AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

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

GACP-GMP Operations Categories

The operational categories described below are intended to provide direction regarding the sections of the AHPA GACP-GMP document that are applicable to the described operational function(s). Companies may have operations that encompass one or more of these categories and should utilize all sections of the GACP-GMP document that may be applicable to their scope of operations. Likewise, companies may undertake only some of the functions described in each GACP-GMP section and should identify those specific elements that are applicable to the scope of their operations.

A summary of each of the sections of the GACP-GMP document applicable to these operations can be found in the GACP-GMP Operations Descriptions that follow.

Wild harvester

Collects one or more botanicals from non-cultivated sites; does no post-harvest handling other than removal of unwanted plant part(s), washing and cleaning, and dehydration.

Section 2 Botanical identity and quality
Section 4 Wild collection
Section 5 General Farm Standards (if applicable) – depends on "produce" definition to determine whether 21 CFR 112 applies; also see Appendices 1 and 2
Section 6 Harvest of cultivated or wild-collected plants
Section 7 Post-harvest handling

Grower/Cultivator

Cultivates one or more botanicals on a farm or other type of growing facility; does no post-harvest handling other than removal of unwanted plant part(s), washing and cleaning, and dehydration.

Section 2 Botanical identity and quality
Section 3 Cultivation
Section 5 General Farm Standards (if applicable) – depends on "produce" definition to determine whether 21 CFR 112 applies; also see Appendices 1 and 2
Section 6 Harvest of cultivated or wild-collected plants
Section 7 Post-harvest handling

Botanical Material Supplier (Ingredient supplier)

Sources raw botanical materials; may consolidate or blend purchased botanical materials into larger lots; may perform functions such as removal of unwanted plant part(s), cleaning, grading, sorting, and size reduction.

Section 2 Botanical identity and quality
Section 7 Post-harvest handling (as applicable)
Section 8 Further processing and handling

Section 9 Food facilities and farm-mixed-type facilities (applicable portions of 21 CFR 117)
Section 10 Recommendations for dietary ingredient processors
Appendix 3 – Registration of food facilities (as applicable)
Appendix 4 – Exemptions from 21 CFR 117 (as applicable)

In addition, these operations may require suppliers of raw botanical material to provide documentation of compliance with the above sections for **Wild harvester** or **Grower/Cultivator**.

Ingredient Manufacturer (Further processor, Extract manufacturer)
Sources raw botanical materials; and performs further processing to produce botanical extracts (liquid, powder, etc.).

Section 2 Botanical identity and quality
Section 7 Post harvest handling (as applicable)
Section 8 Further processing and handling
Section 9 Food facilities and farm-mixed-type facilities (applicable portions of 21 CFR 117)
Section 10 Recommendations for dietary ingredient processors
Appendix 3 – Registration of food facilities (as applicable)
Appendix 4 – Exemptions from 21 CFR 117 (as applicable)

In addition, these operations may require suppliers of raw botanical material to provide documentation of compliance with the above sections for **Wild harvester** or **Grower/Cultivators**.

GACP-GMP Operations Descriptions

Wild Harvester

Section 2 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.

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.

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.

Limits should be established for impurities and contaminants that may adulterate the material or adversely affect its quality.

Section 4 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 botanicals 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.

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.

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.

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.

Section 5 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.

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. 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.
5. Sprouts, mushrooms, and nuts.

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.

Section 6 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.

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.

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

Section 7 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.

For certain materials, additional steps are required to separate the target plant part. 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.

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.

Grower/Cultivator

Section 2 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.

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.

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.

Limits should be established for impurities and contaminants that may adulterate the material or adversely affect its quality.

Section 3 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.

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.

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.

Section 5 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.

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. 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.

5. Sprouts, mushrooms, and nuts.

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.

Section 6 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.

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.

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

Section 7 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.

For certain materials, additional steps are required to separate the target plant part. 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.

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.

Botanical Material Supplier (Ingredient supplier)

Section 2 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.

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.

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.

Limits should be established for impurities and contaminants that may adulterate the material or adversely affect its quality.

Section 7 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.

For certain materials, additional steps are required to separate the target plant part. 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.

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.

Section 8 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.

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.

Plant material may be extracted using various solvents and extraction technologies.

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.

Section 9 Food Facility and Farm Mixed-Type Facility Requirements

When performed on food crops, activities such as size reduction, extraction, and sometimes dehydration are regulated by FDA as food processing[1] 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.

Section 10 Recommendations for Dietary Ingredient Processors

Facilities that manufacture[2], 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.

Dietary ingredient processors may be required to comply with the provisions of 21 CFR Part 111 under two circumstances.[3]

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.

[1] "Processing" in this context includes "manufacturing," because U.S. food regulations generally do not distinguish between "processing" and "manufacturing"; see the definition of "manufacturing/processing." However, there is a subtle but important distinction between "manufacturing/processing" (as used in FDA food regulations) and "processing" (as used in U.S. law). (See the definition of "processed food" for more information.)

[2] "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.)

[3] 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.

Ingredient Manufacturer (Further processor, Extract manufacturer)

Section 2 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.

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.

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.

Limits should be established for impurities and contaminants that may adulterate the material or adversely affect its quality.

Section 7 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.

For certain materials, additional steps are required to separate the target plant part. 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.

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.

Section 9 Food Facility and Farm Mixed-Type Facility Requirements

When performed on food crops, activities such as size reduction, extraction, and sometimes dehydration are regulated by FDA as food processing[4] that is subject to good manufacturing practice (GMP)

[4] "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

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.

Section 10 Recommendations for Dietary Ingredient Processors

Facilities that manufacture[5], 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.

Dietary ingredient processors may be required to comply with the provisions of 21 CFR Part 111 under two circumstances.[6]

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.
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.

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.)

[5] "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.)

[6] Firms that comply with Part 111 are exempt from Part 117 Subparts C and G; see Appendix 4 for more information.