



GOOD AGRICULTURAL AND COLLECTION PRACTICE FOR HERBAL RAW MATERIALS

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Prepared by the Botanical Raw Materials Committee of the American Herbal Products Association in cooperation with the American Herbal Pharmacopoeia

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Acknowledgements

The production of this document was initiated under the auspices of the Botanical Raw Materials Committee of the American Herbal Products Association (AHPA). 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. This document was completed as a cooperative effort between AHPA and the American Herbal Pharmacopoeia (AHP). AHP exists to develop quality control standards for the manufacture of herbal supplements and botanical medicines, as needed to ensure availability of products having a high degree of safety and effectiveness

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AHPA and AHP are not the first organizations to undertake an effort to produce a text that discusses good agricultural and collection practice for herbs. Several earlier published works that address these topics have been valuable resources in the production of the present document. The origin of some of the concepts and language here can be found in various drafts related to agricultural practice published by the European Herb Growers Association, beginning in 1998 and continuing through 2006.¹ This same organization began to address the related issue of good collection practice in 2000 and has now published several drafts of guidelines for harvesting wild plants.²

¹ The current draft, "Guidelines for Good Agricultural Practices (GAP) of Medicinal and Aromatic Plants," Working Copy No. 7.3, is dated April 3, 2006; it can be found at <u>http://www.europam.net/Working%20documents.htm</u>.

² See "Guidelines for Good Wildcrafting Practice (GWP) of Medicinal and Aromatic Plants," Working Copy No. 5.3, also dated April 3, 2006, and also available at <u>http://www.europam.net/Working%20documents.htm</u>.

Other documents that have been valuable in the process of preparing and reviewing this work include the ongoing efforts of the European Herbal Infusions Association;³ both the Working Party on Herbal Medicinal Products and the Committee on Herbal Medicinal Products of the European Medicines Agency;⁴ and the World Health Organization.⁵ Finally, involvement by AHPA members and staff (Josef Brinckmann and Michael McGuffin) in the ongoing drafting of International Standards for Sustainable Wild Collection of Medicinal and Aromatic Plants (ISSC-MAP)⁶ has provided useful insights for the part of this document that addresses good collection practice. Appreciation is therefore due to the organizers of that international effort: Germany's Federal Agency for Nature Conservation, WWF Germany, and TRAFFIC, as well as the International Union for the Conservation of Nature, Medicinal Plant Specialist Group.

Preface

Organizations involved in any 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.

Herbal products such as teas, dietary supplements, drugs and cosmetics 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. Many manufacturers produce some or all of their own herbal ingredients, while some buy these 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 finished products that contain the plant or ingredients derived from the plant. Regardless of these trade variables, agricultural and collection practice has product quality, cultural, and environmental implications.

The emergence of the idea that good agricultural practice (GAP) needs to be clearly described and documented is a fairly recent development, even for conventional agricultural crops. For example, it was only in 2003 that the

³ Their most recent document, dated June 23, 2006, is called *Guidelines for Good Agricultural and Hygiene Practices for Raw Materials Used for Herbal Infusions (GAHP)* and is found at <u>http://www.ehia-online.org/documents/FINAL%20GAHP-EN2006.pdf</u>.

⁴ In particular, their Guideline on Good Agricultural and Collection Practice for Starting Materials of Herbal Origin, dated February 20, 2006. This document can be accessed online at: <u>http://www.emea.eu.int/pdfs/human/hmpc/24681605en.pdf</u>.

⁵ WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. 2003; found at <u>http://whqlibdoc.who.int/publications/2003/9241546271.pdf</u>.

⁶ Information about this effort is maintained at <u>http://www.floraweb.de/proxy/floraweb/map-pro/</u>.

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 policies on GAP.⁷ As of this date, there is no prescribed GAP established by the U.S. Department of Agriculture for farmers in this country or for foreign farms that export their crops to the United States. Similarly, the interest in publishing meaningful and well-designed good collection practice (GCP) guidelines has only recently come into focus.

The members of the American Herbal Products Association and the American Herbal Pharmacopoeia believe that the time is right to distribute the ideas contained here in order to address the related but separate issues of good practice in cultivating and collecting herbal raw materials. As the national trade association and voice of the herbal products industry in the United States, AHPA represents growers, harvesters, manufacturers and marketers of herbal products. AHP is actively engaged in the development of standards of identity, purity, and analysis for botanicals, and in the critical review of traditional and scientific data regarding their efficacy and safety. AHPA and AHP have a shared mission to promote responsible use of and commerce in herbal products. No other organizations are so uniquely positioned to develop and provide the guidelines contained in this document. Even though organizations in other countries have developed good agricultural and collection practice guidelines in the last several years, AHPA and AHP have identified the need for a document that considers the specific nature of doing business in the United States.

Introduction

This draft AHPA-AHP Good Agricultural and Collection Practice (GACP) document provides guidance to growers and collectors of herbs that are used in consumer products. Its goals are to ensure that the herbal raw materials used in these products are accurately identified and 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 authoritative body, such as the American Herbal Pharmacopoeia or the United States Pharmacopeia.

The AHPA-AHP GACP has relevance to herbal raw materials in all herbal products, including foods, dietary supplements, drugs, cosmetics, etc. This GACP is intended to have applications to all herbal raw material production,

⁷ FAO. Development of a Good Agricultural Practice Approach. November 5, 2003. This document is online at <u>http://www.fao.org/prods/GAP/archive/GAPCONCEPT12_en.pdf</u>.

whether the herbs are cultivated by conventional or organic methods or harvested from the wild. While this document may be useful in any country, it is limited to rules in the United States when it addresses regulatory issues.

This guidance serves as a template that growers and harvesters 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.

There is one section of this document that is focused only on agricultural issues, while another section looks only at topics related to collection of wild plants. Thus, Part 1 is titled "Good Agricultural Practice" and Part 2 is "Good Collection Practice." Three additional parts of the text are relevant to both agricultural and wild-collection enterprises. These are "Part 3: Post-harvest handling;" "Part 4: Personnel;" and "Part 5: Record-keeping and retention samples."

This document does not serve as a substitute for the empirical knowledge that has been passed down from preceding generations involved in the cultivation, and especially wildcrafting, of medicinal plants. Readers are encouraged to give due consideration to long-established practices in growing and harvesting 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 to Chinese herbal materials prior to use. Today's herbal products industry can benefit through awareness of these and other traditional techniques.

This document is presented as a draft for discussion and review. Comments on the draft, especially by farmers and collectors who use the draft in their facilities and operations, will be welcome and should be submitted to AHPA at the email or physical address listed on the cover. Revisions may be made to this GACP as additional insights are gained through this review process.

Finally, while this document is complete in itself, the AHPA Botanical Raw Materials Committee and AHP have already identified the need to develop a companion to this work, by providing worksheets and checklists that will assist farmers and collectors in implementing the guidance provided here. 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 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.

Good Agricultural and Collection Practice

General principles

Growers and collectors of herbal raw materials that are produced for use as ingredients in herbal products for human consumption must make every reasonable effort to ensure that all such ingredients are fit for their intended use. Several specific principles are essential in such efforts.

- *Identification*. Whether cultivated or harvested from wild plant populations, all plant materials must be accurately identified. Usually, identification of genus and species will be sufficient to meet this demand, but any material offered as a particular subspecies, variety, cultivar, hybrid, or other lesser division of a species must in fact be that exact taxon.
- *Quality Assurance*. Herbal raw materials must meet all specifications represented by accompanying certificates, by reference to standards or official compendia, and by written agreements between buyers and sellers.
- *Cleanliness*. Farmers and collectors of plants used in consumer products must take necessary steps in cultivation, harvest and post-harvest practices to ensure that their herbs are not contaminated with unacceptable levels of substances that may cause harm.
- Environmental stewardship.
 - Growers of herbs 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.
 - Wild plant harvesters must minimize damage to the specific populations in which they harvest and take appropriate steps to ensure survival of local plant communities. They must also protect the wildlife habitats from which they extract plant materials and recognize that many wild plants provide sources of food for wildlife.
- *Legal conformity*. Both growers and wild harvesters must be aware of and in conformity with national and regional laws that govern their practices.
- *Optimal harvest conditions*. For many plants that are used in consumer products, there are optimal times and conditions for planting and harvest to ensure that quality standards are met. Producers must take such factors into account when planning their raw material production.

Part 1: Good Agricultural Practice

Good agricultural practice is relevant to every stage in the life of the plants that are cultivated for use as ingredients in herbal products. Attention must be paid to the seed or planting stock; to the soil in which herbs are planted; to the water and nutrients that nurture them throughout their life cycle; to the harvest and handling of the crop. In this section, guidance is provided for issues that must be addressed in each of the various stages of cultivated plant production, from propagation to harvest. Note that good practice for post-harvest handling, for personnel, and for record-keeping and retention samples are addressed in separate sections of this GACP. Each of these issues must also be addressed by herb growers to comply with good agricultural practice.

1.1 Propagation material

The quality of a harvested herbal crop begins with the quality of the propagation material from which it is grown. All propagation materials, whether sexual (seed) or asexual (root, rhizome, vegetative cuttings, etc.), should be used subject to the following conditions:

- **1.1.1.** Identity. Accurately identify the seeds or vegetative planting stock as to genus and species, and to subspecies, variety, cultivar, and/or hybrid if applicable.⁸
- **1.1.2.** Health and cleanliness. Evaluate all propagation material to ensure that it is free of pests and diseases as necessary to guarantee healthy plant growth.
- **1.1.3.** Purity. Examine propagation material to make sure that it is free of weeds or other species that are not the species to be cultivated.
- **1.1.4.** Genetically modified material. 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 crops produced from these materials are informed of such use.

⁸ A good general reference for plant identification is *Good Practices for Plant Identification for the Herbal Industry*, published in 2004 by the Saskatchewan Herb and Spice Association and the National Herb and Spice Coalition (Canada). The document can be found at http://www.saskherbspice.org/Good%20Practices%20for%20plant%20identification.pdf.

1.2 Site selection

It is important to know something about the specific agricultural requirements of any herbal crop, and to evaluate whether the field or other setting in which a specific crop is to be planted is likely to provide those requirements. Information should be obtained on each of the following to ensure proper site selection:

- **1.2.1.** Soil fertility. Conduct soil sampling and analysis in accordance with adequate sampling plans,⁹ to quantify essential soil nutrients prior to planting.
- **1.2.2.** Soil contaminants. If soil history is unknown, conduct tests in accordance with appropriate sampling procedures to determine that contaminants, such as residual pesticides or potentially toxic heavy metals, are not present in the soil at unacceptably high levels.¹⁰ Knowledge of a crop's potential to accumulate these contaminants may assist in proper site selection.
- **1.2.3.** Site location and setting. Record and maintain any information that may have relevance to either improving or damaging the crop or the site itself. Consider at a minimum each of the following:
 - **1.2.3.1.** Annual and seasonal rainfall at the specific location, or at least in the location's vicinity.
 - **1.2.3.2.** Facing in relation to cardinal direction (north, south, east, west, etc.) and the amount of available sunlight.
 - **1.2.3.3.** Access to water if the crop requires irrigation.
 - **1.2.3.4**. Slope, to minimize erosion and loss of topsoil.
 - **1.2.3.5.** Identity of crops that will be grown on adjoining sites, if known, and any treatments that may be applied to those crops.
 - **1.2.3.6.** Location in relation to potential sources of contamination, such as industrial facilities; mine tailings; parking lots; golf courses; waterways; underground storage tanks; etc.
- **1.2.4.** Site history. Prepare and maintain a thorough history of prior uses of the crop area. Identify at a minimum each of the following:

1.2.4.1. The most recent crop grown on the site.

⁹ See *A*&*L Reference Guide*: *Soil Sampling*, prepared by A&L Laboratories, Inc. and available online at <u>http://www.al-labs.com/publications/soilsampling.pdf</u>.

¹⁰ Tolerable pesticide levels in herbal ingredients vary from country to country. For example, in the United States, no detectable amount is allowed of any pesticide for which a specific tolerance has not been established *for the specific crop*, and such tolerances are rarely established for herbal crops. For herbs sold in Europe, the European Pharmacopoeia has set limits for a number of pesticides in their chapter 2.8.13 on "Pesticide Residues." Aside from conforming to such legal standards, herbal crops must meet any established specifications for pesticide limits.

- **1.2.4.2.** Crops grown on any adjoining sites in the prior year.
- **1.2.4.3.** Any recent use of pesticides on the site, including herbicides and fungicides, and information about the rate at which any such pesticides break down.
- **1.2.4.4**. 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.
- **1.2.4.5.** Any corrective actions that have been taken to prepare any site where prior environmental contamination is known.

1.3 Crop fertilization

When using fertilizers on any agricultural crop, including an herbal crop, consideration must be given to the value of such use in producing better and larger yields, as well as on numerous factors related to the effects such use may have in the environment. Also, federal, state and local regulations may apply to some of the chemical fertilizers that may be used on commercially grown herbal crops. Organic growers are required to refrain from using any such chemicals, and instead supply naturally-sourced amendments when needed. As previously mentioned, this document is not a substitute for federal laws for organic growers. The guidance offered below, however, addresses both organic and conventional farmers, and both can follow the applicable procedures.

- **1.3.1.** For chemical fertilizers:
 - **1.3.1.1.** Apply in accordance with federal, state and local regulations that are applicable to the specific fertilizer, if any.
 - **1.3.1.2.** Use in accordance with all label directions; for example, for application rates, for safe handling, etc.
 - **1.3.1.3.** Store chemical fertilizers carefully and according to labels.
- **1.3.2.** For manure- and/or compost-based fertilizers:
 - **1.3.2.1.** Do not include sewage sludge or human feces in on-farm produced compost. Do not use manure- or compost-based fertilizers produced with sewage sludge or human feces.
 - **1.3.2.2.** Do not use untreated manure of any kind for crop fertilization. Use only fertilizers that have been adequately treated through an aerobic process.
 - **1.3.2.3.** Monitor for undesirable microbial pathogens through periodic testing that follows approved procedures.
 - **1.3.2.4.** For manure- and/or compost-based fertilizers that are produced or openly stored on-farm, monitor runoff from composting and storage sites.

- **1.3.3.** For all fertilizers:
 - **1.3.3.1.** Ensure that only properly trained personnel apply crop fertilizers.
 - **1.3.3.2.** Apply fertilizers at a sufficiently early phase in the crop's cycle to allow for an appropriate interval between application and harvest. This practice assures that the fertilizer has fully broken down before the crop is harvested.
 - **1.3.3.3.** Apply water-soluble foliar fertilizers within 24 hours of preparation. Such prompt use may optimize effectiveness of the application and prevent microbial contamination of the solution.
 - **1.3.3.4.** Ensure that water used for mixing any soluble fertilizer meets all established criteria for agricultural irrigation water.
 - **1.3.3.5.** Apply fertilizers in a manner that does not contribute to contamination of water.
 - **1.3.3.6.** 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.

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. The following steps should be applied to address a farmer's responsibility for assuring water quality and efficient use in farm operations.

- **1.4.1.** Water source. Identify all water used in field production as to its source (for example, on-farm well(s), open irrigation canal(s), reservoir(s), a municipal supply, or other sources).
- **1.4.2.** Water monitoring. Establish and follow testing procedures to monitor for pathogenic microbes that may be present in water supplies (e.g., *E. coli* and other coliforms), and also for heavy metals, pesticide residues or other contaminants. The frequency of such procedures should take into account the water source(s) and results of previous tests.
- **1.4.3.** Irrigation systems. Do not use irrigation systems or equipment that may contaminate water or crops, such as those that use lead pipes or fittings. Maintain irrigation systems in good working condition to prevent wasting of water and to avoid high soil moisture levels that may contribute to mold and fungal problems.
- **1.4.4**. Application of irrigation. Apply irrigation according to the needs of the plant and in a manner that adequately contains the water to avoid runoff.
- **1.4.5.** Legal conformity. Conform to all rules that are applicable to the local or state water district.

1.5 Crop protection and maintenance

Strategies other than those discussed above can also be implemented in agricultural settings to protect and maintain a crop and/or to maximize the success of the harvest. Each of the following ideas can be examined for applicability.

- **1.5.1.** Crop-specific cultivation. Adapt tilling and other cultivation practices to the requirements of the specific crop.
- **1.5.2.** Companion plants. Consider planting companion plants that are known to provide a benefit to the primary crop.
- **1.5.3.** Insecticide options. Evaluate alternatives to insecticides, such as beneficial insect applications and integrated pest management techniques. Check with state agricultural agencies for guidance.
- **1.5.4.** Pesticide use. If pesticides, herbicides, insecticides, or fungicides, whether from natural or synthetic sources, are used on a crop, properly trained personnel should apply these at the minimum effective rates. Only those chemicals that have been approved for use on the specific crop may be applied, and application levels must ensure that established tolerance levels for the crop are not exceeded. Application and storage of such products must be in accordance with label recommendations and all regulations.¹¹

1.6 Harvest

The condition of the crop at the time of harvest has a significant effect on the quality of the crop, as do weather conditions and all of the actual practices that are used to conduct the harvest. Consideration should therefore be given to the many factors that make up the harvesting process.

1.6.1. Crop condition. Schedule harvest when the crop is in a condition that will result in a harvest that meets quality requirements. Consider such factors as the life-stage of the plants and measured constituent levels, if applicable.

¹¹ The federal Worker Protection Standard is applicable and enforceable whenever using a pesticide product with labeling that refers to this standard. The U.S. Environmental Protection Agency (EPA) recently revised its guidance on this topic (How to Comply with the Worker Protection Standard for Agricultural Pesticides – What Employers Need to Know), and this document is available at http://www.epa.gov/agriculture/epa-735-b-05-002.pdf. In the event that this 141-page manual can not be studied in its entirety, growers should at least acquaint themselves with the Quick Reference Guide found on pages 2-3 of this document, which is available separately at http://www.epa.gov/agriculture/epa-735-b-05-002_unit1.pdf.

- **1.6.2.** Weather conditions.
 - **1.6.2.1.** Evaluate weather conditions at the actual time of harvest. Avoid harvesting when rain and other sources of moisture (dew, excessively-high humidity, etc.) are present, if the presence of such moisture could have a negative effect on the quality of the crop.
 - **1.6.2.2.** Consider weather forecasts for several days immediately following harvest if rain or other inclement weather could have a negative effect on the quality of the crop by adversely impacting its post-harvest handling.
 - **1.6.2.3.** If harvest must occur under wet conditions, take extra care to dry the material well in order to avoid damage, such as mold.
- **1.6.3.** Harvest equipment (including not only mechanical equipment, but also wagons, buckets and other containers, tarps, hand tools, brooms and brushes, etc.).
 - **1.6.3.1.** Use only harvest equipment that is made of non-toxic and noncorrosive materials. Avoid the use of harvest equipment made of wood or other materials that cannot be easily and thoroughly cleaned.
 - **1.6.3.2.** Examine all farm equipment that is used in harvest operations to make sure it is in proper working order; repair as necessary.
 - **1.6.3.3.** Maintain all harvest equipment in a clean condition. Pay particular attention to ensuring that those parts of equipment that come in direct contact with the crop during harvest are clean and free of potential contaminants (e.g., chipping paint, lubricants, etc.).
 - **1.6.3.4.** Remove remnants of any prior harvest from harvest equipment to prevent cross-contamination.
 - **1.6.3.5.** Do not use harvest containers for storing or containing non-harvest materials, such as tools or farm chemicals.
 - **1.6.3.6.** Ensure that all personnel are properly trained in the use of harvest 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 harvested material.
- **1.6.4.** Harvest contaminants.
 - **1.6.4.1.** Conduct the harvest in a manner that minimizes the presence of foreign matter in the harvested crop, such as soil, weeds, trash, etc. Remove foreign matter prior to transporting the harvest from the field, if practical.

- **1.6.4.2.** Examine the harvest carefully and remove damaged and/or degraded plant material. Also remove any weed species that may have been inadvertently collected with the harvested crop, with special attention to any local weed species that are toxic or potentially toxic.
- **1.6.4.3.** Protect the harvested crop from moisture to minimize growth of yeasts and molds.
- **1.6.4.4.** Protect the harvested crop from contact with birds, rodents, insects, and other animals, and from unnecessary exposure to the elements.
- **1.6.4.5.** Transfer the crop to an appropriate receiving station as soon as possible after harvest to prevent degradation of the crop.

Part 2: Good Collection Practice

Many of the plants that are used in consumer products are produced by collectors who gather these products from woods, fields, seashores, and other habitats. Local customs from one country to another impose varying degrees of oversight and management of collectors. Only a few North American wild species are collected by organized groups of harvesters, as the norm here is for individual collectors to work independently.

Regardless of whether collectors operate individually or under some degree of supervision, good collection practice is essential for providing accurately identified and good quality botanical raw material from wild-harvest sources and for protecting the species from unsustainable harvest. The focus of this section is on assisting harvesters who gather raw material from native plant populations at the point of wild-collection. Guidance is provided on issues ranging from proper permits to plant identity, and outlines of some long-established harvest practices are also included. Note that good practice for post-harvest handling, for personnel, and for record-keeping and retention samples are addressed in separate sections of this GACP. Each of these issues must also be addressed by collectors of wild-harvested herbs to comply with good collection practice.

2.1 Permits and permission to collect

Whether wild harvest occurs on public or private property, the harvester must conform to rules established by federal, state and local governments, and by land managers and owners. The following actions should be completed in advance of harvest on public lands or entering private property.

- **2.1.1.** Public property.
 - **2.1.1.1.** If harvesting in a 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 and obtain a permit, if required, before harvesting. Remember that harvest of plants is not allowed in any National Park.
 - **2.1.1.2.** If harvesting on state-owned public lands,¹² contact the appropriate state office before harvesting. Note that some states do not allow plants to be collected on state-owned lands. Obtain a

¹² The boundary of each coastal state extends for three miles seaward from its coastline. Most coastal states have policies that require permits for commercial harvest of seaweeds, and collectors of these plants must adhere to relevant state rules.

state harvest license if collection occurs in a state where such a license is required for the harvest crop.¹³

- **2.1.1.3.** Follow all rules that apply to permitted harvests on public lands, including limits and seasonal requirements, if any; established restraints on harvests in camping areas and near trails and roadsides; requests for submission of harvest data; fee payment; and any other rules.
- **2.1.1.4**. Carry all required permits and licenses while collecting.
- 2.1.2. Private property.
 - **2.1.2.1.** Obtain permission from the owner or owner's agent to enter and to harvest on any private property on which collection occurs.
 - **2.1.2.2.** Obtain permission in writing when state or local laws have established such a requirement.
 - **2.1.2.3.** Obtain a state harvest license if collection occurs in a state where such a license is required for the harvest crop.
 - **2.1.2.4.** Comply with any agreements that have been made with the owner or agent of private property on which collection occurs.
 - **2.1.2.5.** Carry a copy of applicable permissions when collecting.

2.2 Site selection

While it is obvious that collectors should select harvest sites where the target plant can be readily found, it is just as important that sites be evaluated to ensure that the collected materials are likely to be of good quality and free of contamination from pollution and other negative environmental influences. Choice of collection site can impact marketability of the collected material. Adherence to the following steps will assist in making good decisions on site selection and in addressing buyers' requests for harvest information.

- **2.2.1.** 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.
- 2.2.2. Site history.
 - **2.2.2.1.** Obtain information about prior use of the site, if any. Consider especially:
 - **2.2.2.1.1.** If the site has been recently under cultivation, determine what, if any, fertilizers and pesticides were used.

¹³ For example, a license is required to harvest wild American ginseng in Illinois or Wisconsin, whether collected on public or private land, and permits are needed to collect plant materials in National Forests where such collection is allowed.

- **2.2.2.1.2.** On state or federal property, determine whether any recent chemical applications have been made to control insects or invasive species, or for other management purposes.
- **2.2.2.1.3.** 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.
- **2.2.2.2.** 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.).
- **2.2.2.3.** Be aware of any buried utilities that are present at the site.
- **2.2.2.4.** Consider the information compiled in evaluating a site history, and refrain from harvesting if there is any history that indicates that the site may harbor environmental hazards.
- **2.2.3.** Proximity to features of concern.
 - **2.2.3.1.** Do not harvest in close proximity to roads or to railroad rights-of way.
 - **2.2.3.2.** Do not harvest under above-ground power lines if the buyer has specified a concern about such locations.

2.3 Collection equipment

Equipment used in harvesting of wild-harvested crops (including mechanical equipment, buckets and other containers, tarps, hand tools, brooms and brushes, etc.) must be suitable for its purpose, properly maintained, and clean. The following factors are relevant to collection equipment:

- **2.3.1** Materials. Use only equipment that is made of non-toxic and non-corrosive materials. Avoid the use of equipment made of wood or other materials that cannot be easily and thoroughly cleaned.
- **2.3.2** Maintenance. Examine all equipment used in collection operations and maintain in proper working order; repair as necessary.
- **2.3.3** Cleanliness. Maintain all collection equipment in clean condition. Pay particular attention to ensuring that those parts of equipment that come in direct contact with the crop during collection are clean and free of potential contaminants (e.g., chipping paint, lubricants, etc.).
- **2.3.4** Absence of cross-contamination. Remove remnants of any prior harvest from harvest equipment to prevent cross-contamination.
- **2.3.5** Dedicated storage containers. Do not use collection containers for storing or containing non-plant materials, such as tools or chemicals.

2.3.6 Training. Ensure that all personnel are properly trained in the use of the collection 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 collected material.

2.4 Identification

Wild plant harvesters must have sufficient training and experience to ensure that all harvested plants are correctly identified, and they must limit their harvest to plants that they can positively identify. The necessary knowledge can be obtained from other experienced harvesters, in a classroom setting, or with information provided from authoritative references, such as a local flora. Also, buying agents who purchase collected materials are often a good source of information on identification of plants and plant materials. While this document is not a substitute for training on plant identification, the following practices will assist collectors to accurately identify harvested wild materials.¹⁴ Whenever necessary, engage the services of a qualified botanist or taxonomist who has the requisite skills for providing positive identification of the harvested species.

- **2.4.1.** Training and experience. Obtain sufficient training from knowledgeable experts and/or sufficient experience from actual practice to ensure that all collected plant material is accurately identified to species, and to subspecies and/or variety if applicable.
- **2.4.2.** Use of local floras. Collect a sample of the flowering plant and use a local or regional flora to identify the plant by determining that it conforms to its key characteristics.
- **2.4.3.** Use of voucher specimens. Collect a sample of a flowering plant and ensure positive identification by comparison with one or more voucher specimens that have been accurately identified by a qualified expert, and which can be found at herbaria located at local colleges or public gardens. Consider preparation of the sample as a new voucher specimen¹⁵ to keep a record of harvest.
- **2.4.4.** Consideration of plant's life-phase. Positive identification to species of many, if not most plants can only be determined by floral or fruit

¹⁴ This is not meant to imply that all of these practices must be used for every collected lot of a wild-harvested species. Collectors must be positive of each plant's identification and should use whatever tools are appropriate to establish certain identification.

¹⁵ The Appendix at the end of this document (pp. 31-32) provides succinct instructions for preparing voucher specimens. Other such guides can be found in *Good Practices for Plant Identification for the Herbal Industry* (2004), pp. 24-28 (<u>http://www.saskherbspice.org/Good%20Practices%20for%20plant%20identification.pdf</u>) and in the July 2004 draft standard operating procedure for "Collection of a Voucher Sample" under development by AOAC International (<u>http://www.aoac.org/dietsupp6/Dietary-Supplement-web-site/SOPdraft.pdf</u>).

structures, which may not be present at the time of collection. If collecting plants in a life-phase in which flowers and fruit are not present, ensure positive identification by one of the following:

- **2.4.4.1.** Determine positive identification from a flowering sample collected from the harvest population in a prior season, and conduct harvest in the previously identified population.
- **2.4.4.2.** Determine positive identification from plant parts other than flowers or fruit, if the harvested species bears non-floral or non-fruit characteristics that can be used to make such identification with absolute certainty.
- **2.4.5.** Substitutes and adulterants. Be aware of any local species that are known to be readily confused with the target species, and take additional care to exclude these from the harvest.¹⁶
- **2.4.6.** Positive identification. Any time that the identity of the collected material cannot be determined with absolute certainty, submit a sample to a knowledgeable expert for confirming identification.

2.5 Sustainable harvest

Harvesters of wild plants must 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 plant populations, harvest practices must also minimize damage to the local habitat.

This document can not serve as a substitute for the experience gained by years of harvesting wild plants, or for the training that can be provided by a qualified and experienced collector. 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. To make sure that harvests minimize damage while enhancing the health of the collected species, collectors should follow any of the below-listed practices that are applicable.¹⁷

2.5.1. Endangered species. Do not collect plants that are listed as endangered under the U.S. Endangered Species Act¹⁸ or that are listed on Appendix I

¹⁶ This is particularly relevant to potential substitutes that may be toxic. For example, the aerial parts of germander (*Teucrium chamaedrys*) have been reported to have been mixed in with lots of skullcap (*Scutellaria* spp.) herb. Germander is considered to be damaging to the liver.

¹⁷ 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.

¹⁸ This document is focused primarily on herbal raw materials produced in the United States. Collectors that harvest wild plants in other countries should be aware of the domestic status of these plants. For example, information on Canada's Species At Risk Act can be found at <u>http://www.sararegistry.gc.ca/the_act/HTML/Content_e.cfm</u>. Harvesters in Canada should be

of the Convention on International Trade in Endangered Species (CITES)¹⁹ or that are not allowed to be harvested under state regulations due to concerns about over-harvest.

- **2.5.2.** Abundance. Collect only from abundant stands of the harvest species. Avoid harvesting from stands where the plant is sparse or that are outside of the species' normal range. Refrain from harvesting in the same location as earlier harvests until the population is sufficiently reestablished.
- **2.5.3**. Maintaining population stability.
 - **2.5.3.1.** When harvesting reproductive plant parts that must be collected prior to seed maturation (e.g., flowers, fruit) do not take all of those plant parts from any plant population, but leave enough so that each population will be able to produce an adequate amount of seeds to sustain the population.
 - **2.5.3.2.** When harvesting other plant parts that do not remove the entire plant (e.g., leaves, seeds), leave enough of these in each plant population so that it will regenerate and prosper.
 - **2.5.3.3.** When harvesting leaves from trees or woody plants, refrain from excessive defoliation of any individual plant.
 - **2.5.3.4**. For harvests of barks from trees or shrubs:
 - **2.5.3.4.1.** 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.
 - **2.5.3.4.2.** Whenever possible and acceptable for meeting quality standards, harvest bark from branches of the tree rather than from its trunk.
 - **2.5.3.4.3.** Whenever 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.²⁰

aware of the regulations implementing this law and of the status of the plants that they collect under those regulations.

¹⁹ There are no North American species listed on CITES Appendix I that are commonly in trade as ingredients in herbal products. Similarly, none of the common articles of trade are listed as endangered in the Endangered Species Act, although the Tennessee purple coneflower (*Echinacea tennesseensis*) is ESA listed. Inadvertent collection of this species must be avoided.

²⁰ A discussion of this practice as applied to cascara sagrada can be found on page 19 in Davidson, J, 1942, *The Cascara Tree in British Columbia*. This text is available online (thanks to Michael Moore) at: <u>http://www.swsbm.com/Ephemera/Cascara_Sagrada_in_BC.pdf</u>.

- **2.5.3.4.4.** 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.
- **2.5.3.5.** For harvests that involve taking the entire plant (e.g., roots):
 - **2.5.3.5.1.** Limit harvest in any population to leave a portion sufficient for regeneration of that population.
 - **2.5.3.5.2.** Harvest by thinning plants instead of collecting all of the plants along the margins or in one particular part of a colony.
 - **2.5.3.5.3.** Harvest only after the fruit has ripened and the seed has been released if the species is seed propagated.
 - 2.5.3.5.4. When harvesting roots of perennials:
 - **2.5.3.5.4.1.** Leave some plants from each life stage (seedling, juvenile, mature).
 - **2.5.3.5.4.2.** Collect only plants that are mature enough to have produced viable seed.
 - **2.5.3.5.4.3.** 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.
- **2.5.4.** Propagation and regeneration.
 - **2.5.4.1.** Propagation by seed. Plant seeds of collected species that reproduce sexually in a suitable environment.
 - **2.5.4.2.** Asexual propagation. Plant whole or divided root crowns, as appropriate, or prepare other asexual propagation material and plant in a suitable environment.
 - **2.5.4.3.** Pruning. Consider pruning of trees and woody plants to enhance leaf and flower (and therefore fruit and seed) production.
- 2.5.5. Habitat stewardship.
 - **2.5.5.1.** Minimize habitat disruption. Avoid trampling of surrounding plants and use appropriate equipment for harvest. Take care to repair any unavoidable impacts (for example, by filling holes after digging roots).
 - **2.5.5.2.** 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.

2.6 Timing and handling of harvest

Harvest season and harvest time are important factors in the collection of good quality wild plant material. In general and ideally, above-ground parts of plants should be collected early in the day but after any dew has evaporated, and in dry weather (though these time-of-day and weather restrictions are not relevant to barks). Listed below are additional guidelines to assist in determining the best time of year to harvest the various plant parts that come into trade. Keep in mind that these are only general in nature, and that actual seasons and life cycles for collecting any particular plant material may vary. Review harvest research that has been conducted to evaluate the optimal harvest times for some wildharvested plant materials in trade. Also, always take into account any harvest season specifications that have been set by the material's buyer.

Note that this discussion of timing of harvest must be considered in the context of the prior section on sustainable harvest. For example, while leaves and roots of annual plants should be collected prior to flowering to ensure good quality, this must be done in a manner that ensures that adequate seed production will follow collection in each harvested plant population in which harvest occurs.

Equally important to quality are the actual handling practices used at the time of and immediately following harvest. For example, dirt and other foreign matter (e.g., other plant parts, insects, bird nests, spider webs, lichens or fungi on barks, etc.) should be removed from harvested material simultaneous with collection, whenever feasible. Some guidance on more specific harvest handling factors is also included in this section.

- **2.6.1.** 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 must be harvested in a particular season to maximize desired constituents. Limit the proportion of discolored leaves in any leaf harvest to meet established specifications, if any. Handle leaf material that is rich in essential oils carefully to prevent bruising of the leaves that could result in essential oil degradation.
- **2.6.2.** Flowers. In general, harvest flowers (or if specified, flowering tops) when they have just opened or shortly enough afterwards to avoid any faded or brown blossoms. If harvest specifications require flower buds, collect these before the buds open. Encourage departure of insects from harvested flowers by shaking the material and by allowing it to sit for some time. Handle flowers carefully to prevent degradation, as these are generally more delicate than other plant materials. Handle flower material that is rich in essential oils carefully to prevent bruising that could result in essential oil degradation.

- **2.6.3.** Fruits. Harvest fruits when they are mature and ripe, unless specifications require collection of immature fruit. Only collect unbruised fruits and handle the collected fruit in a manner than prevents bruising after harvest. If collection is done by shaking fruits from trees, collect onto a clean tarp to prevent direct contact with soil.
- **2.6.4.** Seeds. In general, harvest seeds just as they are ripening or when they, or the fruit in which they are contained, are fully ripe.
- **2.6.5.** 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. Handle root material that is rich in essential oils carefully to prevent bruising of the epidermis, where the oils typically reside, which could result in essential oil degradation.
- **2.6.6.** Barks. Harvest barks in the early spring, prior to any new growth, or in the late fall or winter.
- **2.6.7.** 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.
- **2.6.8.** 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 at which flowers are emerging.

Part 3: Post-harvest handling

After an herb is harvested, whether as an agricultural product on a farm or as a wildcrafted material in a non-cultivated setting, the care with which the material is handled has a considerable impact on product quality. Immediate post-harvest practices must stabilize the harvest to prevent degradation of the fresh material, which is particularly vulnerable due to the naturally-occurring moisture content of plants. Later steps, such as washing, cutting, dehydrating, refrigerating or freezing, packaging, and storing, must also be properly undertaken so that product quality is preserved throughout the chain of custody, from the field to the point of manufacture.

In this section, several post-harvest handling issues are addressed. As has been stated elsewhere, these matters are relevant to both good agricultural practice and good collection practice. Also, note that good practice related to personnel, record-keeping and retention samples is addressed in separate sections of this GACP. Each of these issues must also be addressed in post-harvest operations to comply with good agricultural and collection practice.

3.1 Handling during and immediately after harvest

At the time of actual harvest and immediately following harvest, the herbal crop must be handled, stored, and consolidated in a manner that ensures that the collected material does not degrade in transit. Threats to product quality include, among others, cross contamination from other crops and materials, insect or other infestation, product compaction, exposure to the elements, and temperature build-up and overheating. The following practices are relevant to the handling operations.

- **3.1.1.** Containers. Place all harvested materials in suitable containers. Harvest containers must be clean and must not have been used for storing non-harvest materials, such as tools or farm chemicals.
- **3.1.2.** Avoidance of compaction. Do not fill or stack sacks or other harvest containers to levels that will result in compacting of harvested materials.
- **3.1.3.** Protection from external sources of contamination. Protect the harvested material from contact with birds, rodents, insects, and other animals, and from exposure to the elements that can adversely affect the harvested material, such as excessive direct sunlight, rainfall, etc.
- **3.1.4.** Timing. Minimize the transit time from the point of harvest to the location used for consolidation and cleaning.
- **3.1.5.** Temperature and moisture control. Ensure that both the temperature and moisture of the harvested material is controlled throughout post-harvest handling as needed to prevent degradation. This can best be accomplished by minimizing transit time and by providing adequate air circulation,

though use of refrigeration, packing in dry ice, or other cooling steps may also be considered when needed and appropriate.

3.2 Facilities

The buildings and facilities used in all post-harvest handling operations must be of suitable design and sound construction. Such facilities should meet the following standards at a minimum.

- **3.2.1.** Light. Design post-harvest handling facilities to provide sufficient space and light²¹ to accomplish the operations undertaken in the facility.
- **3.2.2.** Pest control. Design, manage, and monitor post-harvest handling facilities to keep out pests, including insects, rodents, and other animals.
- **3.2.3.** Order and cleanliness. Design and maintain post-harvest handling facilities with sufficient order and cleanliness to prevent contamination of crops treated in these locations.

3.3 Equipment

Each of the above sections have addressed the need for providing and maintaining equipment used in harvest and collection activities so that the equipment is adequate for the intended use, functions properly, and is clean. All of the same factors apply to equipment (including utensils) used in post-harvest handling, and the following points should be considered.

- **3.3.1.** Materials. Use only post-harvest handling equipment that is made of non-toxic corrosion-resistant materials that can be easily and thoroughly cleaned.
- **3.3.2.** Maintenance. Examine all equipment used in post-harvest handling operations and maintain in proper working order; repair as necessary.
- **3.3.3.** Cleanliness. Design and install post-harvest handling equipment in a manner that permits easy access for cleaning, and maintain all post-harvest handling equipment in clean condition. Pay particular attention to ensuring that those parts of equipment that come in direct contact with the plant material are clean and free of potential contaminants (e.g., chipping paint, lubricants, etc.).
- **3.3.4.** Absence of cross-contamination. Clean all post-harvest handling equipment to remove remnants of any other material for which the equipment was used.

²¹ The WHO guidelines on good agricultural and collection practice identified in footnote number 5 provide specific minimum lighting recommendations of not less that 540 lux (one lux = one lumen per square meter) at all inspection points throughout a processing facility; not less than 220 lux in work rooms; and not less than 110 lux in other areas.

- **3.3.5.** Dedicated containers. Do not re-use containers that are used for storing harvested materials at any post-harvest handling stage for any other storage purpose.
- **3.3.6.** Training. Ensure that all personnel are properly trained in the use of postharvest handling 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 harvested material.

3.4 Washing and cleaning

Many harvested materials, especially roots, need to be washed immediately after harvest to remove dirt and soil from the crop. Cleaning is also needed to remove any foreign matter that may have been inadvertently mixed in with the harvest. The following activities apply to all washing and cleaning operations.

- **3.4.1.** Water quality. Use only potable water for washing the harvested plant material.
- **3.4.2.** Facility design. Carry out washing operations in a facility designed to prevent build-up of mud and other possible sources of contamination.
- **3.4.3.** Drainage. Provide adequate drainage from the washing facility, sufficient to dispose of peak water usage. The drainage system must be designed to avoid contamination of potable water supplies.
- **3.4.4.** Drying. Arrange and handle washed harvest material in a manner that ensures adequate drying of the material.
- **3.4.5.** Removal of foreign matter. Inspect for and remove all visible foreign matter and sub-standard material. 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 crop to fail to meet its specifications. Conduct the inspection for foreign matter and sub-standard material while the crop is sufficiently well displayed to allow for their ready visibility (e.g., on a conveyor, or spread out on tables, screens, or tarps).

3.5 Special preparation

Certain crops require special attention to meet quality specifications. For example, in some species the outer bark is required to be removed (referred to as "rossing"), and some root crops require peeling to produce the desired product. Traditional preparation of herbs used in Ayurvedic or traditional Chinese medicine is also sometimes called for, and may include such actions as roasting, frying, steaming, fermenting, etc. Information about such preparation must be obtained from knowledgeable sources and is beyond the scope of this document. Any such post-harvest preparation must be done in a manner than ensures that the prepared product meets specifications, and must be done by personnel with sufficient training and with appropriate equipment in a suitably clean environment.

3.6 Dehydration

Many of the plants that are grown or collected for use in herbal products 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 plant compounds and can greatly affect the quality of the traded material. Insufficient drying can result in microbial or mold growth, while either insufficient or excessive drying can result in compound degradation. Adherence to proper dehydration conditions is therefore an essential part of post-harvest handling operations.

- **3.6.1.** Timing. Conduct the dehydration process as quickly after harvest as is feasible.
- **3.6.2.** 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.
- **3.6.3.** Temperature control. The optimal drying temperature differs for various plants and plant parts, though, in general, an air temperature of 110° F (45° C) is appropriate for a wide range of herbal materials. Some plants, however, are particularly susceptible to excessive temperatures. 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 herbal material itself to rise above the temperature at which damage to the quality of the crop may occur.
- **3.6.4.** Cutting before drying. When drying large roots, slice, chop or split these in accordance with product specifications to ensure that they dry quickly and thoroughly.
- **3.6.5.** Air drying. Many operations conduct drying processes in open air, either outdoors or in enclosed areas, such as barns and sheds. These may rely entirely on ambient heat or may also, if indoors, use artificial heat. The following practices are essential to all such operations.
 - **3.6.5.1.** Design outdoor drying operations with sufficient covering over the dehydrating herbal material (e.g., a 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.

- **3.6.5.2.** Design indoor drying operations to ensure that there is sufficient ventilation for airborne moisture to escape.
- **3.6.5.3.** 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.
- **3.6.5.4.** Place material to be dried in thin layers on clean food-grade surfaces that afford adequate air circulation.
- **3.6.5.5.** Carefully turn the dehydrating material as needed to facilitate rapid and complete drying.
- **3.6.5.6.** 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 hazardous combustion emissions coming into contact with the crop and thereby contaminating the material.
- **3.6.6.** 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 herbal material is maintained.
- **3.6.7.** Finished moisture content. Ensure that the moisture content of the material at the time that dehydration is completed is in conformity with the specifications for the crop. If a moisture specification is expressed quantitatively (e.g., 12 percent), use adequate analytical tools to accurately measure moisture content. Recommended moisture content of many plant materials and appropriate tests are provided in pharmacopoeial monographs.

3.7 Cutting and milling

Plant material can be traded in a number of forms, including whole, chopped, cut and sifted, teabag cut, shredded, and powder. Cutting of plant materials can occur either before or after dehydration, while milling to powder is always undertaken after drying. Cutting and milling operations must be conducted with practices that ensure that the material's quality and purity is maintained.

- **3.7.1.** Timing. Conduct cutting and milling operations as close to the time of manufacture of finished products as is feasible, in order to reduce quality degradation that may be associated with storage of cut or powdered forms.
- **3.7.2.** Advance cleaning and preparation. Before conveying herbal materials into cutting or milling equipment, perform all necessary in-line cleaning and screening steps. These may include, for example, use of a de-stoner, a gravity separator, or a metal detector.

- **3.7.3.** Protection of operators. Provide adequate ventilation in the cutting and milling facility to protect operators' health. Also provide any needed protective gear, such as breathing masks, eye protection, and ear plugs.
- **3.7.4.** Equipment maintenance. Maintain all cutting and milling equipment in clean and well-functioning condition.
- **3.7.5.** Absence of cross-contamination. Establish and follow procedures to adequately clean cutting and milling equipment that is used for more than one crop, to ensure that cross-contamination with other crops does not occur.
- **3.7.6.** Temperature control. Do not allow the temperature in milling equipment to rise above the temperature at which damage to the quality of the crop may occur.
- **3.7.7.** Size requirements. Ensure that the cut or milled product meets all established specifications with regard to particle size and length and density requirements.
- **3.7.8.** Retention samples. Take a retention sample, in a form that is sufficiently whole to allow for visible identification, of each lot of the herbal material before cutting or milling. Also take a retention sample of the cut or milled form, and store these related samples in a manner that maintains their correlation in the event that assurance of accurate identity needs to be reconfirmed at a later date. See Part 5 of this document for additional information on retention samples.

3.8 Packaging and storage

The use of adequate packaging equipment and materials will affect the quality of packaged herbal crops, as will storage conditions. The following practices are relevant to packaging (including drums, boxes, bags and all other packaging) and storage operations for bulk herbs.

- **3.8.1.** Packaging materials. Use only food- or pharmaceutical-grade packaging materials. Do not reuse any packaging material, except that packaging material that includes recycled material is acceptable so long as the recycling process results in packaging material that maintains food-grade or pharmaceutical-grade status.
- **3.8.2.** Conformity to specifications. Use only packaging material that conforms to the product's packaging specifications, if any. For example, high-volatile-oil-containing herbs should be stored in non-plastic containers.
- **3.8.3.** Package labeling. Label all packages to identify the contents by the plant name (both by its common English name²² and by its scientific binomial name); the part of the plant; the form of the material (e.g., "whole,"

²² If the species is listed in the American Herbal Products Association's *Herbs of Commerce*, 2nd *Edition,* the standardized common name in that reference should always be used.

"teabag cut," "powder," etc.); the name and contact information of the grower and/or the distributor; the country of harvest or collection; a date of production; the quantity by weight in the package; the item number (if any); the identity and quantity or proportion of any substances added to the material, if any (e.g., anticaking or flow agents used in a milling operation); and a lot number. 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.

- **3.8.4.** Storage. Store packaged herbal crops in cool, dry areas away from direct sunlight and exterior walls and off the ground in containers that protect against excessive exposure to air, light, and moisture. Storage facilities should be dry, well ventilated, and have sufficient insulation or other temperature-control features to avoid extreme temperature fluctuations.
- **3.8.5.** Separation from non-food storage. Segregate packaged herbal materials in different areas from non-food items.
- **3.8.6.** Control of odor absorption. Segregate herbal 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 confinement with black tea leaf.

3.9 Shipping

The quality of herbal materials must be maintained through the shipping procedures, and these must be designed and carried out to minimize damage and degradation.²³

- **3.9.1.** Shipping containers. Ensure that shipping containers are suitable for transporting food- or pharmaceutical-grade products, as applicable, are clean and dry, and are designed to meet any special needs of the crop. For example, fresh material must be shipped in containers that provide adequate ventilation, while dehydrated plants must be packed in containers that will protect against moisture.
- **3.9.2.** Carriers. Ship herbal crop products via carriers that are suitable for transportation of food- or pharmaceutical-grade products, as applicable, with special emphasis on temperature control.
- **3.9.3.** Classification. Specify on bills of lading the accurate freight classifications or, for international shipments, the appropriate Harmonized Tariff System code.²⁴

²³ Herbal materials that are represented as conforming with 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.

Part 4: Personnel

There are three primary areas related to good agricultural and collection practice over which growers and collectors of herbal plant materials must exercise some control of their personnel. These are training, safety and hygiene. Guidance for addressing these three personnel issues follows, and is relevant to all phases of growing, collecting and post-harvest handling.

4.1 Training

- **4.1.1.** Relevance to tasks. Provide relevant and adequate training for all tasks undertaken by each individual involved in plant growing, collection, and post-harvest activities.
- **4.1.2.** Plant identification. Ensure that personnel responsible for plant identification have adequate training and experience to be certain in their identification of any species for which they are responsible.
- **4.1.3.** Hygiene. Provide personnel who handle herbal materials with appropriate training in proper hygienic practices with specific attention to preventing microbial contamination of handled crops.

4.2 Safety

- **4.2.1.** Clothing. Ensure that personnel wear clothing and shoes that provide protection that is appropriate to the work environment.
- **4.2.2.** Protective gear. Provide additional protective gear as appropriate, such as face masks, eye coverings, ear plugs, gloves water-proof boots and raingear, etc.
- **4.2.3.** Environmental factors. Consider and establish procedures to protect personnel from environmental factors that are relevant to worker safety, such as extreme heat or cold, presence of noxious plants, insects, or animals in collection areas, work environments in which personnel may encounter excessive noise, dust or other factors related to specific operations, etc.
- **4.2.4.** Tools and equipment. Maintain all tools, equipment and vehicles used by personnel to ensure that these will be reasonably expected to be reliable and safe.

²⁴ These can be found at <u>http://www.census.gov/foreign-trade/schedules/b/2005/browse-html.html</u>.

4.3 Hygiene

- **4.3.1.** Prevention of contamination. As noted in the training section above, provide personnel who handle herbal plant materials with adequate training in proper personal hygiene, with specific attention to preventing microbial contamination of handled crops.
- **4.3.2.** Toilet facilities. Provide toilets, hot running water and soap at postharvest handling facilities. Provide portable toilets at field locations as appropriate. Ensure that all such facilities are adequately stocked, for example with toilet paper and single-use paper towels; that they comply in number, location, installation, and function, including effluence, drainage, and sewage functions, with all relevant local, state, and federal regulations; and that they are maintained in a clean and functioning condition to ensure that herbal materials are protected from contamination due to personnel hygiene.
- **4.3.3.** Hand washing. Establish minimum hand washing requirements for washing with soap and hot water before beginning work, after using the bathroom, and after meal breaks. Place instructive signs in appropriate areas such as bathrooms, kitchens, and lunch areas, and in multiple languages as needed.
- **4.3.4.** Personnel health. Do not allow personnel to work in any handling operation if they are sick or if they have open wounds, sores or skin infections.

Part 5: Record-keeping and retention samples

An integral part of any good practice guideline is a focus on record-keeping. Accurate records must be prepared at every stage of cultivation, harvest, and post-harvest handling of herbal raw materials, as well as to adequately record relevant personnel issues. These records must also be maintained for a sufficient time to ensure that they are available should a need arise at a later time in any ingredient's distribution through subsequent channels of trade.

In addition, in order to facilitate any eventual need to trace back a specific herbal raw material to its source, retention samples should be taken and maintained for each lot of herbal material produced. Guidance for taking and maintaining retention samples is also included in this part.

5.1 Record-keeping

Record-keeping. Make written and dated records for all of the below listed factors that apply to each grown, collected or handled crop. Maintain all such records for a period of not less than five years after the last shipment of any lot of the herbal crop.

- **5.1.1.** Agricultural crops. A harvest record should be prepared for each cultivated crop, consisting of any of the following that are relevant to the specific crop.
 - **5.1.1.1.** Identity and source of all propagation material, with sufficient specificity to ensure that the material conforms to all established standards and can be traced to its source. Make such records whether material is obtained from an off-site source or produced on-farm. If genetically modified propagation material is used, include a record of that fact in these records.
 - **5.1.1.2.** Any information about the crop site that may have relevance to either improving or damaging the crop or the site itself, and also a thorough history of prior uses of the crop site. Consider at a minimum all of the information identified in sections 1.2.3 and 1.2.4.
 - **5.1.1.3.** All fertilizers used on each agricultural crop and, if applicable, steps taken to monitor manure- or compost-based fertilizers for undesirable microbial pathogens and to monitor runoff from sites where composts are produced or stored.
 - **5.1.1.4.** Information about water sources and equipment used in irrigation systems, as well as records of all tests performed to monitor water supplies used in irrigation and any records that establish conformity to applicable irrigation regulations.

- **5.1.1.5.** Steps taken to protect and maintain crops, including, at a minimum, a record of all pesticides, herbicides, insecticides, or fungicides used on each crop.
- **5.1.1.6.** Additional information consisting of, at a minimum, the quantity of the harvest; dates of planting and of harvest; a precise description of the agricultural site; the life-stage of the crop at the time of harvest; and other relevant crop conditions throughout its cultivation. A lot number or other identifying code should be assigned to each specific harvested crop.
- **5.1.2.** Wild-harvested crops. A collection record should be prepared for each wild-harvested crop, consisting of any of the following that are relevant to the specific collection.
 - **5.1.2.1.** Actual legal permits and licenses, as well as permissions obtained from property owners to harvest wild plants on public or private property.
 - **5.1.2.2.** Identification of collection sites, including a general description of the site; site location (if required by regulation or by buyers); site history; proximity to roadways; and other relevant information.
 - **5.1.2.3.** All steps taken to identify harvested wild plants. If a voucher specimen was prepared, include either the specimen itself, or the specimen's unique tracking or identification number and information about where the specimen is stored.
 - **5.1.2.4.** Information to show that each wild-harvested crop was collected in a manner that ensures the survival of the species. Include, for example, general information about the species' biology, life cycle, and reproductive strategy and specific information about each of the factors identified in Section 2.5 of this document (e.g., the plant's abundance in the collection areas; the plant's life-stage at the time of harvest; the proportion of plants harvested from each population; specific harvest practices; steps taken to promote propagation and regeneration; etc.).²⁵
 - **5.1.2.5.** Additional information consisting of, at a minimum, the quantity of the harvest; the date of harvest; and the life-stage and other relevant conditions of the collected material. A lot number or

²⁵ The current draft (June 2006) of the ICCS-MAP document identified in our acknowledgements provides a useful template, especially in its "Annex 1" on pages 15-26, to articulate all of the factors that can be considered in evaluating the sustainability of any wild-harvested species. Collectors should pay particular attention to those factors relevant to the collection manager's methods of control to address each of the listed criteria. The document can be found at http://www.floraweb.de/proxy/floraweb/MAP-pro/draft_3.pdf.

other identifying code should be assigned to each specific collected crop.

- **5.1.3.** Post-harvest handling. Prepare additional records for each post-harvest handling operation performed, including any of the following that are applicable.
 - **5.1.3.1.** Identification of each facility in which any post-harvest operation was undertaken for each crop, including information about pest control plans and cleaning and maintenance procedures at each such facility.
 - **5.1.3.2.** Description of equipment used in all post-harvest handling operations. Such records should adequately describe the equipment used for each post-harvest operation, and should also provide information about equipment maintenance.
 - **5.1.3.3.** All washing and cleaning operations. Include information to identify the water source for such operations, general information on washing and cleaning procedures, and specific information about washing and cleaning of each crop.
 - **5.1.3.4.** Special preparation, if any, which may include peeling of root barks, removal of outer bark, cooking, fermenting; etc. Records should be sufficiently specific so that buyers of the crop are completely informed of all information needed to ensure that crop specifications have been met.
 - **5.1.3.5.** Drying operations, including documentation of drying conditions and times; beginning and ending weights of each crop; beginning and ending moisture content of each crop, if required by the crop's specifications; and any additional information relevant to the drying process.
 - **5.1.3.6.** Cutting and milling operations. These records should correlate the specific identity (e.g., lot number, source, harvest date, etc.) of the lot or lots of whole herbal materials that are cut or milled (i.e., the pre-cut/pre-milled lot(s)) with each specific lot of cut or milled material (i.e., the post-cut/post-milled lot); and that document cutting and milling conditions; beginning and ending weights; presence, identity, and percentage of flow or anticaking agents used in the cutting and milling process, if any; and any additional information relevant to the cutting and milling process.
 - **5.1.3.7.** Packaging operations, with sufficient detail to allow trace-back of any packaged lot to the specific point of agricultural or collection origin.

- **5.1.3.8.** Shipping records, with sufficient detail to trace distribution of each crop, if necessary, throughout the chain of custody, from the agricultural or collection source to the buyer(s) who receive(s) any portion of the crop.
- **5.1.4.** Personnel. Make and maintain dated personnel records. These records should adequately describe all training received by each person involved in any phase of the production of herbal raw materials, and should also describe the steps that are taken to ensure worker safety and hygiene.

5.2 Retention samples

Take retention samples of each lot of herbal material produced, as applicable and in accordance with the following practices. Maintain retention samples for a sufficient period of time to meet any recall needs that may arise in relation to consumer products that will contain the herbal ingredient, and not less than three years after the last shipment of the herbal material lot.

- **5.2.1.** Representative. Take retention samples that are representative of the entire lot by use of an appropriate sampling plan.²⁶
- **5.2.2.** Labeling. Label retention samples to identify the contents by the plant name (both by its common English name and by scientific name); the part of the plant; the form of the material (e.g., "whole," "teabag cut," "powder," etc.); the name and contact information of the grower and/or the distributor; the country of harvest or collection; the harvest year; the item number (if any); and the lot number.
- **5.2.3.** Storage. Store retention samples separately from product inventories.
- **5.2.4.** Correlated samples at time of cutting or milling. Take a retention sample, in a form that is sufficiently whole to allow for visible identification, of each lot of the herbal material before cutting or milling, and also a retention sample in the cut or milled form, and store these related samples in a manner that maintains their correlation in the event that assurance of accurate identity needs to be reconfirmed at a later date.

- END -

²⁶ See, for example, pages 12-13 (under "General Advice on Sampling") in the World Health Organization's *Quality Control Methods for Medicinal Plant Materials*. This can be accessed at <u>http://whqlibdoc.who.int/publications/1998/9241545100.pdf#search=%22WHO%20Quality%20</u> <u>Control%20Methods%2C%20pdf%22</u>.

APPENDIX: Preparation of herbarium specimens by Wendy Applequist, Ph.D., Missouri Botanical Garden

The ideal voucher material is an herbarium specimen, which preserves an intact plant or portion of the plant, including leaves and any reproductive structures present at the time of collection. Preparation of an herbarium 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 herbarium specimens, the material to be preserved should fit on standardsized herbarium 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 herbarium 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 herbarium 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.