is intended to be certified organic per the USDA National Organic Program,<sup>71</sup> conform to all relevant federal and regional regulations governing organic certification. Disclose the organic status of the crop in records and labeling to ensure that downstream recipients of materials produced from these crops are informed of the organic status.
- iii. Environmental stewardship. Growers should take steps to protect and improve the stability and quality of the topsoil that is essential to their farms' longevity. Farm water should be used resourcefully and in a manner that protects the immediate water supply, as well as all downstream supplies. To the degree possible, growers should maintain and enhance the biodiversity of their farms, and minimize the deleterious effects of fertilizers and pesticides on groundwater and surrounding areas.
- iv. Produce crops. If the crop being grown meets the definition of "covered produce" in 21 CFR Part 112, comply with the requirements of those regulations.<sup>72</sup> Certain elements of Part 112 will require more stringent, more specific, or more extensive standards than what is suggested herein, for example with respect to agricultural water quality, exclusion of animals, etc.

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<sup>70</sup> 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.

<sup>71</sup> In the US, only crops grown and certified under the USDA National Organic Program or that are recognized as organic crops through USDA international agreements are permitted to be called "organic." See <https://www.ams.usda.gov/services/organic-certification/international-trade>.

<sup>72</sup> See Appendix 1 for a discussion of "covered produce."



## WILD COLLECTION

Many botanicals in trade are collected in the wild rather than cultivated. From the choice of collection location to the collection techniques used, careful consideration of the relevant factors will help ensure the wild collection operation yields properly identified botanical materials of the desired quality, and is able to do so year after year on a sustainable basis.

Wild collectors of fresh produce such as blueberries may be (depending on certain exemptions) subject to specific agricultural practice requirements established in 21 CFR Part 112. Whether or not Part 112 applies, this section outlines recommended practices to ensure the identity, quality and sustainability of the crops produced.

### 4. WC.1 Wild collection

#### WC.1.1. Permits and permissions

Whether wild collection occurs on public or private property, the wild collector must conform to rules established by federal, state and local governments, and by land managers and owners.

- i. Procure the necessary permits, licenses, and permissions prior to collecting from public lands or entering private property.<sup>73</sup> Allow sufficient time for the processing and issuance of these permits at the planning stage. Maintain permits, licenses, and written permissions on file for as long as they remain relevant to the collection activities and for several years thereafter.
- ii. Public property.
  1. If collecting from government-owned land, contact the appropriate government office and obtain a permit or license, if required, before collecting.
    - When collecting from U.S. National Forest or National Grasslands, or on land controlled by the Bureau of Land Management, contact the appropriate office of the U.S. Forest Service regarding permits.
    - Collection of plants is not allowed in any U.S. National Park.

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<sup>73</sup> Depending on the circumstances, permits, licenses and permissions may be arranged by the collector or by the dealer who will buy the harvest.



- If collecting on U.S. state-owned public lands,<sup>74</sup> contact the appropriate state office before harvesting. Note that some states do not allow plants to be collected on state-owned lands. Obtain a state harvest license if required for the harvest crop.<sup>75</sup>
2. Follow all rules that apply to permitted collecting on public lands, including limits and seasonal requirements, if any; established restraints on collection in camping areas and near trails and roadsides; requests for submission of harvest data; fee payment; and any other rules.
  3. Carry all required permits and licenses while collecting.
- iii. Private property.
1. Obtain permission from the owner or owner's agent to enter and to collect on any private property. Certain state or local laws may require such permission to be in writing.
  2. Obtain a state harvest license if collection occurs in a state where such a license is required for the plant to be collected.
  3. Comply with any agreements that have been made with the owner or agent of private property on which collection occurs.
  4. Carry a copy of applicable permissions when collecting.

### WC.1.2. Collection site

- i. Collectors should select harvest sites where the target plant can be readily found and is also likely to be of good quality and free of pollution and other deleterious contaminants. Choice of collection site can impact the marketability of the material.
- ii. Species habitat. Be aware of the normal habitat for the species and choose collection sites to target healthy stands of plants growing in their normal range. Survey potential collection areas to determine whether the target species occurs in large enough quantities for collection to be sustainable.
- iii. Site characteristics. Record and maintain relevant information regarding the collection site. Such records should be maintained for as long as collections are conducted at the site, and for several years thereafter. Factors to consider and document may include:

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<sup>74</sup> The boundary of each U.S. coastal state extends for three miles seaward from its coastline. Most U.S. coastal states have policies that require permits for commercial harvest of seaweeds, and collectors of these plants must adhere to relevant state rules.

<sup>75</sup> For example, a license is required to harvest wild American ginseng in some U.S. states, whether collected on public or private land.





1. Obtain information about prior use of the site, if any.
2. If the site has been recently under cultivation, try to determine what, if any, fertilizers and pesticides were used.
3. Determine whether any recent chemical applications have been made to control insects or invasive species, or for other management purposes.
4. Consider soil tests prior to harvest on locations that have been the site of significant human activity, such as abandoned home sites, dumps or landfills, quarries, etc.
5. Determine whether water sources at or near the site are potential sources of pollution (e.g., downstream from industrial facilities, mine tailings, parking lots, golf courses, underground storage tanks, etc.).
6. Be aware of any buried utilities that are present at the site.
7. Refrain from harvesting if there are indications that the site may harbor environmental hazards.
8. Do not harvest in close proximity to roads or to railroad rights-of-way if these pose a risk of unacceptable contamination; a risk assessment may be appropriate.
9. Do not harvest under above-ground power lines if the buyer has specified a concern about such locations.

### WC.1.3. Sustainability

- i. Collectors of wild plants should apply collection practices that address not only their need to gain economic benefits from the sale of wild-harvested plants, but that also make sure that each of the collected species survives. In addition to preserving (or preferably enhancing) plant populations, collection practices should also minimize damage to the local habitat.
- ii. Collectors should be knowledgeable about each of the plants they harvest and should use collection practices that are appropriate to each species and collection area. Training should preferably be obtained from a qualified and experienced collector.
- iii. To make sure that harvests minimize damage while enhancing the health of the collected species, collectors should use the practices in the following paragraphs as applicable.<sup>76</sup>

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<sup>76</sup> Note that the guidelines provided here may not be particularly relevant to the collection of weedy or invasive species, where eradication may be viewed as a desired outcome.



- iv. Endangered species. Consult national and local legislation such as national “red” lists, as well as international guidance such as the Appendices to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). Do not collect species listed in CITES Appendix I or that are otherwise designated as endangered. In the U.S., do not collect plants that are listed as endangered under the U.S. Endangered Species Act <sup>77</sup> or that are not allowed to be harvested under state regulations due to concerns about over-harvest.
- v. Abundance. Collect only from stands of the target species that are abundant and healthy, with multiple plants of differing ages (seedling, juvenile, and mature), to ensure population stability. Avoid collecting from stands where the plant is sparse or that are outside of the species’ normal range. Refrain from collecting in the same location as earlier harvests until the population is sufficiently reestablished.
- vi. Maintaining population stability.
  1. When collecting reproductive plant parts (e.g., flowers, fruit, seed), do not take all of those plant parts from any plant population. Rather, leave enough so that each population will be able to produce an adequate amount of seeds to sustain the population.
  2. When collecting leaves from trees or woody plants, refrain from excessive defoliation of any individual plant.
  3. For collection of bark from trees or shrubs:
    - Do not “girdle” trees by removing the bark all the way around the tree, unless the tree has been or is to be removed for other purposes (e.g., for timber harvest) or is otherwise to be destroyed.
    - Whenever possible and acceptable for meeting quality standards, harvest bark from branches of the tree rather than from its trunk.
    - When possible and applicable to the particular species, prune trees and shrubs in a manner that encourages bark-producing growth, for example, by coppicing, which involves periodic cutting to encourage growth of suckers.

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<sup>77</sup> No North American species listed on CITES Appendix I are commonly in trade as dietary ingredients. At the current time, only one North American species used as a dietary ingredient is listed as endangered under the U.S. Endangered Species Act, the Tennessee purple coneflower (*Echinacea tennesseensis*); inadvertent collection of this species must be avoided.



- As necessary and appropriate, use a dressing that will protect the exposed portion of the tree from invasion of pathogens, rodents, or insects that may cause further damage to the plant.
4. For collection that involves taking the entire plant (e.g., roots):
    - Limit collection in any one population to leave sufficient numbers for regeneration of that population.
    - Collect by thinning plants instead of collecting all of the plants along the margins or in one particular part of a colony.
    - If the species is seed propagated, collect only after the fruit has ripened and the seed has been released, where possible.
  5. When collecting roots of perennials:
    - Leave some plants from each life stage (seedling, juvenile, mature).
    - Collect only plants that are mature enough to have produced viable seed, where possible.
    - For species that can regenerate from portions of roots or root crowns, leave a portion of the root in the ground or replant whole or divided crowns, as appropriate.

vii. Propagation and regeneration.

1. Propagation by seed. For collected species that reproduce sexually, plant the seeds in a suitable environment near the collection site.<sup>78</sup>
2. Asexual propagation. Plant whole or divided root crowns, as appropriate, or prepare other asexual propagation material and plant in a suitable environment near the collection site.<sup>79</sup>
3. Pruning. Consider pruning of trees and woody plants to enhance leaf and flower (and therefore fruit and seed) production.

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<sup>78</sup> If there is a threat of development or other habitat depletion is apparent, it may be preferable to plant the seeds in a different but ecologically similar location.

<sup>79</sup> If there is a threat of development or other habitat depletion is apparent, it may be preferable to plant the propagation material in a different but ecologically similar location.



viii. Habitat stewardship.

1. Minimize habitat disruption. Avoid trampling of surrounding plants and use appropriate equipment for collection. Take care to repair any unavoidable impacts (for example, by filling holes after digging roots).
2. Be aware of land-use and zoning activities in collection areas and provide input to community leaders to protect these habitats. Also, report any signs of trespassing, property damage or habitat loss in collection areas.
3. Protect wildlife habitat and keep in mind that many wild plants provide important food for wildlife.
4. Consider making note of the species, age classes, cover species, abundance, and other habitat parameters so any changes can be recorded and shared with land regulating agencies.

ix. Records.

1. Records should be maintained to document information and collection practices that ensure the sustainability of the harvest, such as:
  - Information about the plant's biology, life cycle, reproduction, etc.
  - Information about the plant's age(s), abundance, and health at the collection site(s).
  - Any special collection practices used, the proportion of plants harvested from any given population, and any steps taken to propagate or regenerate the plant.
2. All records with relevance to a particular cycle of 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.<sup>80</sup>

### WC.1.4. Identification

- i. Wild collectors should have appropriate training and experience to ensure that all harvested plants are correctly identified. Wild collectors should limit their harvest to plants that they can accurately identify to the correct species, and to subspecies and/or variety where applicable.

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<sup>80</sup> 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.



- ii. Consider bringing an authenticated specimen or voucher to the field for comparison during collection. This may be especially important if the plant parts most easily used for identification (e.g., flowers) are not present at harvest time.
- iii. If the collector is unsure of the identity while in the field, specimens should be taken to a local expert for verification before returning to the field to collect; alternately, the specimens may be compared to taxonomic keys, pharmacopoeial descriptions, etc.
- iv. If positive identification requires examination of the flower or fruit, but at the time of collection the flowers or fruits are not present, visit the collection site during the flowering or fruiting period to confirm the identification prior to collecting from that site.
- v. Be aware of any local species that are easily confused with the target species, and take special care to exclude these from the harvest. This is especially critical if a toxic plant may be confused with the target plant.
- vi. Whenever necessary to ensure identity, engage a qualified botanist, pharmacognosist, or similarly qualified expert to provide positive identification of the harvested material.
- vii. Maintain records of all steps performed to ensure the correct identification of wild collected plants, including the qualifications of wild collectors. Maintain such records for at least several years; or for collectors, for as long as a wild collector is active in collections.

### WC.1.5. Other considerations

- i. Consider developing a comprehensive written wild collection plan.
- ii. Produce crops. If the material being collected is a food meeting the definition of “covered produce” in 21 CFR Part 112 (e.g., wild blueberries, wild mushrooms, etc.), and if the wild collecting operation does not qualify for the exemptions in 21 CFR §112.4 and §112.5, then the wild collector must comply with the sections of Part 112 that apply to the activities the wild collector performs (such as harvesting, sorting, washing, or packing).<sup>81</sup>
- iii. Non-covered-produce crops. If the material being collected is not a food or does not meet the definition of “covered produce” in 21 CFR 112 comply with the general farm standards described in Section 5 of this document.<sup>82</sup>

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<sup>81</sup> See Appendices 1 and 2 for further information. The wild collector does not have to comply with those standards in Part 112 that apply to activities the collector does not perform. For example, since the wild collector is not performing growing activities, the wild collector does not have to comply with sections of Part 112 that apply to growing (e.g., standards for agricultural water quality or biological soil amendments).

<sup>82</sup> Wild collection operations are defined as “farms” under U.S. regulations. However, not all farms have to comply with the requirements of 21 CFR Part 112.



- iv. Organic materials. If the crop is intended to be certified organic per the USDA National Organic Program,<sup>83</sup> conform to all relevant federal and regional regulations governing organic certification. Disclose the organic status of the crop in records and labeling to ensure that downstream recipients of materials produced from these crops are informed of the organic status.

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<sup>83</sup> In the U.S., only crops grown and certified under the USDA National Organic Program or that are recognized as organic crops through USDA international agreements are permitted to be called “organic.” See <https://www.ams.usda.gov/services/organic-certification/international-trade>.



## 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.

### 5. GF.1 General farm standards

#### GF.1.1. 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.<sup>84</sup> 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.<sup>85</sup>
  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

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<sup>84</sup> See Appendix 2 for more information.

<sup>85</sup> 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.



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 8 and 9 of this document.
  4. In addition, if a farm or farm mixed-type facility dehydrates raw agricultural commodities that are “produce”<sup>86</sup> 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.

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<sup>86</sup> Note that this establishes a requirement applicable to all produce, not just “covered produce” as defined in Part 112.





### GF.1.2. Farm buildings

Buildings used for farm activities that do not require food facility registration as defined in 21 CFR Part 117<sup>87</sup> 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.<sup>88</sup>
- 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.
- vi. Grounds. Minimize the presence of trash, landscape plants, pooling water, and other harborage for pests around the exterior of farm buildings.
- vii. 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.

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<sup>87</sup> See Appendix 3.

<sup>88</sup> 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 1 and 2.



### GF.1.3. Farm equipment

Equipment (including utensils) used for farm activities that do not require facility registration as defined in 21 CFR Part 117<sup>89</sup> 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

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<sup>89</sup> See Appendix 3.



- 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.<sup>90</sup> 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.

#### **GF.1.4. 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.

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<sup>90</sup> Note that depending on the harvest location it may not be possible to provide toilet and/or hand-wash facilities.



- 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.

#### **GF.1.5. 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.<sup>91</sup>

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<sup>91</sup> 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.



# HARVEST OF CULTIVATED AND WILD COLLECTED PLANTS

Harvesting procedures for both cultivated and wild collected plants require proper attention in order to ensure botanical quality. Harvest timing, weather conditions, handling of the harvested material, and other factors must be carefully considered. This section recommends good harvesting practices applicable to farms in general; it does not include any specialized requirements established in 21 CFR 112 for covered produce farms.

## 6. H.1 Harvest of cultivated and wild collected plants

### H.1.1. Harvest conditions

Harvest season and harvest time are important factors in the collection of good quality plant material. Furthermore, the condition of the plants themselves at the time of harvest has a significant effect on quality, as do ambient weather conditions and the actual practices that are used to conduct the harvest.

- i. Crop condition. Schedule the harvest, both in terms of time of year and time of day, when the crop is in the proper condition to meet established quality requirements. Consider such factors as the maturity of the plants or degree of ripeness, size, color, moisture levels, and other characteristics, as well as measured constituent levels if applicable.
- ii. Weather conditions.
  1. Evaluate weather conditions at the actual time of harvest. Depending on the circumstances, it may be preferable to avoid harvesting when rain, dew, or excessive humidity are present; alternately it may be preferable expedite the harvest and move the material to a dry area. It may also be preferable to avoid harvesting in hot weather, especially if the crop is susceptible to wilting.
  2. Consider weather forecasts for several days immediately following harvest if rain, heat, or other weather could adversely affect the quality of the harvested material.
  3. Wet weather may pose greater problems with delicate plant parts such as leaves and flowers and fewer problems for harvest of sturdy plant parts, such as bark or roots. However, splashing from rain or hail may contribute to excessive levels of dirt in the harvested material, which will need to be removed.



4. If harvest must occur under wet conditions, take care where necessary to dry the material promptly and properly to avoid damage and spoilage from mold or soil bacteria.
- iii. Harvest timing. The following guidelines may assist in determining the best time to harvest various types of crops. However, these are only general in nature; the actual seasons and life cycles for collecting any particular plant material may vary.
1. Always take into account any harvest season specifications that have been set by the material's buyer.
  2. Review harvest research that has been conducted to evaluate the optimal harvest times for various plants.
  3. Consider the timing of harvest in light of other needs, such as allowing seed to mature for the next season's planting or for regeneration of a wild population after collection.
  4. It is often preferable for above-ground parts of plants to be collected early in the day but after any dew has evaporated. (This may be less relevant to harvest of bark.)
  5. Leaves. Collect leaves from herbaceous plants before the plant flowers, unless otherwise specified. Collect tree leaves anytime during the growing season, except that leaves from some deciduous species should be harvested in a particular season to maximize desired constituents.
  6. Flowers. In general, harvest flowers (or if specified, flowering tops) when they have just opened or shortly enough afterwards to avoid faded or brown blossoms. If harvest specifications require flower buds, collect these before the buds open.
  7. Fruits. Harvest fruits when they are mature and ripe, unless specifications require collection of immature fruit.
  8. Seeds. In general, harvest seeds just as they are ripening or when they, or the fruit in which they are contained, are fully ripe.
  9. Roots. Dig the roots of annual plants when the plants are well developed, but generally before flowering. Harvest roots of perennials late in the fall or early in the spring. Collect biennial roots in either the fall of the first year or spring of the second year.
  10. Barks. Where possible, harvest barks in the early spring, prior to any new growth, or in the late fall or winter.



11. Saps and pitches. Collect tree saps and other exudates late in the winter or early in the spring. Leave a protective layer of sap or pitch to provide protection for the tree against infiltration by insects and pathogens.
12. Whole plants. When collecting whole herbaceous plants, or the entire aerial parts of herbaceous plants, harvest prior to any visual decline in any of the plant parts. This is typically at the stage when flowers are emerging.

### H.1.2. Harvest quality

Harvest and handling practices have a significant impact on the quality of the harvested material.

- i. To the extent possible, avoid harvesting plant materials that are broken or moldy, exhibit insect damage or excessive insect infestation, or are otherwise undesirable.
  1. Limit the proportion of discolored leaves in any leaf harvest to meet established specifications, if any.
  2. Collect only unbruised fruits and pack them carefully if necessary to prevent bruising.
  3. Encourage departure of insects from harvested flowers by shaking the material and by allowing it to sit for some time.
  4. Handle carefully any delicate plant parts such as flowers, tender leaves, and ripe fruit to avoid bruising and spoilage.
- ii. For leaves, flowers, and roots that are rich in essential oils, handle the material carefully to prevent release and degradation of the oils. Essential oils commonly occur in glands on the surface of the plant, and the more the glands are disturbed the more essential oils will be lost.
- iii. Conduct the harvest in a manner that minimizes the presence of foreign matter in the harvested crop, such as soil, weeds, insects, bird nests, spider webs, lichen, trash, plant parts other than the desired part, etc.
  1. If collection is done by shaking plant material from trees, collect onto a clean tarp to prevent direct contact with soil.
  2. Remove foreign matter at the time of harvest or prior to transporting the harvest from the field, if practical.
- iv. Examine the harvest carefully and remove damaged, degraded, moldy, off-color, improperly sized, or otherwise undesirable plant material, and remove non-target plant



parts where they occur (as by separating berries or flowers from stems).<sup>92</sup> Also remove any contaminant species that may have been inadvertently collected with the harvested crop, with special attention to any local species that are toxic or potentially toxic. During this inspection, remove as much dirt as possible.

- v. Ensure that harvested materials are kept clean and isolated from contaminants such as dirt, dung, smoke, and exhaust.<sup>93</sup> Where the harvest is stored on the ground temporarily, consider using plastic sheeting or another clean material between the harvest and the soil; however, this is not appropriate for all crops, especially large-volume crops that are cut and left in the field to dry (e.g., alfalfa).
- vi. In general, avoid compaction of the harvested material as this may cause physical damage as well as temperature build-up and overheating.
- vii. Protect the harvested crop from moisture where necessary to minimize growth of bacteria, yeast, and mold. Unless fermentation is desired, ensure adequate air circulation around the harvested material, especially if stored in containers or under a cover.<sup>94</sup>
- viii. Protect the harvested crop from contact with birds, rodents, insects, and other animals.
- ix. Control exposure of the harvest to the elements (sunlight, heat, wind, etc.) as appropriate. In many cases, the harvested material should be protected from the elements in order to preserve freshness. In other cases (e.g., where sun-drying is desired) such exposure may be beneficial.
- x. Transfer the crop to an appropriate receiving station. Ensure that the harvest is not inappropriately fumigated during transport.

### H.1.3. Harvest documentation and samples

- i. A lot number should be assigned to harvested materials on an appropriate basis (e.g., one day's harvest is one lot; one field's harvest is one lot; or one collector's harvest is one lot).<sup>95</sup> Whichever criteria are used, ensure the material in one lot can reasonably be expected to be uniform and consistent.
- ii. Records.

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<sup>92</sup> The process of separating the target plant material from unusable or undesirable material is known as "garbling."

<sup>93</sup> Smoke and exhaust contain polycyclic aromatic hydrocarbons (PAHs), which are known carcinogens. Many governments have imposed limits on the permissible content of PAHs in foods and other products.

<sup>94</sup> Some crops are fermented after harvest in order to prepare the material for use (e.g., vanilla, cocoa, and other spices); in such cases, post-harvest storage conditions should be appropriately chosen to stimulate the necessary fermentative enzymes and/or microorganisms.

<sup>95</sup> AHPA strongly recommends use of lot numbers for both food and non-food crops in order to facilitate quality assurance.





1. Records should be kept of the following:
  - Botanical identity of the harvested crop, including plant part.
  - Lot number(s).
  - Harvest date(s).
  - Harvest quantity(s).
  - Harvest location(s) (e.g., field numbers or collection sites).
  - The identity of personnel involved (e.g., collectors and harvesters; supervisors and managers).
  - The age and/or life stage of the crop at the time it is harvested, where necessary for clarity.
  - Field conditions at the time of harvest, where relevant.
  - Other information as needed.
2. Consider making a photographic or videographic record of the cultivation or collection site and of the plant population(s) and individual plant specimens.
3. All records with relevance to a particular cycle of 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.<sup>96</sup>
- iii. Labeling. Label harvested materials as appropriate to prevent the possibility of mix-ups. Include the lot number. Include the presence of any allergens and the grade such as organic or non-GMO, especially when needed to distinguish between similar crops on the same farm.
- iv. Voucher specimens. Consider preparing appropriate voucher specimens of the harvested plants. This may be particularly important for wild harvested plants.<sup>97</sup>
  1. For wild harvest, it may be appropriate for each collector to submit a voucher that is representative of the plants harvested by that collector.
  2. Vouchers should be labeled with the botanical identity, date of preparation, person who prepared the voucher, and person who harvested the plant. Details such as the harvest/collection date, harvest/collection site (e.g., country and latitude/longitude), and general descriptions of the plant and habitat at the time

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<sup>96</sup> 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.

<sup>97</sup> See Appendix 7 for detailed information about preparing voucher specimens.



of harvest should be annotated on the voucher or maintained in associated documentation.

3. Each voucher should be assigned a voucher number and records should be kept of which harvest lot numbers are represented by a given voucher.
- v. Keep a retention sample of each lot of harvested material.
1. The sample may be taken either immediately after harvest, after washing and cleaning the harvest (if performed), and/or after dehydration (if performed). In any case, at least one retention sample should be taken before the harvested material is subject to any size reduction steps.
  2. Label the retention sample with the botanical identity, lot number, and any other relevant information.
  3. 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.
  4. Maintain the retention sample in storage for several years or as long as the records associated with the lot are retained.



## 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.

### 7. PH.1 Post-harvest handling

#### PH.1.1. 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.

### PH.1.2. 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).<sup>98</sup>

### PH.1.3. 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.<sup>99</sup>
  1. Water quality. Use only potable water for washing the harvested plant material.<sup>100</sup>
  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.

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<sup>98</sup> 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, 1998) and the 1999 FDA [Guidance for Industry: Antimicrobial Food Additives](#), July 1999.)

<sup>99</sup> For washing and cleaning performed in a registered food facility, additional requirements apply; see section 9.

<sup>100</sup> EPA’s primary drinking water standards can be found at <https://www.epa.gov/ground-water-and-drinking-water/table-regulated-drinking-water-contaminants>.



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.

#### **PH.1.4. 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.”<sup>101</sup> 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.<sup>102</sup>
  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.<sup>103</sup> 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”

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<sup>101</sup> Dehydration that does not create a distinct food commodity is considered part of “holding” (see the definition of “holding”).

<sup>102</sup> 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.”

<sup>103</sup> 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.”



dehydrates raw agricultural commodities that are “produce”<sup>104</sup> 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.<sup>105</sup>

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<sup>106</sup> 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

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<sup>104</sup> Note that this establishes a requirement applicable to all produce, not just “covered produce” as defined in Part 112.

<sup>105</sup> 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 10 of this document for further information.

<sup>106</sup> See Sections 9 and 10 regarding the applicability of 21 CFR Part 117 and Part 111.



relatively uniform pieces to ensure they dry quickly, thoroughly, and consistently.<sup>107</sup>

- 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.<sup>108</sup>
- 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

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<sup>107</sup> 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.

<sup>108</sup> 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.





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



## 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.

### 8. FP.1 Further processing and handling

#### FP.1.1. 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.

#### FP.1.2. 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.<sup>109</sup>
- 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.<sup>110</sup>

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<sup>109</sup> If additional processing will be performed, it may be appropriate to delay the final metal detection step until after all other processing is complete.

<sup>110</sup> 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 in the process.



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.

### FP.1.3. Extraction

- i. Plant material may be extracted using various solvents and various extraction technologies.<sup>111</sup>
- 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:

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<sup>111</sup> Refer to AHPA's "Guidance for the Manufacture and Sale of Bulk Botanical Extracts" for a more extensive discussion.



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.



#### FP.1.4. 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/packaging 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.<sup>112</sup>
- 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.

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<sup>112</sup> See California Office of Environmental Health Hazard Assessment (OEHHA) website <https://www.p65warnings.ca.gov/factsheets/bisphenol-bpa> for more information regarding bisphenol A and Proposition 65.



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;<sup>113</sup>
  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;

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<sup>113</sup> 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).



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.





### FP.1.5. 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.



## FOOD FACILITY AND FARM MIXED-TYPE FACILITY REQUIREMENTS

When performed on food crops, activities such as size reduction, extraction, and sometimes dehydration<sup>114</sup> are regulated by FDA as food processing<sup>115</sup> 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.

### 9. FF.1 Food facility and farm mixed-type facility requirements

#### FF.1.1. 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.<sup>116</sup>
- 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.

#### FF.1.2. 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

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<sup>114</sup> See the definitions of “farm,” “raw agricultural commodity,” and “processed food.”

<sup>115</sup> “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.)

<sup>116</sup> 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).



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).

### FF.1.3. 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.
1. 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.
2. 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.
3. 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.

4. Provide, where necessary, adequate screening or other protection against pests.

#### FF.1.4. 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.

#### **FF.1.5. 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.



### FF.1.6. 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.



# RECOMMENDATIONS FOR DIETARY INGREDIENT PROCESSORS

Facilities that manufacture<sup>117</sup>, pack, or hold dietary *supplements* are subject to the regulations in 21 CFR Part 111, while those that manufacture, pack, or hold dietary *ingredients* are technically subject only to the requirements of Part 117. However, in order to ensure their own compliance with the requirements of Part 111, dietary supplement manufacturers often expect their ingredient suppliers to go above and beyond the basic requirements set forth in Part 117, particularly with respect to raw material controls, process controls, recordkeeping, and general quality systems management. Therefore, dietary ingredient processors that do not follow the full requirements of Part 117 may want to consider implementing the additional recommendations set forth below. However, these are only recommendations to be considered; they are not legal or regulatory requirements except as noted in DI.1.1 (ii)(1) below.

## 10. DI.1 Recommendations for dietary ingredient processors

### DI.1.1. Regulations

- i. Companies that process dietary ingredients for distribution in the U.S. are, under U.S. regulations, generally required to comply with 21 CFR Part 117, even if the processing facilities are located outside the US.
- ii. However, dietary ingredient processors may be required to comply with the provisions of 21 CFR Part 111 under two circumstances.<sup>118</sup>
  1. Under U.S. regulations, a dietary ingredient processor is considered to be a dietary supplement manufacturer, and therefore subject to Part 111, if the dietary ingredient is packaged as a dietary supplement without further processing. For example, if Company A sells cut and sifted ginseng root to Company B who packages the cut and sifted ginseng root in retail packages that are labeled as a dietary supplement, without performing any other processing of the ginseng root, then Company A is a dietary supplement manufacturer and must comply with Part 111.

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<sup>117</sup> “To manufacture” in this context includes “to process,” and vice versa. 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.)

<sup>118</sup> Firms that comply with Part 111 are exempt from Part 117 Subparts C and G; see Appendix 4 for more information.



2. In an effort to ensure product quality, dietary supplement manufacturers and packagers may require their suppliers to comply with Part 111 as a condition of purchase for the dietary ingredient.
- iii. Whether or not full compliance with Part 111 is required, dietary ingredient processors should consider implementing various controls that go beyond the requirements of Part 117 to ensure the quality of their products. The following sections outline a number of suggestions to this end. Dietary ingredient processors that are required to comply with Part 111 must consult the full text of Part 111 to determine the applicable additional requirements for their operations.<sup>119</sup>

### DI.1.2. Component controls

- i. For each component (including botanical ingredients, other ingredients, processing aids, packaging materials, and labels), appropriate specifications should be established. These specifications should address the component's identity, grade, ingredients or materials of construction, limits on impurities, and/or other characteristics as applicable. For botanical components, the specifications should address the applicable quality parameters discussed in Section 2 of this document.
- ii. Incoming shipments of components should be assigned a lot number and quarantined pending sampling, inspection, testing, and disposition (approval or rejection).
- iii. Incoming shipments of components should be properly labeled (e.g., with the buyer's or seller's item number, description, and/or lot number) and examined for damage or contamination.
- iv. Components should be sampled in accordance with appropriate sampling plans and procedures to ensure representative samples are obtained.
- v. Appropriate steps should be taken to ensure each component lot meets its established specifications. These steps may include:
  1. Review of certificates of analysis, specifications, guarantees, and other documents provided by the supplier.
  2. Tests and examinations performed by the dietary ingredient processor.
  3. Tests and examinations performed by an independent laboratory or expert.
- vi. All documentation and test results for a lot should be reviewed before the disposition of the lot (e.g., approval or rejection) is decided.

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<sup>119</sup> Dietary ingredient manufacturers may also consider other certification models, such as from the Global Food Safety Initiative (GFSI).



- vii. Approved component lots should be stored under appropriate conditions of temperature, humidity, and light so that the quality of the components is not affected.
- viii. Rejected components should be moved to a separate storage location from other components.
- ix. A retention sample of each component lot should be kept for several years or as long as the records associated with the lot are retained, or as required by regulation. Retention samples should be stored in a manner to protect against insects, microbial growth, moisture, excessive heat, and other sources of degradation. Where the lot consists of fresh plant material or is otherwise likely to spoil, samples may be stored in a frozen or dried state.
- x. All documents related to the lot should be marked with the component item number (if used) and lot number, and should be kept on file as a packet for at least several years or as required by regulation.
- xi. For each component lot, an inventory control log or other recordkeeping system should be used to document all inventory transactions related to the lot (e.g., usage of the component lot in the manufacture of a particular finished product batch).

### **DI.1.3. Processing operations and finished product controls**

- i. For each manufacturing and packaging process, comprehensive processing specifications should be established and documented that will ensure finished product quality specifications are reliably met. Such a specification document is called a “master manufacturing record” (MMR). Each batch size of product should have a separate MMR. The MMR should include:
  - 1. The processing steps to be performed. For manual operations this should include:
    - The double-checking by a second operator of the weighing or measuring of all components.
    - The double-checking by a second operator of each addition of components to the batch.
  - 2. The equipment to be used.
  - 3. The identities and quantities of components to be used, including packaging components and labels.
  - 4. The identities of any processing aids to be used.
  - 5. Equipment settings and other processing parameters.



6. In-process control steps.
  7. In-process sampling and testing to be performed.
  8. Expected yields after each major process step and at the completion of production.
- ii. Where desired, the MMR may include empty spaces for batch-specific data to be recorded.
  - iii. Each time a cycle of manufacturing or packaging occurs, a document should be created to record the processing of the batch. This document is called a “batch production record” (BPR) and is often created by making or printing a copy of the MMR. The BPR should be used to record the following:
    1. The batch number.
    2. The dates and where applicable the times at which each step is performed.
    3. The identity of operators that perform each step.
    4. The identity of actual equipment used.
    5. The actual equipment settings used and/or readings obtained.
    6. The lot number of each component used.
    7. The quantity of each component used.
    8. Results of in-process monitoring and/or testing.
    9. Actual yields and percent of theoretical yield at appropriate stages of production and after completion of the batch.
    10. An example of any finished product label used, preferably coded with the relevant lot or batch number and the date of manufacture and/or expiration.
    11. A record of any deviations or variances that occur during processing of the batch.
    12. Approval by Quality personnel of any deviations or variances that occur.
    13. Approval at appropriate stages of production and after completion of production by supervisors, managers, and Quality personnel as appropriate.
  - iv. The allocation of components or issuance of labels for use in manufacturing or packaging should be appropriately controlled to ensure that (a) the components and labels are the proper ones for the product to be made, and (b) only approved lots are used.
  - v. Finished product batches should be sampled in accordance with appropriate sampling plans and procedures to ensure representative samples are obtained.



- vi. Appropriate steps should be taken to ensure each finished product batch meets its established specifications. These steps may include:
  - 1. Review of the batch production record.
  - 2. Tests and examinations performed by the dietary ingredient processor.
  - 3. Tests and examinations performed by an independent laboratory or expert.
- vii. All documentation and test results for a batch should be reviewed before the disposition of the batch (e.g., approval or rejection) is decided.
- viii. Approved finished product batches should be stored under appropriate conditions of temperature, humidity, and light so that the quality of the product is not affected.
- ix. Rejected finished product batches should be moved to a separate storage location from other finished products.
- x. All documents related to the batch should be marked with the product item number (if used) and batch number, and should be kept on file as a packet for at least several years or as required by regulation.
- xi. For each finished product batch, an inventory control log or other recordkeeping system should be used to document all inventory transactions related to the batch (e.g., distribution of the batch to various customers).
- xii. A retention sample of each finished batch should be kept for several years or as long as the records associated with the lot are retained, or as required by regulation. Retention samples should preferably be stored in the same packaging and under the same storage conditions used for the distributed product, or else in similar packaging and conditions.<sup>120</sup> Where the finished product is not shelf stable, samples may be stored in a frozen or dried state.

#### DI.1.4. Laboratory operations

- i. Test methods should be maintained in writing and should be suitable for their intended purpose. Test methods should be appropriately accurate, precise, and specific. Chemical and physical test methods used for purely internal purposes such as in-process monitoring may not need the same degree of scientific validity as methods used for other purposes.
- ii. Appropriate analytical standards should be used for laboratory testing. Primary chemical standards should be properly qualified either in-house or by the vendor, to ensure the

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<sup>120</sup> For product distributed in bulk (e.g., 50-lb bags), it is often not possible to keep retention samples packed in precisely the same manner as the distributed product.





purity is accurately known. Botanical reference standards should be authoritatively authenticated, either in-house or by the vendor.

#### DI.1.5. Personnel

- i. Personnel should be qualified by training or experience for the tasks to be performed.
- ii. Personnel qualifications and training should be documented and maintained on file.
- iii. Personnel training should include:
  1. Health, safety, and environmental protection procedures.
  2. Personal hygienic practices.
  3. Food safety procedures.
  4. Good manufacturing practices.
  5. Job-specific information.

#### DI.1.6. Equipment

- i. Processing, packaging, and testing equipment should be suitable for its intended purpose and capable of operating satisfactorily as required by the process.
- ii. Processing, packaging, and testing equipment should be properly cleaned, and sanitized where appropriate. In general, processing and packaging equipment should be cleaned (and sanitized where appropriate) either in between each batch or between products, or (for continuous processing operations) on a daily basis or at another suitable frequency.
- iii. Processing, packaging, and testing equipment should be properly maintained. In general, preventive maintenance should be performed in accordance with the equipment manufacturer's instructions.
- iv. Processing, packaging, and testing equipment should be properly verified or calibrated at suitable frequencies to ensure proper performance. Calibration standards should be traceable to an authoritative reference standard (e.g., NIST<sup>121</sup>) where possible.

#### DI.1.7. Quality management

- i. Appropriate quality assurance practices should be implemented to ensure product quality and GMP compliance.
- ii. Standard operating procedures should be written for manufacturing, packaging, laboratory, warehousing, and quality management operations.

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<sup>121</sup> "NIST" is the National Institute of Standards and Technology, a U.S. government laboratory that provides authoritative reference standards for physical, chemical, and other measurements.



- iii. Records should be kept of all activities performed in the facility that may have direct or indirect bearing on product quality or GMP compliance. All records should be made contemporaneously with the operation performed and should be maintained on file for several years or as required by regulation.
- iv. A system should be implemented for receiving, documenting, and investigating product-related customer complaints, including but not limited to adverse events.
- v. A system should be implemented for receiving, quarantining, and determining the disposition of returned goods.
- vi. Quality management personnel should approve or reject all specifications, controls, tests, examinations, standard operating procedures, master manufacturing records, labels, and other documents or procedures that may affect the quality of the botanical product, and also approve or reject all deviations from these documents and procedures, including any reprocessing or repackaging.
- vii. Quality management personnel should approve or reject all component lots, finished product batches, and returned goods.
- viii. Quality management personnel should review records of facility and equipment cleaning and sanitization; pest control; equipment verifications and calibrations; employee training; sampling records; and customer complaints.
- ix. Quality management personnel should approve or reject all changes to facilities, equipment, specifications, controls, tests, examinations, standard operating procedures, master manufacturing records, labels, and any other changes that may affect the quality or GMP compliance of the botanical product.



## APPENDIX 1: COVERED PRODUCE SUBJECT TO PART 112

Botanical food crops are required to be cultivated or collected in accordance with 21 CFR Part 112 if they meet the definition of “covered produce.” The following provisions of 21 CFR Part 112 explain what is, and is not, “covered produce.”

FDA has issued Draft Guidance for Industry: Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities (Aug. 2016) which is available on the FDA website.

<https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm517567.htm>

Application of FDA’s regulations is fact specific and those using this document should consult with counsel or experienced consultants regarding their application to specific facts. FDA has established a portal for asking questions regarding the application of the Food Safety Modernization Act and its regulations.

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>

### Title 21: Food and Drugs

#### PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

##### Subpart A—General Provisions

##### §112.1 What food is covered by this part?

(a) Unless it is excluded from this part under §112.2, food that is produce within the meaning of this part and that is a raw agricultural commodity (RAC) is covered by this part. This includes a produce RAC that is grown domestically and a produce RAC that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(b) For the purpose of this part and subject to the exemptions and qualified exemptions therein, covered produce includes all of the following:



(1) Fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and unqi fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams; and

(2) Mixes of intact fruits and vegetables (such as fruit baskets).

### **§112.2 What produce is not covered by this part?**

(a) The following produce is not covered by this part:

(1) Produce that is rarely consumed raw, specifically the produce on the following exhaustive list: Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

(2) Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management; and

(3) Produce that is not a raw agricultural commodity.

(b) Produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1), (2), and (3) of this section) under the following conditions:



(1) The produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of part 113, 114, or 120 of this chapter, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products; and

(2) You must disclose in documents accompanying the produce, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance;” and

(3) You must either:

(i) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from the customer that performs the commercial processing described in paragraph (b)(1) of this section that the customer has established and is following procedures (identified in the written assurance) that adequately reduce the presence of microorganisms of public health significance; or

(ii) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from your customer that an entity in the distribution chain subsequent to the customer will perform commercial processing described in paragraph (b)(1) of this section and that the customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and

(B) Will only sell to another entity that agrees, in writing, it will either:

(1) Follow procedures (identified in a written assurance) that adequately reduce the presence of microorganisms of public health significance; or

(2) Obtain a similar written assurance from its customer that the produce will receive commercial processing described in paragraph (b)(1) of this section, and that there will be disclosure in documents accompanying the food, in accordance with the practice of



the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and

(4) You must establish and maintain documentation of your compliance with applicable requirements in paragraphs (b)(2) and (3) in accordance with the requirements of subpart O of this part, including:

(i) Documents containing disclosures required under paragraph (b)(2) of this section; and

(ii) Annual written assurances obtained from customers required under paragraph (b)(3) of this section; and

(5) The requirements of this subpart and subpart Q of this part apply to such produce; and

(6) An entity that provides a written assurance under §112.2(b)(3)(i) or (ii) must act consistently with the assurance and document its actions taken to satisfy the written assurance.

### **§112.3 What definitions apply to this part?**

*Covered produce* means produce that is subject to the requirements of this part in accordance with §§112.1 and 112.2. The term “covered produce” refers to the harvestable or harvested part of the crop.

*Produce* means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat,



amaranth, quinoa, buckwheat, and oilseeds (*e.g.*, cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

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## APPENDIX 2: FARMS EXEMPT FROM PART 112

Farms that grow or collect “covered produce” may nevertheless be exempt from the requirements of Part 112, if they meet certain criteria as set forth below.

### Title 21: Food and Drugs

## PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

### Subpart A—General Provisions

#### §112.3 What definitions apply to this part?

*Covered produce* means produce that is subject to the requirements of this part in accordance with §§112.1 and 112.2. The term “covered produce” refers to the harvestable or harvested part of the crop.

*Produce* means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (*e.g.*, cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

*Qualified end-user*, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in §1.227) that is located:

- (1) In the same State or the same Indian reservation as the farm that produced the food; or





(2) Not more than 275 miles from such farm.

#### **§112.4 Which farms are subject to the requirements of this part?**

(a) Except as provided in paragraph (b) of this section, a farm or farm mixed-type facility with an average annual monetary value of produce (as “produce” is defined in §112.3(c)) sold during the previous 3-year period of more than \$25,000 (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment, is a “covered farm” subject to this part. Covered farms subject to this part must comply with all applicable requirements of this part when conducting a covered activity on covered produce.

(b) A farm is not a covered farm if it satisfies the requirements in §112.5 and we have not withdrawn the farm's exemption in accordance with the requirements of subpart R of this part.

#### **§112.5 Which farms are eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?**

(a) A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if:

(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in §112.3(c)) the farm sold directly to qualified end-users (as defined in §112.3(c)) during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and

(2) The average annual monetary value of all food (as defined in §112.3(c)) the farm sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

(b) For the purpose of determining whether the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.



## APPENDIX 3: FOOD FACILITY REGISTRATION REQUIREMENTS

The following are the FDA regulations that govern which farms and other operations must register with FDA as a food processing facility.

### Title 21: Food and Drugs

#### PART 1—GENERAL ENFORCEMENT REGULATIONS

##### Subpart H—Registration of Food Facilities

##### §1.225 Who must register under this subpart?

(a) You must register your facility under this subpart if you are the owner, operator, or agent in charge of either a domestic or foreign facility, as defined in this subpart, and your facility is engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States, unless your facility qualifies for one of the exemptions in §1.226.

(b) If you are an owner, operator, or agent in charge of a domestic facility, you must register your facility whether or not the food from the facility enters interstate commerce.

(c) If you are the owner, operator, or agent in charge of a facility, you may authorize an individual to register your facility on your behalf.

##### §1.226 Who does not have to register under this subpart?

This subpart does not apply to the following facilities:

(a) A foreign facility, if food from such facility undergoes further manufacturing/processing (including packaging) by another facility outside the United States. A facility is not exempt under this provision if the further manufacturing/processing (including packaging) conducted by the subsequent facility consists of adding labeling or any similar activity of a *de minimis* nature;

(b) Farms;<sup>122</sup>

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<sup>122</sup> Note however that if a farm performs food processing operations beyond what is permitted in the “farm” definition, the farm is classed as a “farm mixed-type facility” and is required to register as a food processing facility.



(c) Retail food establishments;

(d) Restaurants;

(e) Nonprofit food establishments in which food is prepared for, or served directly to, the consumer;

(f) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel. However, those fishing vessels otherwise engaged in processing fish are subject to this subpart. For the purposes of this section, “processing” means handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding, or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel;

(g) Facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*);

### §1.227 What definitions apply to this subpart?

*Facility* means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

(1) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(2) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.



## APPENDIX 4: EXEMPTIONS FROM PART 117

21 CFR Part 117 establishes good manufacturing practice regulations intended to assure food safety. However, food facilities are exempted from parts of Part 117 under certain circumstances, such as (a) if other good manufacturing practice regulations already apply; (b) if the facility is a small or very small business that is a farm mixed-type facility performing what FDA deems to be low-risk activities; or (c) if the foods involved are inherently low risk (e.g., alcoholic beverages; packaged shelf-stable foods; dried agricultural commodities).

### Title 21: Food and Drugs

#### PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

##### Subpart A—General Provisions

##### §117.3 Definitions.

*Qualified end-user*, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in §1.227 of this chapter) that:

(1) Is located:

(i) In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or establishment; or

(ii) Not more than 275 miles from such facility; and

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

*Qualified facility* means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is



sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

### §117.5 Exemptions.

(a) Except as provided by subpart E<sup>123</sup> of this part, subparts C<sup>124</sup> and G<sup>125</sup> of this part do not apply to a qualified facility. Qualified facilities are subject to the modified requirements in §117.201.

(b) Subparts C and G of this part do not apply with respect to activities that are subject to part 123 of this chapter (Fish and Fishery Products) at a facility if you are required to comply with, and are in compliance with, part 123 of this chapter with respect to such activities.

(c) Subparts C and G of this part do not apply with respect to activities that are subject to part 120 of this chapter (Hazard Analysis and Critical Control Point (HACCP) Systems)<sup>126</sup> at a facility if you are required to comply with, and are in compliance with, part 120 of this chapter with respect to such activities.

(d)(1) Subparts C and G of this part do not apply with respect to activities that are subject to part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at a facility if you are required to comply with, and are in compliance with, part 113 of this chapter with respect to such activities.

(2) The exemption in paragraph (d)(1) of this section is applicable only with respect to the microbiological hazards that are regulated under part 113 of this chapter.

(e) Subparts C and G do not apply to any facility with regard to the manufacturing, processing, packaging, or holding of a dietary supplement that is in compliance with the requirements of part 111 of this chapter (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements) and section 761 of the Federal Food, Drug, and Cosmetic Act (Serious Adverse Event Reporting for Dietary Supplements).

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<sup>123</sup> Subpart E establishes procedures for revoking a facility's status as a "qualified facility" that enjoys exemptions from Part 117.

<sup>124</sup> Subpart C establishes requirements for hazard analysis and risk-based preventive controls, similar to "HACCP" systems used by food regulators in other countries.

<sup>125</sup> Subpart G establishes requirements for creating a program to control the facility's supply chain.

<sup>126</sup> Part 120 establishes requirements for HACCP-based food safety controls in the processing of juices (e.g., fruit juice).



(f) Subparts C and G of this part do not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).<sup>127</sup>

(g)(1) The exemption in paragraph (g)(3)<sup>128</sup> of this section applies to packing or holding of processed foods on a farm mixed-type facility, except for processed foods produced by drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins, and drying/dehydrating fresh herbs to produce dried herbs), and packaging and labeling such commodities, without additional manufacturing/processing (such as chopping and slicing), the packing and holding of which are within the “farm” definition in §1.227 of this chapter. Activities that are within the “farm” definition, when conducted on a farm mixed-type facility, are not subject to the requirements of subparts C and G of this part and therefore do not need to be specified in the exemption.

(2) For the purposes of paragraphs (g)(3) and (h)(3) of this section, the following terms describe the foods associated with the activity/food combinations. Several foods that are fruits or vegetables are separately considered for the purposes of these activity/food combinations (*i.e.*, coffee beans, cocoa beans, fresh herbs, peanuts, sugarcane, sugar beets, tree nuts, seeds for direct consumption) to appropriately address specific hazards associated with these foods and/or processing activities conducted on these foods.

(i) *Dried/dehydrated fruit and vegetable products* includes only those processed food products such as raisins and dried legumes made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.

(ii) *Other fruit and vegetable products* includes those processed food products that have undergone one or more of the following processes: acidification, boiling, canning, coating with things other than wax/oil/resin, cooking, cutting, chopping, grinding, peeling, shredding, slicing, or trimming. Examples include flours made from legumes (such as chickpea flour), pickles, and snack chips made from potatoes or plantains. Examples also include dried fruit and vegetable products made with additional manufacturing/processing (such as dried apple slices; pitted, dried plums, cherries, and apricots; and sulfited raisins). This category does not include dried/dehydrated fruit and vegetable products made without additional manufacturing/processing as described in paragraph (g)(2)(i) of this section. This category also does not include products that require time/temperature control for safety (such as fresh-cut fruits and vegetables).

(iii) *Peanut and tree nut products* includes processed food products such as roasted peanuts and tree nuts, seasoned peanuts and tree nuts, and peanut and tree nut flours.

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<sup>127</sup> This means that farm activities performed on covered produce at a farm mixed-type facility are exempt from Part 117 Subparts C and G.

<sup>128</sup> This provision (g) establishes exemptions from Subparts C and G of Part 117 for the packing and holding of certain processed foods when performed by small or very small businesses that are farm mixed-type facilities.



(iv) *Processed seeds for direct consumption* include processed food products such as roasted pumpkin seeds, roasted sunflower seeds, and roasted flax seeds.

(v) *Dried/dehydrated herb and spice products* includes only processed food products such as dried intact herbs made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.

(vi) *Other herb and spice products* includes those processed food products such as chopped fresh herbs, chopped or ground dried herbs (including tea), herbal extracts (*e.g.*, essential oils, extracts containing more than 20 percent ethanol, extracts containing more than 35 percent glycerin), dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars. This category does not include dried/dehydrated herb and spice products made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling as described in paragraph (g)(2)(v) of this section. This category also does not include products that require time/temperature control for safety, such as fresh herb-infused oils.

(vii) *Grains* include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat and oilseeds for oil extraction (such as cotton seed, flax seed, rapeseed, soybeans, and sunflower seed).

(viii) *Milled grain products* include processed food products such as flour, bran, and corn meal.

(ix) *Baked goods* include processed food products such as breads, brownies, cakes, cookies, and crackers. This category does not include products that require time/temperature control for safety, such as cream-filled pastries.

(x) *Other grain products* include processed food products such as dried cereal, dried pasta, oat flakes, and popcorn. This category does not include milled grain products as described in paragraph (g)(2)(viii) of this section or baked goods as described in paragraph (g)(2)(ix) of this section.

(3) Subparts C and G of this part do not apply to on-farm packing or holding of food by a small or very small business, and §117.201 does not apply to on-farm packing or holding of food by a very small business, if the only packing and holding activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk packing or holding activity/food combinations—*i.e.*, packing (or re-packing) (including weighing or conveying incidental to packing or re-packing); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

(i) Baked goods (*e.g.*, bread and cookies);



(ii) Candy (*e.g.*, hard candy, fudge, maple candy, maple cream, nut brittles, taffy, and toffee);

(iii) Cocoa beans (roasted);

(iv) Cocoa products;

(v) Coffee beans (roasted);

(vi) Game meat jerky;

(vii) Gums, latexes, and resins that are processed foods;

(viii) Honey (pasteurized);

(ix) Jams, jellies, and preserves;

(x) Milled grain products (*e.g.*, flour, bran, and corn meal);

(xi) Molasses and treacle;

(xii) Oils (*e.g.*, olive oil and sunflower seed oil);

(xiii) Other fruit and vegetable products (*e.g.*, flours made from legumes; pitted, dried fruits; sliced, dried apples; snack chips);

(xiv) Other grain products (*e.g.*, dried pasta, oat flakes, and popcorn);

(xv) Other herb and spice products (*e.g.*, chopped or ground dried herbs, herbal extracts);

(xvi) Peanut and tree nut products (*e.g.*, roasted peanuts and tree nut flours);

(xvii) Processed seeds for direct consumption (*e.g.*, roasted pumpkin seeds);

(xviii) Soft drinks and carbonated water;

(xix) Sugar;

(xx) Syrups (*e.g.*, maple syrup and agave syrup);

(xxi) Trail mix and granola;

(xxii) Vinegar; and





(xxiii) Any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form).

(h)(1) The exemption in paragraph (h)(3)<sup>129</sup> of this section applies to manufacturing/processing of foods on a farm mixed-type facility, except for manufacturing/processing that is within the “farm” definition in §1.227 of this chapter. Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins, and drying/dehydrating fresh herbs to produce dried herbs), and packaging and labeling such commodities, without additional manufacturing/processing (such as chopping and slicing), are within the “farm” definition in §1.227 of this chapter. In addition, treatment to manipulate ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling the treated raw agricultural commodities, without additional manufacturing/processing, is within the “farm” definition. In addition, coating intact fruits and vegetables with wax, oil, or resin used for the purpose of storage or transportation is within the “farm” definition. Activities that are within the “farm” definition, when conducted on a farm mixed-type facility, are not subject to the requirements of subparts C and G of this part and therefore do not need to be specified in the exemption.

(2) The terms in paragraph (g)(2) of this section describe certain foods associated with the activity/food combinations in paragraph (h)(3) of this section.

(3) Subparts C and G of this part do not apply to on-farm manufacturing/processing activities conducted by a small or very small business for distribution into commerce, and §117.201 does not apply to on-farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk manufacturing/processing activity/food combinations:

(i) Boiling gums, latexes, and resins;

(ii) Chopping, coring, cutting, peeling, pitting, shredding, and slicing acid fruits and vegetables that have a pH less than 4.2 (e.g., cutting lemons and limes), baked goods (e.g., slicing bread), dried/dehydrated fruit and vegetable products (e.g., pitting dried plums), dried herbs and other spices (e.g., chopping intact, dried basil), game meat jerky, gums/latexes/resins, other grain products (e.g., shredding dried cereal), peanuts and tree nuts, and peanut and tree nut products (e.g., chopping roasted peanuts);

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<sup>129</sup> This provision (h) establishes exemptions from Subparts C and G of Part 117 for the manufacturing/processing of certain foods when performed by small or very small businesses that are farm mixed-type facilities.



(iii) Coating dried/dehydrated fruit and vegetable products (*e.g.*, coating raisins with chocolate), other fruit and vegetable products except for non-dried, non-intact fruits and vegetables (*e.g.*, coating dried plum pieces, dried pitted cherries, and dried pitted apricots with chocolate are low-risk activity/food combinations but coating apples on a stick with caramel is not a low-risk activity/food combination), other grain products (*e.g.*, adding caramel to popcorn or adding seasonings to popcorn provided that the seasonings have been treated to significantly minimize pathogens, peanuts and tree nuts (*e.g.*, adding seasonings provided that the seasonings have been treated to significantly minimize pathogens), and peanut and tree nut products (*e.g.*, adding seasonings provided that the seasonings have been treated to significantly minimize pathogens));

(iv) Drying/dehydrating (that includes additional manufacturing or is performed on processed foods) other fruit and vegetable products with pH less than 4.2 (*e.g.*, drying cut fruit and vegetables with pH less than 4.2), and other herb and spice products (*e.g.*, drying chopped fresh herbs, including tea);

(v) Extracting (including by pressing, by distilling, and by solvent extraction) dried/dehydrated herb and spice products (*e.g.*, dried mint), fresh herbs (*e.g.*, fresh mint), fruits and vegetables (*e.g.*, olives, avocados), grains (*e.g.*, oilseeds), and other herb and spice products (*e.g.*, chopped fresh mint, chopped dried mint);

(vi) Freezing acid fruits and vegetables with pH less than 4.2 and other fruit and vegetable products with pH less than 4.2 (*e.g.*, cut fruits and vegetables);

(vii) Grinding/cracking/crushing/milling baked goods (*e.g.*, crackers), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (*e.g.*, raisins and dried legumes), dried/dehydrated herb and spice products (*e.g.*, intact dried basil), grains (*e.g.*, oats, rice, rye, wheat), other fruit and vegetable products (*e.g.*, dried, pitted dates), other grain products (*e.g.*, dried cereal), other herb and spice products (*e.g.*, chopped dried herbs), peanuts and tree nuts, and peanut and tree nut products (*e.g.*, roasted peanuts);

(viii) Labeling baked goods that do not contain food allergens, candy that does not contain food allergens, cocoa beans (roasted), cocoa products that do not contain food allergens, coffee beans (roasted), game meat jerky, gums/latexes/resins that are processed foods, honey (pasteurized), jams/jellies/preserves, milled grain products that do not contain food allergens (*e.g.*, corn meal) or that are single-ingredient foods (*e.g.*, wheat flour, wheat bran), molasses and treacle, oils, other fruit and vegetable products that do not contain food allergens (*e.g.*, snack chips made from potatoes or plantains), other grain products that do not contain food allergens (*e.g.*, popcorn), other herb and spice products (*e.g.*, chopped or ground dried herbs), peanut or tree nut products, (provided that they are single-ingredient, or are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration, or both (*e.g.*, roasted or seasoned whole nuts, single-ingredient peanut or tree nut flours)), processed seeds for direct consumption, soft drinks



and carbonated water, sugar, syrups, trail mix and granola (other than those containing milk chocolate and provided that peanuts and/or tree nuts are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration), vinegar, and any other processed food that does not require time/temperature control for safety and that does not contain food allergens (*e.g.*, vitamins, minerals, and dietary ingredients (*e.g.*, bone meal) in powdered, granular, or other solid form);

(ix) Making baked goods from milled grain products (*e.g.*, breads and cookies);

(x) Making candy from peanuts and tree nuts (*e.g.*, nut brittles), sugar/syrups (*e.g.*, taffy, toffee), and saps (*e.g.*, maple candy, maple cream);

(xi) Making cocoa products from roasted cocoa beans;

(xii) Making dried pasta from grains;

(xiii) Making jams, jellies, and preserves from acid fruits and vegetables with a pH of 4.6 or below;

(xiv) Making molasses and treacle from sugar beets and sugarcane;

(xv) Making oat flakes from grains;

(xvi) Making popcorn from grains;

(xvii) Making snack chips from fruits and vegetables (*e.g.*, making plantain and potato chips);

(xviii) Making soft drinks and carbonated water from sugar, syrups, and water;

(xix) Making sugars and syrups from fruits and vegetables (*e.g.*, dates), grains (*e.g.*, rice, sorghum), other grain products (*e.g.*, malted grains such as barley), saps (*e.g.*, agave, birch, maple, palm), sugar beets, and sugarcane;

(xx) Making trail mix and granola from cocoa products (*e.g.*, chocolate), dried/dehydrated fruit and vegetable products (*e.g.*, raisins), other fruit and vegetable products (*e.g.*, chopped dried fruits), other grain products (*e.g.*, oat flakes), peanut and tree nut products, and processed seeds for direct consumption, provided that peanuts, tree nuts, and processed seeds are treated to significantly minimize pathogens;

(xxi) Making vinegar from fruits and vegetables, other fruit and vegetable products (*e.g.*, fruit wines, apple cider), and other grain products (*e.g.*, malt);



(xxii) Mixing baked goods (*e.g.*, types of cookies), candy (*e.g.*, varieties of taffy), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (*e.g.*, dried blueberries, dried currants, and raisins), dried/dehydrated herb and spice products (*e.g.*, dried, intact basil and dried, intact oregano), honey (pasteurized), milled grain products (*e.g.*, flour, bran, and corn meal), other fruit and vegetable products (*e.g.*, dried, sliced apples and dried, sliced peaches), other grain products (*e.g.*, different types of dried pasta), other herb and spice products (*e.g.*, chopped or ground dried herbs, dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars), peanut and tree nut products, sugar, syrups, vinegar, and any other processed food that does not require time/temperature control for safety (*e.g.*, vitamins, minerals, and dietary ingredients (*e.g.*, bone meal) in powdered, granular, or other solid form);

(xxiii) Packaging baked goods (*e.g.*, bread and cookies), candy, cocoa beans (roasted), cocoa products, coffee beans (roasted), game meat jerky, gums/latexes/resins that are processed foods, honey (pasteurized), jams/jellies/preserves, milled grain products (*e.g.*, flour, bran, corn meal), molasses and treacle, oils, other fruit and vegetable products (*e.g.*, pitted, dried fruits; sliced, dried apples; snack chips), other grain products (*e.g.*, popcorn), other herb and spice products (*e.g.*, chopped or ground dried herbs), peanut and tree nut products, processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola, vinegar, and any other processed food that does not require time/temperature control for safety (*e.g.*, vitamins, minerals, and dietary ingredients (*e.g.*, bone meal) in powdered, granular, or other solid form);

(xxiv) Pasteurizing honey;

(xxv) Roasting and toasting baked goods (*e.g.*, toasting bread for croutons);

(xxvi) Salting other grain products (*e.g.*, soy nuts), peanut and tree nut products, and processed seeds for direct consumption; and

(xxvii) Sifting milled grain products (*e.g.*, flour, bran, corn meal), other fruit and vegetable products (*e.g.*, chickpea flour), and peanut and tree nut products (*e.g.*, peanut flour, almond flour).

(i)(1) Subparts C and G of this part do not apply with respect to alcoholic beverages at a facility that meets the following two conditions:

(i) Under the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 *et seq.*) the facility is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States, or is a foreign facility of a type that would require such a permit, registration, or approval if it were a domestic facility; and



(ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act the facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages.

(2) Subparts C and G of this part do not apply with respect to food that is not an alcoholic beverage at a facility described in paragraph (i)(1) of this section, provided such food:

(i) Is in prepackaged form that prevents any direct human contact with such food; and

(ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(j) Subparts C and G of this part do not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

(k)(1) Except as provided by paragraph (k)(2) of this section, subpart B<sup>130</sup> of this part does not apply to any of the following:

(i) “Farms” (as defined in §1.227 of this chapter);

(ii) Fishing vessels that are not subject to the registration requirements of part 1, subpart H of this chapter in accordance with §1.226(f) of this chapter;

(iii) Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities;

(iv) Activities of “farm mixed-type facilities” (as defined in §1.227 of this chapter) that fall within the definition of “farm”; or

(v) Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing/processing, such as roasting nuts).

(2) If a “farm” or “farm mixed-type facility” dries/dehydrates raw agricultural commodities that are produce<sup>131</sup> as defined in part 112 of this chapter to create a distinct commodity, subpart B of this part applies to the packaging, packing, and holding of the dried commodities. Compliance with this requirement may be achieved by complying with subpart B of this part or with the applicable requirements for packing and holding in part 112 of this chapter.

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<sup>130</sup> Subpart B establishes basic requirements for food processing facilities, equipment, personnel, etc.

<sup>131</sup> Note that this establishes a requirement applicable to all produce, not just “covered produce” as defined in Part 112.



### **§117.7 Applicability of subparts C, D,<sup>132</sup> and G of this part to a facility solely engaged in the storage of unexposed packaged food.**

(a) *Applicability of subparts C and G.* Subparts C and G of this part do not apply to a facility solely engaged in the storage of unexposed packaged food.

(b) *Applicability of subpart D.* A facility solely engaged in the storage of unexposed packaged food, including unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in §117.206 for any unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

### **§117.8 Applicability of subpart B of this part to the off-farm packing and holding of raw agricultural commodities.**

Except as provided by §117.5(k)(1), subpart B of this part applies to the off-farm packaging, packing, and holding of raw agricultural commodities. Compliance with this requirement for raw agricultural commodities that are produce as defined in part 112 of this chapter may be achieved by complying with subpart B of this part or with the applicable requirements for packing and holding in part 112 of this chapter.

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<sup>132</sup> Subpart D sets forth simplified requirements for certain types of operations.



## APPENDIX 5: SOURCES OF SPECIFICATIONS AND TEST METHODS

Appropriate specifications and/or test methods for botanical materials are available from a variety of sources.

### Compendia

#### American Herbal Pharmacopoeia

The American Herbal Pharmacopoeia® began developing qualitative and therapeutic monographs in 1994, and produces monographs on botanicals, including many of the Ayurvedic, Chinese and Western herbs most frequently used in the United States. These monographs represent the most comprehensive and critically reviewed body of information on herbal medicines in the English language, and serve as a primary reference for academicians, health care providers, manufacturers, and regulators.

<http://www.herbal-ahp.org/>

#### British Herbal Compendium

Published by the British Herbal Medicine Association (BHMA) Scientific Committee, the British Herbal Compendium is a two volume publication containing monographs which offer authoritative summaries of Constituents (with phytochemical structure diagrams) and Therapeutics, copiously referenced to worldwide scientific literature, together with a section on Regulatory Status and excerpts from French guidelines and German Commission E monographs.

More information about Vol. 1 (1992) is available at <http://bhma.info/index.php/british-herbal-compendium-vol-1/>.

More information about Vol. 2 (2006) is available at <http://bhma.info/index.php/british-herbal-compendium-vol-2/>.

#### British Herbal Pharmacopoeia (1996)

Published by the BHMA, the British Herbal Pharmacopoeia Monographs of the British Herbal Pharmacopoeia (BHP) provide quality standards for 169 herbal raw materials – basically those listed for the two volumes of the British Herbal Compendium plus six others.



Those herbs official in the European Pharmacopoeia or British Pharmacopoeia at the time of publication are covered by abbreviated monographs in this volume. Subsequent work by the European Pharmacopoeia Commission (Council of Europe) has led to the introduction of many more herbal monographs in the European Pharmacopoeia.

More information about the British Herbal Pharmacopoeia is available at <http://bhma.info/index.php/british-herbal-pharmacopoeia-1996/>.

### **European Pharmacopoeia**

The European Pharmacopoeia (Ph. Eur.) is Europe's legal and scientific benchmark for pharmacopoeial standards which contribute to delivering high quality medicines in Europe and beyond. The Ph. Eur. is applicable in 37 European countries and used in over 100 countries worldwide.

More information about the European Pharmacopoeia 9<sup>th</sup> edition (2016) is available at <https://www.edqm.eu/en/ph-eur-9th-edition>.

### **United States Pharmacopeia – National Formulary (USP-NF)**

The United States Pharmacopeia and The National Formulary (USP–NF) is a book of public pharmacopoeial standards for chemical and biological drug substances, dosage forms, compounded preparations, excipients, medical devices, and dietary supplements. USP–NF is a combination of two compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). Monographs for drug substances, dosage forms, and compounded preparations are featured in the USP. Monographs for dietary supplements and ingredients appear in a separate section of the USP. Excipient monographs are in the NF.

More information about the USP-NF is available at <http://www.usp.org/usp-nf>.

### **Food Chemicals Codex**

The Food Chemicals Codex (FCC) is a compendium of internationally recognized standards for the purity and identity of food ingredients published by the U.S. Pharmacopoeial Convention (USP). It features over 1,200 monographs, including food-grade chemicals, processing aids, foods (such as vegetable oils, fructose, whey, and amino acids), flavoring agents, vitamins, and functional food ingredients (such as lycopene, olestra, and short chain fructooligosaccharides).

More information about the FCC is available at <http://www.usp.org/store/products/food-chemicals-codex-fcc>.





### Official Methods of Analysis of AOAC International

AOAC International is an independent, third-party, nongovernment association of international industry organizations, government agencies, research institutions, and individual scientists. AOAC's Official Methods of Analysis is an international source of methods, with many countries and organizations contributing their expertise to standards development and method validation. The Official Methods of Analysis is the most comprehensive and reliable collection of chemical and microbiological methods available in the world and are contained in many of the Codex food standards.

More information about AOAC International's Official Methods of Analysis is available at <http://www.eoma.aoc.org/>.

### Pharmacopoeia of the People's Republic of China (2015)

Compiled by the Pharmacopoeia Commission of the Ministry of Public Health, the Chinese Pharmacopoeia (CP) covers 784 medicinal herbs, plant oils, and Chinese formulated medicines and 967 western medicines and preparations. The 2015 edition of CP was adopted at the plenary session of the Executive Committee of the Tenth Chinese Pharmacopoeia Commission. On June 5, 2015, China Food and Drug Administration (CFDA) promulgated the 2015 edition of Chinese Pharmacopoeia, which went into effect on December 1, 2015.

English editions of the CP are available through on-line retailers.

## Books

American Herbal Pharmacopeia, (2011). Microscopic Characterization of Botanical Medicines. BocaRaton, FL: CRC Press.

Reich, E. and Schibli, A. (2007) High-Performance Thin-Layer Chromatography for the Analysis of Medicinal Plants. New York, NY: Thieme Medical Publishers Inc.

Wagner, H. and Bladt, S. (1996) Plant Drug Analysis. Berlin, Germany: Springer-Verlag.

Wichl, M. (2004) Herbal Drugs and Phytopharmaceuticals. Boca Raton, FL: CRC Press.

## Online resources

### AHPA's Botanical ID References Compendium

The AHPA Botanical Identity References Compendium is maintained by AHPA and was developed by AHPA with the support of many individuals and organizations with a common interest in sharing knowledge and resources relevant to accurate identification of herbal materials.



The AHPA Compendium is a cooperative and centralized source of information on physical characteristics and test methods that can be used by qualified and experienced analysts to determine the identity of plant species and articles of trade obtained from these plants.

[http://www.botanicalauthentication.org/index.php/Main\\_Page](http://www.botanicalauthentication.org/index.php/Main_Page)



## APPENDIX 6: OTHER GOOD AGRICULTURAL PRACTICE GUIDELINES

Other documents that have been valuable in the process of preparing and reviewing this work are referenced here.

### **European Herb Growers Association (EUROPAM)**

Guidelines for Good Agricultural and Wild Collection Practices for Medicinal and Aromatic Plants (GACP-MAP), Working Copy No. 8.0 (2010)

[http://www.europam.net/documents/gacp/EUROPAM\\_GACP\\_MAP\\_8.0.pdf](http://www.europam.net/documents/gacp/EUROPAM_GACP_MAP_8.0.pdf)

### **European Medicines Agency's Working Party on Herbal Medicinal Products and the Committee on Herbal Medicinal Products**

*Guideline on Good Agricultural and Collection Practice for Starting Materials of Herbal Origin*, (2006)

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC50003362.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC50003362.pdf).

### **FairWild Foundation**

International Standards for Sustainable Wild Collection of Medicinal and Aromatic Plants (ISSC-MAP) (2007)

<http://www.floraweb.de/proxy/floraweb/map-pro/>

### **Global G.A.P.**

General Regulations – Part 1, General Rules (2012)

[http://www1.globalgap.org/north-america/upload/Standards/IFA/v4\\_0-1/120206\\_gg\\_gr\\_part\\_i\\_eng\\_v4\\_0-1.pdf](http://www1.globalgap.org/north-america/upload/Standards/IFA/v4_0-1/120206_gg_gr_part_i_eng_v4_0-1.pdf)

### **Rainforest Alliance**

Global Non Timber Forest Product Certification Addendum FM-33 (2012)



[http://www.rainforest-alliance.org/business/sites/default/files/site-documents/forestry/documents/FM-33\\_RA\\_Global\\_NTFP\\_addendum\\_01Mar12.pdf](http://www.rainforest-alliance.org/business/sites/default/files/site-documents/forestry/documents/FM-33_RA_Global_NTFP_addendum_01Mar12.pdf)

### **Tea and Herbal Infusions Europe (formerly the European Herbal Infusions Association)**

Guidelines for Good Agricultural and Hygiene Practices for Raw Materials Used for Herbal and Fruit Infusions (GAHP) (2014)

[http://www.thie-online.eu/fileadmin/inhalte/Publications/HFI/2\\_2014-06\\_PU\\_GAHP\\_Version\\_6.pdf](http://www.thie-online.eu/fileadmin/inhalte/Publications/HFI/2_2014-06_PU_GAHP_Version_6.pdf).

### **World Health Organization**

WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. (2003)

<http://apps.who.int/iris/bitstream/10665/42783/1/9241546271.pdf>.



## APPENDIX 7: PREPARATION OF VOUCHER SPECIMENS

**by Wendy Applequist, Ph.D., Missouri Botanical Garden**

A “voucher” is a specimen that documents the identity of plant material observed or collected at a particular place, at a particular time. The ideal voucher specimen is composed of plant material which preserves an intact plant or portion of the plant, including leaves and any reproductive structures present at the time of collection. Preparation of a voucher specimen has four steps: collection of the material to be preserved; arranging the material in a plant press; drying it; and mounting it.

First, purchase or make a plant press. A homemade press may be made by assembling two lattices of narrow wooden lath about ¼” thick, with four parallel 18” strips overlaid by five parallel 12” strips and solidly attached at the intersections. An alternative is to use two pieces of solid plywood with a grid of large holes drilled to permit some airflow; these are much heavier and less desirable. The press should contain a small stack of 12” by 18” pieces of corrugated cardboard; folded single-page sheets of newspaper will also be needed, and if possible, some 12” by 18” blotters or pieces of felt. A pair of sturdy buckled straps are needed to hold the press together.

### 1. Collection of material

For preparation of voucher specimens, the material to be preserved should fit on standard-sized voucher sheets (most frequently 16.5” by 11.5”). If the species to be collected is a small herbaceous plant, collect a whole plant for each sheet, or even multiple plants per sheet if they are tiny. Bend a tall single-stemmed plant into a V or N shape to allow it to fit on a sheet. If the plants are large, cut portions that adequately represent the aboveground parts present, including, for example, a stem portion with small leaves, a large leaf, and an inflorescence. If a variety of developmental stages are present, add a fragment with developing fruits to a flowering specimen or vice versa. For small herbs, include the root (with soil removed); for trees, it is desirable to include a piece of bark. Slice thick organs (e.g., large fruits or roots) before pressing; separately preserve large hard structures that cannot be sliced. For plants with large parts, e.g., palms, it may be necessary to collect only portions of a plant organ and to prepare more than one sheet’s worth of material from each plant. Specific guidance on how to prepare specimens from difficult plants is available in the Missouri Botanical Garden’s guide to field procedures: <http://www.mobot.org/MOBOT/molib/fieldtechbook/welcome.shtml>.



Take field notes at the time of collection. These should include the collectors' names, the date, the exact locality (with altitude if known), and the habitat type (e.g., forest, cultivated field), together with any morphological data that will not be visible in the finished specimen (e.g., height of a large plant, whether a large herb is branched, flower color).

## **2. Pressing**

For some species, a delay in pressing will lead to a deterioration of the material. Have a plant press handy and at least place the material in the press temporarily, after which final specimen arrangement may be delayed for hours. Place the material for each specimen in a sheet of newspaper and mark the outside of the sheet with the collection number. Place the specimens between sheets of corrugated cardboard in the press, then put the straps on the press. Orient all sheets of newspaper in the same direction so that the press can be set on edge with all folded edges downwards (so that loose bits do not fall out of the open side).

After material has been in the press for a few hours, it will have relaxed somewhat and may be easier to arrange into the final shape desired for it. Numerous layers of overlapping branches, leaves, etc. are not desirable, as they impede drying and the lower layers are not visible. If the specimen is too big or has too much overlapping material, trim off some side branches, leaves, etc. Leave a small stub, if possible, to show where material was removed. Spread out remaining parts to display the material to best advantage. If necessary, material can be dried in two newspaper sheets and overlapped on a single voucher sheet later (e.g., a large leaf and a separate inflorescence). Ensure that both leaf surfaces are visible by twisting a branch or individual leaves, or folding over one edge of a single large leaf; multiple views of large flowers are also desirable. After the material has been finally arranged, sandwich each newspaper sheet between two pieces of blotter paper or felt (or, if blotters are not available, two sections of several sheets of newspaper) and then between pieces of cardboard. Close the press as tightly as possible; lean on the press or have someone stand on it to compress it while pulling on the straps.

## **3. Drying**

To avoid molding, moisture needs to be removed as quickly as possible. A variety of means have been devised to speed drying of pressed samples by encouraging the flow of air, preferably warm, through the press. If an electric plant press dryer is not available, the press may be suspended over almost any source of warmth, such as a heat lamp; use caution, as material will be damaged by too-intense heat and even more so by catching on fire! Place the press on its side with the folded edge of the newspapers down and the open long edge up, so that air can flow through the corrugated cardboards in the press. Airflow through the press may be increased by placing it in front of a fan or even tying it to the roof of a field vehicle. Change blotters regularly (every day for very fleshy plants) and retighten the press straps, as



material will shrink on drying. If no artificial means of drying is available, keep the press in a warm, low-humidity, well-ventilated place and change the blotters or extra pieces of newspaper frequently (if possible, twice per day). Continue drying until even the thickest portions of material are not at all flexible. Dry out damp blotters before stacking and storing them, or they may mold.

#### **4. Mounting**

Attach dried specimens to a sheet of heavy stock with dots of white glue or strips of mounting tape. Standard-size voucher sheets can be purchased; if material is to be preserved indefinitely, the use of acid-free paper is essential. Use glue or tape only as necessary to fix the specimen in place, preferentially on any stem portions in direct contact with the paper. It is not necessary to coat the whole specimen in glue; avoid gluing or taping flowers and leaves directly. Weight down glued specimens until the glue dries. Leave room on the sheet for a label providing the field data recorded at the time of collection; this is traditionally placed in the lower right corner and should be made from archival-quality, acid-free paper. Place any small loose fragments such as detached fruits into a small paper envelope folded out of acid-free paper and glue it to a convenient empty spot on the sheet.

