

# GUIDANCE:

## Good agricultural practices and good manufacturing practices for hemp and hemp-derived products

June 2021

Prepared by the American Herbal Products Association



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## **Disclaimer**

The information presented here is provided for guidance purposes only. Producers of hemp and hemp-derived products 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 cultivation operation's need to be knowledgeable about growing and harvesting hemp. In addition, it does not address all of the needs of those who produce hemp intended to comply with organic agriculture or other specifically defined agricultural doctrines.

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

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



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## Preface

The American Herbal Products Association (AHPA) chartered a Cannabis Committee in 2010 with the express purpose to address issues related to the safe use and responsible commerce of legally-marketed products derived from *Cannabis* species, including products derived from cultivars categorized as hemp. The AHPA Cannabis Committee developed and in 2013-2014 promulgated a set of guidance documents for cannabis cultivation, processing, manufacturing, packaging, labeling, and holding operations.

In 2006, AHPA in collaboration with the American Herbal Pharmacopoeia (AHP) developed a set of Good Agricultural and Collection Practices for herbal materials. This document was updated and expanded in 2016 to address Good Manufacturing Practices, new developments in food regulation, and the needs of the dietary supplement industry.

In 2018, the US Congress removed hemp, all parts of the hemp plant, and its derivatives from control under the Controlled Substances Act (CSA) and created a framework for federal, state, and tribal regulation of hemp cultivation in the US, thereby easing the pathway for hemp and hemp-derived products to enter the marketplace as foods, dietary supplements, personal care products, and other consumer products. As mandated by the 2018 Farm Bill, USDA issued regulations for domestic hemp production in the form of an interim final rule in October 2019, and as a final rule in January 2021, effective March 2021.

In view of these developments, AHPA is updating its herbal GACP-GMP guidance with respect to cultivation, processing, manufacturing, packaging, and labeling of hemp and hemp-derived products. The guidance reflects the newly expanded, but still in some ways unique, needs of the hemp industry. Laboratory testing of hemp products is addressed by the AHPA document titled *Recommendation for Regulators – Cannabis Laboratory Operations*.



## Introduction

The AHPA Good Agricultural Practices-Good Manufacturing Practices for Hemp and Hemp Derived Products (Hemp GAP-GMP) has relevance to the growing, harvesting, manufacturing/processing, packaging, and labeling of hemp for a wide variety of purposes, including use as foods, drugs, cosmetics, propagative material, etc., but with particular focus on use for food and supplement ingredients and products. Relevant definitions are provided in section 1 and the legal and regulatory requirements for hemp cultivation and subsequent processing into finished products of various categories are summarized in section 2. Botanical quality characteristics (section 3), GAPs (sections 4 to 8), and subsequent processing and handling provisions (section 9) of the document apply to all hemp crops whether conventional or organic, for food or non-food purposes. Section 10 of the document summarizes basic U.S. food GMP provisions applicable to processing of hemp for use as or in food in the U.S.

This guidance does not address hemp and hemp-derived products intended to be inhaled (e.g., vaping oils) or for use as animal food or feed, including pet supplement products.

This document is not intended as a detailed instruction manual for the cultivation, manufacturing/processing, packaging, labeling, or holding of hemp or hemp-derived products. The optimal procedures for each operation will vary depending on the type of hemp grown and its intended purpose and specifications. Similarly, this document does not include the full text of any regulations; for that, readers must consult the applicable sections of the U.S. Code of Federal Regulations (CFR).<sup>1</sup> References to the specific CFR sections are provided for most of these regulations.

Rather, this guidance serves as a general discussion of quality and regulatory considerations that hemp cultivators, manufacturers/processors, packers, and holders can adapt to their own businesses and is designed to have relevance for both small and large firms. By establishing standard operating procedures that address the issues presented here, firms at every level in the supply chain will better ensure the production of good quality hemp components and finished products.

It must not be assumed that every firm should implement every applicable provision of this document. Rather, after identifying which sections of the document are relevant to its operations, firms should carefully review those provisions in light of their own circumstances and needs, and after due consideration should implement whichever recommendations are useful and practical for their situation. Except where local, state, or federal regulations or the firm's certification organizations (e.g., for organic, Kosher, or non-GMO standards) establish actual requirements, firms should view this document as a list of options.

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<sup>1</sup> The Code of Federal Regulations is available at <http://www.ecfr.gov/cgi-bin/ECFR?page=browse>.



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

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All hyperlinks provided throughout this document were last accessed as of the date of publication.





# 1. Definitions

U.S. laws and regulations establish specialized definitions for various words and phrases, which are key to proper understanding of the applicable legal and regulatory requirements; in addition, some terms are unique to the botanical or hemp industry and may be unfamiliar to most English speakers. The user should also consult the AHPA Hemp Lexicon<sup>2</sup> for additional terminology relevant to the hemp industry as well as the marketing of hemp and hemp-derived products.

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

“Acceptable hemp THC level” means for the purpose of compliance with the requirements of State, Tribal, or USDA hemp plans is when the application of the measurement of uncertainty to the reported delta-9 tetrahydrocannabinol content concentration level on a dry weight basis produces a distribution or range that includes 0.3% or less.

“Actual yield” means the quantity that is actually produced at any pre-defined step of manufacture/processing or packaging of a particular hemp-derived product.

“Adulterated,” when used in reference to “food,” is defined by U.S. law<sup>3</sup> to mean the food meets one of the following conditions: (a) the food bears or contains any poisonous or deleterious substance which may render it injurious to health, except if the substance is not an added substance such food is not considered adulterated if the quantity of such substance in such food does not ordinarily render it injurious to health; (b) the food bears or contains any added poisonous or added deleterious substance that is unsafe; (c) the food consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; (d) the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; (e) any valuable constituent has been in whole or in part removed, or any substance has been substituted wholly or in part therefor, or any damage or inferiority has been concealed, or any substance has been mixed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear of better or greater value than it is; (f) the food is a dietary supplement that has been prepared, packed, or held under conditions that do not comply with 21 CFR Part 111; or (g) the food meets various other technical provisions that U.S. law deems to be adulterated.<sup>4</sup>

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<sup>2</sup> Available at <http://www.ahpa.org/News/LatestNews/TabId/96/ArtMID/1179/ArticleID/1617/AHPA-publishes-Hemp-Lexicon.aspx>.

<sup>3</sup> 21 U.S.C. § 342.

<sup>4</sup> See the full text of 21 U.S.C. § 342 for a complete list of the conditions that render food adulterated.



“Adverse event” means a health-related event associated with use of a product that is adverse, and that is unexpected or unusual.

“Batch” means the following:

- with regard to plant material that has not been processed, a specific quantity of plant material harvested during a specified time period from a specified cultivation or harvest area;
- with regard to processed ingredients or finished products, a specific quantity of material or product that is uniform and that is intended to meet its established specifications, and that is produced during a specified time period during a single cycle of manufacture.

“Batch number,” “lot number” or “control number” means any distinctive group of letters, numbers, or symbols, or any combination of them, from which the complete history of the cultivation, harvesting, and packing of a batch or lot of hemp, or the manufacturing/processing, packaging, labeling, packing, or holding of a batch or lot of hemp-derived product, can be determined.

“Botanical” as used in U.S. laws and regulations means any plant, fungus, or alga.<sup>5</sup>

“Composition” means the aggregate mixture which results from the manufacture of a product according to the formula and process defined in the product’s manufacturing protocol.

“Component” means any substance or item intended for use in the manufacture of a product, including those that do not appear in the batch of the product. Components include hemp, hemp-derived products used as ingredients, other ingredients, and processing aids.

“Contact surface” means any surface that directly contacts hemp, components, or hemp-derived product, and any surface from which drainage onto hemp, components, or hemp-derived product, or onto surfaces that contact hemp, components, or hemp-derived product, may occur during the normal course of operations.

“Contamination” means the presence of undesirable foreign matter, microorganisms, chemicals, or radioactivity.

“Cosmetic” is defined by FDA to mean (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

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

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<sup>5</sup> For example, 21 CFR § 101.36(h) states in part, “The common or usual name of ingredients of dietary supplements that are botanicals (including fungi and algae) shall be....”



providing the written assurances required therein; acting consistently with those assurances; and documenting actions taken in compliance with those assurances.<sup>6</sup>

“Covered produce” is defined by FDA as “produce” that is subject to the requirements of 21 CFR Part 112 in accordance with §§112.1 and 112.2; the term refers to the harvestable or harvested part of the crop.<sup>7</sup> Basically, covered produce consists of fruits and vegetables or other produce, or mixtures thereof, that meet all of the following criteria: (a) they are intended for use as “food”; (b) they are “raw agricultural commodities”; (c) they are grown in the U.S. or will be imported to the U.S.; and (d) FDA believes they are commonly eaten raw and therefore require special agricultural controls to ensure food safety (i.e., they are not excluded under 21 CFR § 112.2).<sup>8</sup> Covered produce does not include crops that meet any of the following criteria: They are (a) intended for non-food purposes (e.g., for biofuels, pharmaceuticals, clothing, household products, cosmetics, etc.); (b) grown outside the U.S. and will not be imported to the US; (c) in the FDA’s list at 21 CFR § 112.2(a)(1) of produce rarely eaten raw (e.g., asparagus, winter squash, potatoes); (d) not raw agricultural commodities (i.e., they have been processed beyond their raw or natural state); or (e) produced by an individual for personal consumption or produced for consumption on the same “farm” where they are grown or another farm under the same management.<sup>9</sup>

“Cultivate” means to grow and harvest hemp. A person, group of persons, non-profit entity, or business entity that cultivates is a *cultivator*, and a location where hemp plants are cultivated is a *cultivation operation*.

“Cultivation area” means the physical location of a property at which hemp is cultivated.

“Dietary ingredient” is defined under U.S. law as an ingredient in a “dietary supplement” that is a vitamin; mineral; herb or other botanical; amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of these.<sup>10</sup>

“Dietary supplement” is defined under U.S. law as a “food” product (other than tobacco) intended to supplement the diet that bears or contains one or more “dietary ingredients”; is intended for ingestion

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<sup>6</sup> The definition of “covered activity” under FDA regulations contains additional details. For the complete definition see 21 CFR § 112.3.

<sup>7</sup> 21 CFR § 112.3. See also Appendix 1 for more information.

<sup>8</sup> See additional details in 21 CFR § 112.1. In particular, it is to be noted that the list of examples of crops that are covered by Part 112 (i.e., that are not included on the list of “rarely consumed raw” crops that are exempt from Part 112) includes various crops that many people may assume are customarily cooked before eating, such as artichokes.

<sup>9</sup> See additional details in 21 CFR § 112.2, including the list of botanical crops that FDA considers to be “rarely consumed raw.”

<sup>10</sup> 21 U.S.C. § 321 (ff).



typically in tablet, capsule, powder, softgel, gelcap, or liquid form; is not represented for use as a conventional food or as a sole item of a meal or the diet; and is labeled as a dietary supplement.<sup>11</sup>

“Disposition” means review and approval or rejection of a batch, lot, or other item by quality control personnel.

“Drying” means the dehydration of harvested hemp; depending on the type and purpose of the hemp, moisture levels between 8% and 15% are appropriate. The lower end of this range is often preferable for long-term storage.

“Facility” is defined under FDA regulations<sup>12</sup> as any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that “manufactures/processes,” “packs,” or “holds” “food” for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Non-bottled water drinking water collection and distribution establishments and their structures are not facilities.

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

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

“Farm,” in the context of food production, is defined by FDA regulation as the two types of operations enumerated below.<sup>13</sup> Under these definitions, farm includes both operations that grow crops and operations that merely “harvest” crops (i.e., wild collecting operations).

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

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

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<sup>11</sup> The definition of “dietary supplement” under U.S. law contains additional details. For the complete definition see 21 U.S.C. § 321 (ff).

<sup>12</sup> 21 CFR § 1.227.

<sup>13</sup> 21 CFR § 1.227 and 21 CFR § 112.3.



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

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

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

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

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

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

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

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

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

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

“Food” is defined under U.S. law as (1) articles used for food or drink for man or other animals; (2) chewing gum; (3) articles used for components of any such article.<sup>14</sup> Under FDA regulations, food

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<sup>14</sup> 21 U.S.C. § 321 (f).



includes seeds and beans used to grow sprouts.<sup>15</sup> Examples of food include: Fruits, vegetables, fish, dairy products, eggs, “raw agricultural commodities” for use as food or as components of food, food and feed ingredients, food and feed additives, “dietary supplements” and “dietary ingredients,” infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.<sup>16</sup>

“Gang-printed label” means a label for one product that is printed simultaneously on the same sheet of paper as labels for other products.

“Harvesting” –

- In the context of “food,” harvesting is defined under FDA regulations<sup>17</sup> as activities that are traditionally performed on “farms” for the purpose of removing “raw agricultural commodities” from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on “processed foods” created by drying/dehydrating a raw agricultural commodity without additional “manufacturing/processing,” on a farm.<sup>18</sup> Harvesting does not include activities that transform a raw agricultural commodity into a processed food. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.
- In the context of hemp that will not be used as or in food, harvesting means gathering hemp plants from cultivation medium or to gather specific aerial parts of hemp plants.

“Hemp” means the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis<sup>19</sup>.

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<sup>15</sup> 21 CFR § 112.3.

<sup>16</sup> 21 CFR § 1.227.

<sup>17</sup> 21 CFR § 1.227, 21 CFR § 112.3 and 21 CFR § 117.3.

<sup>18</sup> Activities that are considered “harvesting” when performed on the farm where the crop was grown, may constitute “processing/manufacturing” when performed at a different location by a different company. For example, if apples are washed on the same farm where they were grown, this is a harvesting activity; however, if the apples are sold to a different company which then washes them, this is a food manufacturing/processing activity.

<sup>19</sup> The term “hemp” is consistent with the definition established in the Agricultural Marketing Act of 1946, section 297A.



“Hemp food crop” means a hemp crop that will be used as or in food, including dietary ingredients and dietary supplements.

“Hemp-derived product” means a product, other than hemp itself, which contains or is derived from hemp and is intended for inhalation, oral ingestion, or topical application.

“Hemp operation” means any firm engaged in the cultivation, post-harvest handling, manufacture/processing, packaging, labeling, packing, or holding of hemp or hemp-derived products.

“Hemp planting material” means hemp seeds, seedlings, cuttings, clones, etc. used by a cultivation operation to grow hemp.

“Hemp waste” means hemp or hemp-derived product that is discarded by the operation.

“Holding” –

- In the context of “food,” holding is defined under FDA regulations<sup>20</sup> as storage of food, and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating “raw agricultural commodities” when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a “processed food.” Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.
- In the context of hemp that will not be used as or in food, holding means storing or warehousing hemp in any context other than for retail sale.
- A person, group of persons, non-profit entity, or business entity that holds hemp is a *holder*, and location where holding occurs is a *holding operation*.

“Identity” means the set of characteristics by which an ingredient or product is definitively recognizable or known. In the case of hemp and other botanical ingredients, identity means the plant part and the botanical genus, species, variety, strain, and/or cultivar, as well as any other applicable characteristics as stated on the label or other labeling. In the case of hemp-derived products, identity means the product name, strength, key features of its form or composition, grade, and/or other characteristics as applicable.

“Ingredient” means any substance that is used in the manufacture of a product and that is intended to be present in the finished product.

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<sup>20</sup> 21 CFR § 1.227, 21 CFR § 112.3 and 21 CFR § 117.3.



“Label” (when used as a noun) is defined under U.S. laws and regulations as a display of written, printed, or graphic matter upon the immediate container of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity.<sup>21</sup>

“Label” (when used as a verb) means to affix labeling on packaged hemp or hemp-derived product. A person, group of persons, non-profit entity, or business entity that labels is a *labeler*, and a location where labeling occurs is a *labeling operation*.

“Labeling” (when used as a noun) is defined under U.S. laws and regulations as all “labels” and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.<sup>22</sup>

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

“Lot” means a batch, or a specific identified portion of a batch, that is uniform and that is intended to meet specifications; or, in the case of a product produced by continuous process, a specific identified amount produced in a specified unit of time or quantity in a manner that is uniform and that is intended to meet specifications.

“Manufacturing/processing” –

- In the context of “food,” manufacturing/processing is defined under FDA regulations<sup>23</sup> as making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating “raw agricultural commodities” to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, “labeling,” milling, mixing, “packaging” (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For “farms” and “farm mixed-type” facilities, manufacturing/processing does not include activities that are part of “harvesting,” “packing,” or “holding.”
- In the context of hemp and hemp-derived products that will not be used as or in food, manufacturing/processing means to compound, blend, grind, extract, or otherwise make or

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

<sup>22</sup> 21 U.S.C. § 321 (m); 21 CFR 1.3.

<sup>23</sup> 21 CFR § 112.3 and 21 CFR § 117.3.





prepare a hemp-derived product. Note that in this context for purposes of this document, manufacturing/processing does not include packaging or labeling.

- A person, group of persons, non-profit entity, or business entity that manufactures is a *manufacturer/processor* and a location where manufacture/processing occurs is a *manufacturing/processing operation*.<sup>24</sup>

“Medium” means the nutritive substrate that a cultivator uses to establish a root system.

“Microorganism” means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term “undesirable microorganisms” includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

“Nursery facility” means an indoor, greenhouse, or outdoor cultivation operation that produces hemp plants for the purpose of providing planting material to other cultivation operations.

“Outdoor cultivation” means cultivation of hemp out of doors utilizing natural sunlight and possibly supplemental artificial lighting.

“Packaging component” means any item intended for use in the primary packaging or labeling of hemp-derived products.

“Packaging” (when used as a verb) –

- In the context of “food,” packaging is a “manufacturing/processing” activity in which food is placed into a container that directly contacts the food and that the consumer receives. Placing “raw agricultural commodities” into retail packages on a “farm” or “farm mixed-type facility” is exempt from the food manufacturing/processing regulations in Part 117 unless (a) additional manufacturing/processing that is outside the farm definition is also performed, or (b) raw agricultural commodities that are “produce” as defined in Part 112 are dehydrated to create a distinct commodity, in which case Part 117 Subpart B applies to the packaging, “packing,” and “holding” of the dried commodities.<sup>25</sup>
- In the context of hemp and hemp-derived products that will not be used as or in food, packaging means to place hemp or hemp-derived product into primary packaging for bulk or retail distribution.

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<sup>24</sup> In previous AHPA Cannabis guidance, the term “process” was defined as inspecting, grading, or packing cannabis. These operations have now been combined with the term “packing” for consistency with FDA food regulation and to avoid confusion about the regulatory status of “processing.”

<sup>25</sup> Compliance with this last requirement may be achieved by complying with Part 117 Subpart B or with the applicable requirements for packing and holding in Part 112.



- A person, group of persons, non-profit entity, or business entity that packages is a *packager*, and a facility where packaging occurs is a *packaging operation*.

“Packing” (when used as a verb) –

- In the context of “food,” packing is defined under FDA regulations<sup>26</sup> as placing food into a container other than “packaging” the food and also includes activities performed incidental to packing of a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a “raw agricultural commodity” into a “processed food.” Packing includes, for example, placing immediate packages of food (e.g., individual bottles labeled for retail sale) into secondary packages that will not be received by the consumer (such as cases, master packs, etc.).
- In the context of hemp and hemp-derived products that will not be used as or in food, packing means to place hemp or hemp-derived product into containers for distribution, other than to package the hemp or hemp-derived product, and also includes activities performed incidental to packing of hemp (such as inspecting, sorting, grading, culling, and weighing or conveying incidental to packing or re-packing). Packing includes the placement of hemp into any type of container by cultivation operations as well as the placement of filled primary packaging containers into other containers such as for storage or transport.
- A person, group of persons, non-profit entity, or business entity that packs is a *packer*, and a location where packing occurs is a *packing operation*.

“Personnel” means, for purposes of this guidance, any worker engaged in the performance of operations including full and part-time employees, temporary employees, contractors, and volunteers.

“Pest” means any objectionable insect or other animal at any life stage.

“Pesticide” is defined under U.S. law as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest; any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant; and nitrogen stabilizers.<sup>27</sup> Pesticides include herbicides, fungicides, and insecticides as well as other substances.

“Physical plant” means all or any part of a building or structure used for or in functional connection with manufacturing, packaging, labeling, or holding a hemp-derived product.

“Post-harvest handling” is defined as the temporary storage, sorting, inspection, grading, washing, cleaning, drying, and packing of harvested hemp.

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<sup>26</sup> 21 CFR § 1.227, 21 CFR § 112.3 and 21 CFR § 117.3.

<sup>27</sup> The definition of “pesticide” under U.S. law contains additional details. For the complete definition see 7 U.S.C. § 136 (u).



“Processing aid” means a component used in the manufacturing/processing, packing or packaging of a product which is not present as an ingredient in the finished product other than at trace levels. This may include, for example, food grade oil used to lubricate product-contact equipment parts, inert gas used to flush package headspace, or solvents used in extraction which are fully removed later in processing.

“Processed food” is defined under U.S. law<sup>28</sup> as any human or animal “food” other than a “raw agricultural commodity,” and includes any “raw agricultural commodity” that has been subject to “manufacturing/processing” that alters the general state of the commodity or creates a distinct commodity<sup>29</sup> such as canning, cooking, freezing, drying, or milling. (Under the FDA interpretation of this provision, drying transforms a raw agricultural commodity into a processed food only if the drying “creates a new commodity,” i.e., if the crop is normally traded in fresh form then drying of it constitutes manufacturing/processing. For example, fresh apples are a raw agricultural commodity while dried apples are a processed food. In contrast, drying of commodities normally traded in dried form does not transform the commodity into a processed food (e.g., dried allspice berries and dried cinnamon bark remain raw agricultural commodities even though they have been dehydrated)).<sup>30</sup>

“Produce” is defined under FDA regulations<sup>31</sup> as any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant<sup>32</sup> (such as cabbage or potato) or fleshy fruiting body

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<sup>28</sup> 21 U.S.C. § 321 (gg).

<sup>29</sup> The statutory definition uses the term “processing” here, whereas FDA food regulations use the term “manufacturing/processing.” In the preamble to the proposed Produce Safety rule (78 FR 3540, 2013), FDA explains that manufacturing/processing includes nearly any type of food manipulation, even minor steps such as coloring, washing or waxing, but that a raw agricultural commodity is transformed into a processed food only if the manufacturing/processing alters the general state of the commodity or creates a new or distinct commodity.

<sup>30</sup> The distinction between (a) drying a harvested food crop and thereby creating a distinct commodity from the fresh material (e.g., drying grapes into raisins) versus (b) drying a harvested food crop without creating a distinct commodity (e.g., the drying of hay or grains) stems from the 1998 Joint EPA/ FDA Policy Interpretation ([63 FR 54532](#), 1998). The U.S. Environmental Protection Agency (EPA) and FDA created this distinction for purposes of implementing the U.S. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1996. Under this interpretation, if the dried material is a distinct commodity from the fresh commodity then it is a processed food; if the dried material is not a distinct commodity from the fresh commodity then it remains a raw agricultural commodity. The distinction was carried forward into the FDA regulations implementing FSMA (see for example the definitions of “farm,” “harvesting,” and “holding” in 21 CFR Part 112 and 21 CFR Part 117, and the preambles at 80 FR 74385, 2015; 80 FR 74395-34398, 2015; and 78 FR 3540, 2013).

<sup>31</sup> 21 CFR § 112.3.

<sup>32</sup> The Merriam-Webster dictionary defines “herbaceous” as either “of, relating to, or having the characteristics of an herb”; or “of a stem: having little or no woody tissue and persisting usually for a single growing season; or “having the texture, color, or appearance of a leaf” (<https://www.merriam-webster.com/dictionary/herbaceous>, accessed 12/02/2016). TheFreeDictionary.com defines “herbaceous plant” as “a plant lacking a permanent woody stem” (<http://www.thefreedictionary.com/herbaceous+plant>, accessed 12/02/2016) and Wikipedia



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

“Product complaint” means any communication that contains any allegation, written, electronic, or oral, expressing concern, for any reason, with the quality of a product that could be related to its cultivation, manufacture/processing, packing, holding, or related operations. Product complaints may include reports of adverse events or serious adverse events.

“Propagation materials” means all substances used in the cultivation of hemp, other than hemp planting material.

“Pruning” means cutting away hemp leaves, branches or stems from unharvested plants.

“Purity” means the relative freedom from extraneous matter, contaminants, or impurities, whether or not harmful to the consumer or deleterious to the product.<sup>34</sup>

“Quality” means that the product consistently meets the established specifications for identity, purity, strength, composition, packaging, packing, and labeling, and has been manufactured/processed, packaged, packed, labeled, and held under conditions to prevent adulteration.

“Quality control” means a system for verifying and assuring the quality of a product.

“Quality control personnel” means any person, persons, or group, within or outside of a manufacturing/processing, packing, packaging, labeling or holding operation, which is designated to be responsible for the operation’s quality control operations.

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

<sup>33</sup> Although it is not stated in the definition, FDA clarifies in the preamble to the rule that “algae” are excluded from the definition of produce. (80 FR 74385, November 27, 2015)

<sup>34</sup> In the context of dietary supplement GMPs (21 CFR Part 111), the term “purity” refers to the proportion that represents the intended material. For example, L-alanine containing 95% of the L isomer and 5% of the D isomer is “95% pure D-alanine” and has a purity of 95%.



“Quarantine” means to segregate and withhold from use lots, batches, or other portions of components, packaging components, in-process materials, hemp, or products whose suitability for use must be determined by quality control personnel.

“Raw agricultural commodity” is defined under U.S. law as any human or animal “food” in its raw or natural state, including all fruits that are washed, colored, otherwise treated in their unpeeled natural form prior to marketing.<sup>35</sup> For purposes of this document, raw agricultural commodity also refers to non-food botanical crops in their raw or natural state. The natural state of a raw agricultural commodity may include being dried, but only if the commodity is normally traded in dried form (e.g., pinto beans). Drying of a raw agricultural commodity that is a food normally traded in fresh form (e.g., blueberries) transforms it into a “processed food.”

“Representative sample” means a sample that consists of an adequate quantity of material or number of units that is collected in a manner intended to ensure that the sample accurately portrays the material being sampled.

“Reprocessing” means the performance of a treatment, adjustment, repackaging, relabeling, or other deviation from standard procedures or from the applicable manufacturing protocol, in order to render a nonconforming material or product suitable for use or distribution.

“Reserve sample” means a representative sample of component, packaging component, or product that is held for a designated period of time.

“Retting” means to cut hemp stalks and leave them in the field to rot slightly, in order to begin separating the fibers from the stalk.

“Sanitize” means to adequately treat cleaned equipment, containers, utensils, or any other cleaned contact surface by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other microorganisms, but without adversely affecting the product or its safety for the consumer.

“Scientifically valid method” means an analytical method that is based on scientifically legitimate principles and which is fit for purpose in the analysis of specific ingredients or products.

“Strength” means the measure of a product, expressed as (a) the amount or percent of specific chemical constituents or groups of chemical constituents; (b) the concentration or amount of hemp present in a hemp-derived product; or (c) in the case of extracts, the input quantity of crude botanical to the output quantity of finished extract expressed as a ratio, with all measurements in metric units.<sup>36,37</sup>

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<sup>35</sup> 21 U.S.C. § 321 (r).

<sup>36</sup> Under dietary supplement regulations, the “strength” as defined in (a) will overlap with the “purity” specification, and the “strength” as defined in (b) may overlap with the “purity” and/or “composition” specifications.

<sup>37</sup> This ratio is generally calculated on the dry weight basis; if on the fresh weight basis then this must be disclosed in labeling.



NOTE: In the hemp industry, the term “potency” is often equated to the concentration of a specific constituent such as CBD. The appropriate term to use is “strength” (or, in the context of dietary supplements, also “purity”), as “potency” is associated in U.S. federal regulations with drug products and certain vitamins because it refers to a measure of biological activity rather than simply chemical quantification.<sup>38</sup>

“Theoretical yield” means the quantity that would be produced at any appropriate step of manufacture or packaging of a particular product, based upon the quantity of components or packaging to be used, in the absence of any loss or error in actual production.

“Vendor” means a person, group of persons, non-profit entity, or business entity that supplies hemp, hemp-derived product, ingredients, packaging components, or other materials to cultivation, manufacturing/processing, packing, packaging, labeling or holding operations. For hemp and hemp-derived products, a vendor may be either the direct representative of a cultivation, manufacturing/processing, or other hemp operation, or may function independently of such operations by purchasing hemp or hemp-derived product from such operations and reselling it to other operations.

“Water activity” ( $a_w$ ) is a measure of the free moisture in a component or product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

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<sup>38</sup> To be precise, pharmacological potency refers to a measure of biological activity expressed as the amount of a chemical required to produce an effect of specified intensity.



## 2. Legal and regulatory considerations

Hemp operations must comply with all applicable laws and regulations related to hemp in the jurisdiction in which the operation is located. In addition, hemp operations must comply with all other laws and regulations applicable to such business activities in general.

What follows is a general overview of several of the most important laws and regulations that govern hemp operations.

### 2.1 Hemp cultivation

#### 2.1.1 Agriculture Improvement Act of 2018

The U.S. hemp marketplace was revolutionized with passage of the Agriculture Improvement Act of 2018 (“2018 Farm Bill”),<sup>39</sup> which removed hemp from Drug Enforcement Administration (DEA) regulation as a controlled substance and which established hemp as an agricultural commodity under the U.S. Department of Agriculture (USDA) with a nationwide framework for hemp production. The 2018 Farm Bill authorized individual states and tribal governments to assert primary regulatory authority over hemp production within their borders.

This law provides that state and tribal governments may submit to USDA a “hemp plan” under which the state or tribe will monitor and regulate the production of hemp. The hemp plan must include:

- Information regarding land on which hemp is produced in the state or tribal territory;
- A procedure for testing the delta-9 tetrahydrocannabinol ( $\Delta^9$ -THC) levels in the hemp;
- A procedure for disposal of hemp and hemp products that violate the law;
- A procedure to comply with enforcement procedures required by the law;
- A procedure for conducting annual inspections of a random sample of hemp producers; and
- A certification that the state or tribe has the necessary resources and personnel to regulate the hemp production.

The law furthermore provides that, in the absence of an approved state or tribal hemp plan for a particular jurisdiction, producers in that jurisdiction must comply with a USDA default hemp plan with provisions generally similar to those described above, and they must obtain licenses from USDA.

The law establishes administrative penalties that will apply to hemp cultivators who violate the requirements of the applicable hemp plan, or who produce hemp without a license as required under the USDA default plan. It also gives USDA the authority to issue federal regulations and guidelines for hemp production.

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<sup>39</sup> H.R. 2. The Agriculture Improvement Act of 2018.



## 2.1.2 USDA Final Rule for Domestic Hemp Production

USDA has issued a final rule governing the Establishment of a Domestic Hemp Production Program.<sup>40</sup> The final rule for hemp production became effective on March 22, 2021.

As of the date of this guidance, numerous states and tribal governments have had their hemp production plans approved by USDA, or have submitted plans for review. However, a significant number of states are continuing to administer hemp cultivation programs under the 2014 Farm Bill provisions. USDA maintains the status of state and tribal hemp plans on a public website.<sup>41</sup>

The final rule provides details of the following provisions of the USDA regulatory program:

- Definitions – specific terms used in the regulation are defined.
- Establishment of State and tribal hemp production plans – the general authority and requirements; sampling, testing and harvesting requirements; USDA approval; audit of compliance; violations; and recordkeeping requirements.
- Establishment of USDA hemp production plans – licensing process and approval; reporting of acreage; sampling, testing and harvesting requirements; violations, license suspension and revocation; recordkeeping requirements.
- Appeals – processes for appeals under State, tribal and USDA hemp production plans.
- Administrative provisions and reporting requirements.

USDA also issued separate guidance documents titled “Sampling guidelines for hemp” and “Laboratory testing guidelines” that provide additional details regarding these activities.<sup>42</sup>

## 2.2 Regulations for foods including dietary supplements

### 2.2.1. Good Agricultural Practices (GAP) for foods

Under the Federal Food, Drug, and Cosmetic Act (FDCA), cultivation operations growing hemp for use as human food that will be distributed in the U.S. (including for use as dietary ingredients or dietary

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<sup>40</sup> 86 Fed Reg 5596 (Jan. 19, 2021)

<sup>41</sup> The status of state and tribal hemp production plans is available at: <https://www.ams.usda.gov/rules-regulations/hemp/state-and-tribal-plan-review>.

<sup>42</sup> These documents are available on USDA’s website at: <https://www.ams.usda.gov/sites/default/files/media/SamplingGuidelinesforHemp.pdf> and <https://www.ams.usda.gov/sites/default/files/media/TestingGuidelinesforHemp.pdf>.





supplements)<sup>43</sup> are required to comply with the Produce Safety regulations in 21 CFR Part 112,<sup>44</sup> unless the operation qualifies for an exemption from these regulations. Additional information about 21 CFR Part 112 is available in Appendices 1 and 2 of the AHPA Good agricultural and collection practices and good manufacturing practices for botanical materials (AHPA GACP-GMP),<sup>45</sup> as well as in the Code of Federal Regulations and on the FDA website.<sup>46</sup>

### 2.2.2 Facility registration for foods including supplements

Under FDCA, facilities that manufacture/process, pack, or hold human food for distribution in the US are required to register with FDA as a food facility, and update the registration every 2 years. Additional information about facility registration is available from FDA.<sup>47</sup>

### 2.2.3 Good Manufacturing Practices for foods including dietary supplements

Under FDCA, hemp operations that manufacture/process, pack, or hold hemp or hemp-derived products for food use (including food ingredients, ready to eat foods, dietary ingredients, or dietary supplements) are required to comply with a variety of Good Manufacturing Practice (GMP) regulations.

In general, after the 2011 passage of the Food Safety and Modernization Act (FSMA) all human food operations are required to comply with 21 CFR Part 117 Subpart B,<sup>48</sup> which establishes basic requirements for food facilities and food manufacturing/processing operations. However, some activities are exempt from these requirements if they fall within the scope of what the Food and Drug Administration (FDA) defines as farm activities. The boundary between a farm activity vs. food manufacturing/processing activities can be confusing; it is discussed further in the Section 2 definitions

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<sup>43</sup> With the exception of ingredients derived from hempseed and hempseed oil, FDA does not currently recognize hemp-derived ingredients for use as food and dietary supplements. This is particularly important for hemp-derived products containing cannabidiol (CBD). See FDA Regulation of Cannabis and Cannabis-derived products, Including Cannabidiol (CBD), available at: <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>.

<sup>44</sup> 21 CFR Part 112 - Standards for the growing, harvesting, packing, and holding of produce for human consumption, available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=112>

<sup>45</sup> Available through the AHPA website at [Good Agricultural, Collection and Manufacturing Practices for Botanical Materials \(ahpa.org\)](https://www.ahpa.org)

<sup>46</sup> FDA Draft Produce Safety guidance is available at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm606284.htm>.

<sup>47</sup> Information about registering a food facility is available at <https://www.fda.gov/food/guidanceregulation/foodfacilityregistration/default.htm>.

<sup>48</sup> 21 CFR Part 117 – Current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food, available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=117>



of “farm,” “harvesting,” “holding,” “packing,” and “manufacturing/processing,” as well as in Cultivation section 5.1.1 and Post-Harvest Handling section 7.6.

In addition to 21 CFR Part 117 Subpart B, most human food operations are required to comply with 21 CFR Part 117 Subpart C, unless the operation qualifies for an exemption. Additional information about exemptions from Part 117 is available in Appendix 4 to the AHPA GACP-GMP, as well as in the Code of Federal Regulations and on the FDA website.<sup>49</sup> Human food manufacturers must also comply with any other GMPs established by FDA for specific types of foods (e.g., low acid canned food; juices; etc.).

Dietary supplement facilities are required to comply with specialized GMPs set forth in 21 CFR Part 111,<sup>50</sup> and also to submit to FDA reports of serious adverse events they receive in connection with a dietary supplement (see also Section 2.2.6).<sup>51</sup> Dietary supplement facilities that comply with these requirements are exempt from 21 CFR Part 117 Subparts C and G.

#### 2.2.4. Food ingredient requirements

Ingredients used in food must be expressly authorized by FDA or be considered Generally Recognized as Safe (GRAS) for their intended purpose. Foods may be GRAS either by virtue of historical (pre-1958) use as or in food (e.g., broccoli, wheat, salt) or through scientific evidence reviewed by experts. Additional information regarding GRAS foods is available at the FDA website.<sup>52</sup>

The term “food additive” is defined under the Food, Drug and Cosmetic Act in a manner that explicitly excludes any substance that is generally recognized as safe (GRAS) under the conditions of its intended use. 21 U.S.C. 321(s). There is also an implicit understanding that any substance that is itself a food does not become a food additive when it is combined with other foods (e.g., common vegetables added to soup are not considered food additives). The FDA’s enforcement history in this matter supports this latter implication, as AHPA is aware of no instance in which FDA has taken any enforcement action based on an assertion that a substance that is commonly used as food becomes a food additive when combined with other commonly used food ingredients.

Dietary ingredients used in dietary supplements may or may not be GRAS. Rather, dietary ingredients are classified either as “Old Dietary Ingredients” (ODIs) or “New Dietary Ingredients” (NDIs). ODIs are those dietary ingredients marketed in the US prior to October 15, 1994; NDIs are dietary ingredients

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<sup>49</sup> For example, many small operations called “qualified facilities” enjoy special exemptions; guidance regarding qualified facilities is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-determination-status-qualified-facility>.

<sup>50</sup> 21 CFR Part 111, Current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements, available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=111>.

<sup>51</sup> Information about submitting to FDA a serious adverse event associated with a dietary supplement is available at <https://www.fda.gov/food/dietary-supplements/how-report-problem-dietary-supplements>. Additional information is available from AHPA’s Guidance on adverse event reporting, at <http://ahpa.org/Resources/TechnicalGuidance/AHPAGuidanceDocuments/TabId/401/ArtMID/1244/ArticleID/222/Guidance-on-Adverse-Event-Reporting-AER.aspx>.

<sup>52</sup> FDA provides information about GRAS foods at <https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/>.



introduced after that date. Prior to distributing dietary supplements containing an NDI, a “New Dietary Ingredient” notification must be submitted to FDA by the manufacturer or distributor of the dietary ingredient or the dietary supplement, unless the dietary ingredient already exists in the food supply in the same chemical form. Information about the NDI notification process is available from AHPA and the FDA website.<sup>53</sup>

## 2.2.5 Food and dietary supplement labeling regulations

Human food products must be labeled in compliance with 21 CFR Part 101.<sup>54</sup> More specialized labeling requirements for dietary supplements are set forth in 21 CFR Part 101.36.<sup>55</sup> Food and dietary supplement products must be labeled for the presence of any major food allergens under the provisions of the Food Allergen Labeling and Consumer Protection Act (FALCPA).<sup>56</sup>

Human food products may make authorized health claims in accordance with 21 CFR Part 101 Subpart E. Under certain circumstances, food companies may petition FDA to make qualified health claims for which there is some scientific support but not significant scientific agreement.<sup>57</sup> Except as provided in an authorized or qualified health claim, food labels may not make disease-related claims.

Dietary supplements may make authorized or qualified health claims. In addition, supplements may make claims that the product will affect a nutritional need or a structure or function of the body (“structure/function claims”). For example, a hemp seed oil dietary supplement could have a claim of support for general wellbeing, or for being a source of omega fatty acids. The boundary between an acceptable structure/function claim and an illegal drug claim can be confusing; consult the FDA website or a lawyer for further information.<sup>58</sup> Any claim made for a hemp product, as for any other product,

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<sup>53</sup> See AHPA’s Interim guidance for New Dietary Ingredient (NDI) Notifications for Manufacturers and Distributors <http://www.ahpa.org/Resources/TechnicalGuidance/AHPAGuidanceDocuments/TabId/401/ArtMID/1244/ArticleID/587/Interim-Guidance-for-New-Dietary-Ingredient-NDI-Notifications-for-Manufacturers-and-Distributors.aspx> and the FDA website at <https://www.fda.gov/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/default.htm>. Note: FDA’s latest proposed draft NDI guidance document should not be considered settled practice.

<sup>54</sup> 21 CFR Part 101 Food labeling, available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=101>

<sup>55</sup> FDA provides detailed dietary supplement labeling guidance at <https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm2006823.htm>.

<sup>56</sup> Public Law 108-282, Title II (2006). Accessible at <https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-falcpa>.

<sup>57</sup> Information about qualified health claims is available at <https://www.fda.gov/food/food-labeling-nutrition/qualified-health-claims>.

<sup>58</sup> FDA guidance regarding dietary supplement structure/function claims can be accessed at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-structurefunction-claims>.



must be truthful and not misleading, and the company must possess adequate substantiation for the accuracy of the claim.

AHPA has published guidance on the laws and regulations surrounding retail labeling of dietary supplements, which includes detailed information about required data elements, formatting, and other factors.<sup>59</sup>

### 2.2.5.1 Specific issues relevant to the labeling of hemp products

When developing retail product labels, each company must carefully evaluate the labeling requirements applicable in the State(s), Tribes, or other jurisdictions in which their product will be sold, and ensure their labels comply with those standards.<sup>60</sup> At the current time, label requirements can vary considerably from jurisdiction to jurisdiction. Furthermore, local jurisdiction requirements may change from time to time and are currently rather fluid. Companies must comply with these local jurisdiction requirements in addition to federal FDA requirements for labeling of foods, dietary supplements, and certain topical products.

Various jurisdictions have implemented specific requirements for hemp products labeled for retail sale, as outlined below. These requirements generally do not apply to hemp materials or products packaged in bulk for further processing. In addition, they rarely apply to hemp materials or products derived from the seed.

- Most jurisdictions require the content of individual cannabinoids per serving to be stated on the retail product label, often in the nutritional information panel (“Supplement Facts” box).
- Some jurisdictions additionally require the content of  $\Delta^9$ -THC per serving to be stated on the label, even when the content of  $\Delta^9$ -THC is *de minimis*.
- Some jurisdictions have established definitions for terms such as “isolate,” “broad spectrum extract,” etc.
- Some jurisdictions prohibit or limit use of descriptions such as “THC free,” “non-THC,” or “reduced THC.”
- Some jurisdictions require the components of blended ingredients (e.g., a hemp distillate fortified with isolated CBD) to be listed separately on the retail product label, either in the Supplement Facts box or in the Ingredients statement. (Note: This is also required by U.S. FDA labeling regulations.)
- Some jurisdictions require the product be labeled with a lot or batch number and an expiration, best-by or use-by date; some jurisdictions also require date of manufacture.
- Some jurisdictions require a QR code or URL that directly links to a certificate of analysis (COA) for each lot number of product. Some require the COA to be from a third-party laboratory, and

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<sup>59</sup> See AHPA guidance on available at <http://www.ahpa.org/AHPAResources/TechnicalGuidance/AHPAGuidanceDocuments/TabId/401/ArtMID/1244/ArticleID/1181/Guidance-Federal-Labeling-Requirements-for-Herbal-Dietary-Supplements.aspx>.

<sup>60</sup> Companies who choose to use terminology other than what is allowed by State or other regulators may be the subject of legal action; they should be prepared for the associated expenses, and should have strong justifications to present in defense of their choices.



some require ISO 17025 certification of the laboratory. Some require specific contaminant or other tests in addition to cannabinoid tests.

- For hemp cannabinoid products that contain detectable traces of THC, a California Proposition 65 warning may be required.<sup>61</sup>
- Some jurisdictions require disclosure of whether the cannabinoids in the product are natural or synthesized. (Note: FDA takes the position that all synthesized cannabinoids as well as any other synthesized constituents of botanicals, with very few exceptions, are not dietary ingredients and cannot be used in dietary supplements.)
- Some jurisdictions have specific other labeling requirements, such as:
  - Specific warnings related to safety, use by children, etc.
  - A warning that the product will or may cause the consumer to fail urine or other tests for banned drugs.
  - An “FDA disclaimer” that is modified from the one specified in 21 CFR § 101.93.
  - A specified statement of identity, requiring products to be identified as a “hemp supplement” rather than the more generic “dietary supplement.”
  - Disclosure of the name and address of the testing laboratory.
  - Disclosure of the name and sometimes address of the distributor and hemp processor in addition to the usual disclosure of the manufacturer or marketer.
  - Disclosure of the country or state of origin where the hemp was grown.
  - Limitations on the types of health or structure/function claims that are allowed to be made.
  - Registration numbers for the product, the manufacturer, or both.

Over time, AHPA and other trade associations will work to standardize labeling requirements across the country, so that jurisdiction-specific labeling will hopefully be no longer required. AHPA does not agree that all of these requirements are logical or useful; many are redundant or unnecessarily burdensome, and many serve no important purpose to protect the public. In AHPA’s view, hemp should be regulated like any other botanical food or dietary supplement with few additional or specialized requirements.

### 2.2.5.2 Recommended labeling practices

To the extent possible given the requirements of individual jurisdictions, AHPA recommends the following practices for hemp ingredient and product labeling.<sup>62</sup>

(a) Terms used in labeling should be used in a manner consistent with the definitions set forth in AHPA’s Hemp Lexicon, to the extent possible.

**(b) For purposes of retail product labeling, AHPA recommends the term “cannabinoid” and variations such as “phytocannabinoid” be limited to structural cannabinoids produced by *Cannabis sativa* L and their carboxylic acids, analogs, and transformation products.**

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<sup>61</sup> AHPA Guidance on California Proposition 65 and Hemp Products. Accessible at [http://www.ahpa.org/Portals/0/PDFs/Committee/CC/AHPA\\_Prop65\\_Guidance\\_Hemp\\_Products.pdf](http://www.ahpa.org/Portals/0/PDFs/Committee/CC/AHPA_Prop65_Guidance_Hemp_Products.pdf)

<sup>62</sup> “Labeling” includes labels affixed to the product and other documents accompanying the sale of the product, such as certificates of analysis, product specifications, etc. See definition of “labeling” elsewhere in this document.



(c) All ingredients present in the ingredient or product must be disclosed in labeling, including any concentrated or isolated hemp constituents used to fortify hemp extracts (see “fortified extract” in the Hemp Lexicon).

(1) At a minimum, all ingredients must be listed in the “Ingredients” section of the label. This includes ingredients contained within ingredients except when exempted under 21 CFR §100.100(a)(3). (Note that this exemption does not include isolates or concentrates used to fortify an extract, since these are not “insignificant” and “incidental” to the finished product.)

(2) For dietary supplement products, all dietary ingredients must be listed in the Supplement Facts box. Depending on the ingredients, the requirements of the State where the product will be sold, and the wishes of the marketer, this may take a variety of forms. Below are several examples.

**Example 1: List each dietary ingredient separately in the Supplement Facts box**

<b>Supplement Facts</b>		
Serving Size: 1 capsule		
Servings Per Container: 30		
	Amount Per Serving	% Daily Value*
Hemp aerial parts extract	200 mg	†
CBD isolate	25 mg	†
*Percent Daily Values are based on 2000 calorie diet		
†Daily Value not established		

Other ingredients: Rice powder, gelatin capsule.

**Example 2: List a fortified extract in the Supplement Facts box**

<b>Supplement Facts</b>		
Serving Size: 1 chew		
Servings Per Container: 30		
	Amount Per Serving	% Daily Value*
Calories	xx	
Total Fat	xx g	y%
Saturated Fat	xx g	y%
Total Carbohydrate	xx g	y%



Protein	xx g	y%
THC-free hemp cannabinoid extract fortified with CBD (providing 30 mg of CBD)	250 mg	†
*Percent Daily Values are based on 2000 calorie diet		
†Daily Value not established		

Ingredients: Peanut butter, cocoa, THC-free hemp cannabinoid extract, stevia leaf, CBD isolate, natural chocolate flavor.

Note: The details of the nutritional section of the above example are for illustrative purposes only.

**Example 3: List a proprietary blend in the Supplement Facts box**

<b>Supplement Facts</b>		
Serving Size: 1 piece		
Servings Per Container: 30		
	Amount Per Serving	% Daily Value*
Calories	xx	
Total Fat	xx g	y%
Saturated Fat	xx g	y%
Total Carbohydrate	xx g	y%
Protein	xx g	y%
<b>Joe's Excellent</b> Proprietary Blend	325 mg	
(Providing 25 mg of CBD and 5 mg of CBN)		
Full spectrum hemp resinoid extract.....		†
CBD distillate.....		†
Orange peel terpenes.....		†
*Percent Daily Values are based on 2000 calorie diet		
†Daily Value not established		

Other ingredients: Oat fiber, egg white, stevia leaf, vegetable oil.

Note: The details of the nutritional section of the above example are for illustrative purposes only.



**Example 4: List the cannabinoid and its source in the Supplement Facts box**

<b>Supplement Facts</b>		
Serving Size: ¼ tsp		
Servings Per Container: 30		
	Amount Per Serving	% Daily Value*
CBD (from live resin)	50 mg	†
*Percent Daily Values are based on 2000 calorie diet		
†Daily Value not established		

Ingredients: Hemp flowering tops resin.

(d) The plant part must be disclosed where relevant.

- (1) For crude hemp, AHPA recommends that the plant part of the material always be stated. For dietary supplements that contain crude hemp, FDA regulations require the plant part to be disclosed on the product label.
- (2) For extracts and any kind of distillate made from hemp, AHPA recommends that the plant part used always be disclosed. For dietary supplements containing extracts of hemp, FDA regulations require the plant part to be disclosed on the product label.
- (3) For hemp resins and rosins, AHPA considers the plant part to be “resin” or “rosin,” equivalent to “pine resin” or “boswellia resin” or any other botanical resin.
- (4) For hemp isolates, AHPA does not consider disclosure of the plant part to be relevant.

(e) Hemp ingredients and products marketed to contain specific cannabinoid(s) must clearly state in the labeling the level of each such marketed cannabinoid. In addition, companies should include a statement that “This product contains not more than X% THC” where “X%” is a percentage no higher than the level of THC currently allowed in hemp by federal law.

- (1) Ingredients sold for further processing: The cannabinoid content information may be on the product label or in other labeling.
- (2) Retail products: The amount of each marketed nutrient or dietary ingredient (e.g., cannabinoid) per serving must be stated on the retail label. The product must be formulated with the intent to provide at least 100% of this stated amount.

To evaluate the accuracy of the stated amount of a nutrient for compliance purposes, FDA regulations establish two classes of nutrients<sup>63</sup>:

<sup>63</sup> 21 CFR § 101.9(g)(3)





- (i) Class I. Added nutrients in fortified or fabricated foods; and
- (ii) Class II. Naturally occurring (indigenous) nutrients. When a nutrient is naturally occurring (indigenous) in a food or an ingredient that is added to a food, the total amount of such nutrient in the final food product is subject to class II requirements, except that when an exogenous source of the nutrient is also added to the final food product, the total amount of the nutrient in the final food product (indigenous and exogenous) is subject to class I requirements.

FDA has long taken the position that, if the content of a particular nutrient in an ingredient is controlled or manipulated in any way, then that particular nutrient is a Class I nutrient for conventional foods and dietary supplements made with that ingredient. In contrast, Class II nutrients are naturally occurring in the ingredient and are not added, controlled, or manipulated in any way.

These “nutrient” class definitions apply not only to foods but also to dietary ingredients and constituents of dietary ingredients that are claimed in the Supplement Facts box.

Examples of Class I nutrients relevant to hemp products include:

- Isolated CBD or other isolated cannabinoids;
- CBD in a hemp distillate formulated to provide a defined level of CBD;
- CBD in a hemp extract fortified with concentrated CBD;
- Protein in a hemp protein isolate;
- Canflavin in a hemp leaf extract standardized for canflavin content; and
- Daucosterol in a hemp fruit extract fortified to a defined daucosterol content.

Examples of Class II nutrients relevant to hemp products include:

- CBD and other cannabinoids naturally occurring in crude hemp;
- Protein naturally occurring in crude hemp;
- Oil naturally occurring in crude hemp seed;
- Canflavin naturally occurring in a hemp leaf extract (i.e., an extract that is not standardized for or fortified with canflavin); and
- Alpha-linolenic acid naturally occurring in hempseed oil.

If a particular nutrient or dietary ingredient is present in the product from both Class I and Class II sources, the total amount of the nutrient or dietary ingredient in the final product is subject to Class I requirements.<sup>64</sup>

Class I nutrients must be present at 100% of the value declared on the label throughout the shelf life of the product. Class II nutrients must be present at 80% or more of the value declared on the label throughout the shelf life of the product, after taking into account the variability generally recognized for the analytical method used for testing.

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<sup>64</sup> This is written (somewhat incompletely) into the regulations with the statement, “...when an exogenous source of the nutrient is also added to the final food product, the total amount of the nutrient in the final food product (indigenous and exogenous) is subject to class I requirements.”



Hypothetical examples:

- (i) A dietary supplement manufactured using hemp flowering tops extract whose manufacturing process is designed to concentrate CBD to a minimum level of 80%, and the supplement is labeled as containing 20 mg of CBD per serving on the label (or alternately, labeled as containing 25 mg of hemp flowering tops extract with 80% CBD):
- As the quantity of the nutrient, CBD, is controlled and elevated, CBD qualifies as a Class I nutrient.
  - When tested at any point during its shelf life, the dietary supplement must contain at least 20 mg of CBD (i.e., 100% of the value declared on the label) per labeled serving, without any allowance for the variability of the test method.
- (ii) A dietary supplement manufactured using hemp leaf extract standardized to 0.5% canflavin and labeled as containing 0.5 mg of canflavin per serving on the label (or alternately, labeled as containing 100 mg of hemp leaf extract standardized to 0.5% canflavin):
- As the quantity of the nutrient, canflavin, is standardized (i.e., controlled), canflavin qualifies as a Class I nutrient.
  - When tested at any point during its shelf life, the dietary supplement must contain at least 0.5 mg of canflavin (i.e., 100% of the value declared on the label) per labeled serving, without any allowance for the variability of the test method.
- (iii) A dietary supplement containing 500 mg of hempseed oil and labeled as containing 25 mg of alpha-linolenic acid per serving, where the hempseed oil typically contains around 5% naturally occurring alpha-linolenic acid but its manufacturing is not manipulated to control or elevate the level of alpha-linolenic acid:
- As the nutrient, alpha-linolenic acid, is naturally occurring in the hempseed oil and is not manipulated in any way, it qualifies as a Class II nutrient.
  - When tested at any point during its shelf life, the dietary supplement must contain at least 20 mg (i.e., at least 80% of the 25 mg declared on the label) of alpha-linolenic acid per labeled serving after taking into account the variability of the test method.<sup>65</sup>
- (iv) A dietary supplement containing 500 mg of hemp aerial parts extract and labeled as containing 2 mg of CBD per serving, where the extract typically contains around 0.4% naturally occurring CBD but its manufacturing is not manipulated to control or elevate the level of CBD:
- As the nutrient, CBD, is naturally occurring in the extract and is not manipulated in any way, it qualifies as a Class II nutrient.

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<sup>65</sup> Notwithstanding the fact that the regulations allow for variability in the levels of naturally occurring nutrients, the finished product must be formulated with the intent to provide at least 100% of the labeled amount based on the expected level of the nutrient in the ingredient used. Intentional formulation below 100% of label claim is fraudulent.



- When tested at any point during its shelf life, the dietary supplement must contain at least 1.6 mg (i.e., at least 80% of the 2 mg declared on the label) of CBD per labeled serving after taking into account the variability of the test method.<sup>67</sup>

(f) Other recommendations for hemp ingredients sold for further processing:

(1) The levels of THC and any other declared cannabinoids or constituents must be disclosed as a minimum, maximum, range, or numerical value with the appropriate units.

- For semisolid, solid, or powder materials, the level should be expressed as a concentration on the weight/weight basis (e.g., X mg per g) or as a percent on the weight/weight basis (e.g., X% where the percent is calculated as  $Y \text{ mg per } Z \text{ mg} * 100$ ) where the numerator and denominator in calculating the percentage are in the same unit of measure.
- For liquid materials, the level may be expressed on the weight/volume, volume/volume, or weight/weight basis, either as a concentration or as a percent, so long as the units are always clearly stated and the numerator and denominator used in calculating any percentage are in the same unit of measure.
- In various materials it is appropriate to account for the water content when declaring the level of constituents. AHPA recommends as follows except where otherwise required by a specific jurisdiction:
  - For fresh or dry hemp, constituent levels should be expressed on the dry weight basis (i.e., the loss on drying of the hemp is tested, and the result is used to correct for the moisture content in the hemp when determining constituent levels).
  - For extracts, constituent levels should generally be expressed on the as-is basis (i.e., the extract is tested as-is, without drying or additional testing to correct for the moisture or water content of the extract).
  - For resins, rosins, distillates, isolates, oils, and similar materials, constituent levels should generally be expressed on the as-is basis.
  - Whether the constituent levels are stated on the dry weight basis or the as-is basis should be clearly identified in labeling.

(2) Extract ingredients should disclose in labeling the solvent(s) used (e.g., water, ethanol, carbon dioxide, steam) and the extract ratio or range of ratios (calculated as specified for extract ratios in the Hemp Lexicon).

(3) If the material has been processed starting from fresh hemp rather than dried hemp, this fact should be disclosed in labeling. For extracts to be used in dietary supplements, FDA regulations require use of fresh biomass to be disclosed.

(4) In some cases, information about the level of processing should be disclosed, especially for cannabinoid preparations:

- (i) If the material is a crude cannabinoid extract (rather than a more highly refined cannabinoid extract), this fact should be disclosed in labeling.



- (ii) If the material is a true distillate (as opposed to, say, a carbon dioxide extract), this fact should be disclosed in labeling.
- (iii) If the material has been initially extracted and then refined (e.g., extracted with carbon dioxide and then refined using distillation), this fact should be disclosed in labeling.

### 2.2.6 Adverse event reporting

Under the Dietary Supplement and Nonprescription Drug Consumer Protection Act,<sup>66</sup> products sold as dietary supplements in the U.S. must provide a domestic address or telephone number on product labels to which a report of an adverse event experienced by the consumer can be received by a responsible person designated by the marketer of the product in question. The serious adverse event reporting requirements for dietary supplements are the same as those for over-the-counter medicines. While no presumption of causality is made, marketers must maintain records of adverse event reports and submit detailed reports of all serious adverse events to the FDA within 15 days of receiving such a report. Under this adverse event reporting system, manufacturers and marketers are also required to retain all adverse event reports, including those that are not serious, for six years.

## 2.3 Regulations for cosmetics and personal care products

The FDA oversees governance of the cosmetic and personal care industry under the FDCA. No mandatory GMPs have been promulgated for operations that manufacture, process, package, label, or hold cosmetics for distribution in the US, but FDA has issued a Draft Guidance for Industry: Cosmetic Good Manufacturing Practices.<sup>67</sup>

There is no mandatory facility registration for cosmetic operations, but FDA encourages participation in a voluntary registration program.<sup>68</sup>

Cosmetic products must be labeled in accordance with 21 CFR Part 701<sup>69</sup> as well as regulations on packaging, color additives (21 CFR Part 70<sup>70</sup>), and prohibited and restricted ingredients<sup>71</sup>.

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<sup>66</sup> Public Law 109-462, 2006. Accessible at: <https://www.congress.gov/109/plaws/publ462/PLAW-109publ462.pdf>.

<sup>67</sup> This guidance is available at <https://www.fda.gov/cosmetics/cosmetics-guidance-documents/good-manufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics>

<sup>68</sup> Information about registration of cosmetic facilities is available at <https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program>.

<sup>69</sup> 21 CFR Part 701 Cosmetic labeling; available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=701>. FDA's cosmetics labeling guidance is available at <https://www.fda.gov/cosmetics/cosmetics-labeling-regulations/cosmetics-labeling-guide>.

<sup>70</sup> 21 CFR Part 70 Color additives; available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=70>.

<sup>71</sup> See information at <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics>.



FDA currently notes that cannabis and cannabis-derived ingredients (including those from hemp) are not specifically prohibited or restricted by regulation, but that any such ingredients must comply with all regulations applicable to cosmetics.<sup>72</sup> No claims may be made for a cosmetic product which imply the product is intended to affect the structure or function of the body, or to diagnose, cure, mitigate, treat or prevent disease, even if it affects the appearance. If the function of the hemp-derived ingredient is for one of these purposes, FDA may consider the product to be a new drug, and misbranded as a cosmetic product.

## 2.4 Advertising and marketing

All products advertised or marketed in the U.S. are subject to Federal Trade Commission (FTC) requirements to ensure representations made about the product are accurate and not misleading.<sup>73</sup> In addition, the FTC has developed specialized guidance for dietary supplements.<sup>74</sup>

## 2.5 Organic status

Any crop, food, supplement, or cosmetic for which organic status is claimed must comply with the requirements of the Department of Agriculture's (USDA's) National Organic Program (NOP) and the regulations in 7 CFR Part 205.<sup>75</sup>

For hemp and hemp-derived ingredients and products, the NOP is allowing certification for hemp as an agricultural commodity and as hemp-derived ingredients and products that are compliant with the federal definition of hemp. To be eligible for certification, hemp must be grown by an entity licensed under a hemp production program that is compliant with the requirements of either the USDA Final Rule or the 2014 Farm Bill.<sup>76</sup> All other provisions of the NOP regulations are applicable to hemp and hemp-derived products to be labeled under any of the organic labeling options.

## 2.6 Other laws and regulations

In addition to the regulations outlined above, hemp operations may be subject to a variety of other federal regulations such as those governing pesticides (40 CFR Chapter 1 Subchapter E), worker safety

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<sup>72</sup> See "FDA Regulation of Cannabis and Cannabis-derived Products: Questions and Answers available at <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers#cosmetics>.

<sup>73</sup> Information about general FTC requirements can be accessed at <https://www.ftc.gov/tips-advice/business-center/guidance/advertising-faqs-guide-small-business>.

<sup>74</sup> FTC guidance for dietary supplement claims can be accessed at <https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry>.

<sup>75</sup> Information about the NOP can be accessed at <https://www.ams.usda.gov/about-ams/programs-offices/national-organic-program>.

<sup>76</sup> NOP 2040. Instruction Organic Certification of Industrial Hemp Production. November 26, 2019. Accessed at <https://www.ams.usda.gov/sites/default/files/media/NOP%202040%20Hemp%20Instruction.pdf>.



(29 CFR §§ 1901-1999), sanitary transportation of food (21 CFR Part 1 Subpart O), and preventing intentional adulteration of food (21 CFR Part 121). In addition, hemp operation may be subject to the laws and regulations of individual states such as California's Proposition 65. AHPA has produced a guidance for Proposition 65 and its application to hemp and hemp products.<sup>77</sup>

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<sup>77</sup> AHPA Guidance on California Proposition 65 and Hemp Products. Accessible at [http://www.ahpa.org/Portals/0/PDFs/Committee/CC/AHPA\\_Prop65\\_Guidance\\_Hemp\\_Products.pdf](http://www.ahpa.org/Portals/0/PDFs/Committee/CC/AHPA_Prop65_Guidance_Hemp_Products.pdf)



## 3. Identity and quality

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

### 3.1 Identity and quality

#### 3.1.1 General considerations

- (a) All steps in the production of hemp or hemp-derived products 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, drying, and packing, to final product manufacturing/processing, packing, packaging, and labeling.
- (b) Written specifications. Appropriate written specifications should be established for hemp and hemp-derived products, either by the buyer, the seller, or both. Such specifications should address the various criteria set forth in the sections below with respect to identity, physical and chemical characteristics, and potential contaminants, to the extent applicable to the buyer's or seller's needs.
  - (1) Specifications for components and ingredients to be used in manufacturing should be developed taking into account the effect of the processing on the characteristic in question. For example, an extraction process may serve to either concentrate or remove a contaminant, and the allowed level of the contaminant in the crude botanical should be adjusted accordingly. Similarly, a manufacturing process may serve to destroy microorganisms in the hemp, which may obviate the need to control for pathogens in the component.
  - (2) Specifications for finished processed products should take into account the intended use of the product (e.g., the type of consumer product; whether it will be further processed by another company or whether it will be sold directly to consumers; etc.).
- (c) Sources of information. Recommended specifications and test methods for hemp are provided in pharmacopeial monographs and other compendia, such as the American Herbal Pharmacopoeia's *Cannabis* spp. inflorescence monograph.<sup>78</sup> See also Appendix 5 to the AHPA GACP-GMP.
- (d) Sampling. Tests and examinations for hemp and hemp-derived products must be performed on samples that are properly representative. Crude botanicals such as hemp must be sampled with close attention to their inherent heterogeneity. Many pharmacopoeias provide guidelines for proper sampling of botanical materials.<sup>79</sup>

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<sup>78</sup> Available at <http://www.herbal-ahp.org/index.html>.

<sup>79</sup> As an example, the U.S. Pharmacopoeia (USP) has sampling instructions for articles of botanical origin; see Second Supplement to USO 38 – NF 33, Chemical Tests <561> Articles of Botanical Origin.



With respect to hemp, for the purpose of determining the  $\Delta^9$ -THC content, it is recommended to sample the relevant portion(s) of the plant according to the applicable jurisdictional requirements (state, tribal, or USDA).

- (e) Hemp and hemp-derived products must meet all representations made in labels and labeling, specification documents, certificates of analysis, guarantees, written agreements, and other documentation, not only with respect to test results but also with respect to identity, grade (e.g., organic, non-GMO, Kosher, etc.), form (e.g., whole, powder, extract), locations of harvest and/or processing, dates of harvest and/or processing, and all other representations made regarding the material.

### 3.1.2 Identity

- (a) Any hemp or hemp-derived product represented as a particular subspecies, variety, cultivar, strain, or other lesser division of a species must in fact be that specific taxon.<sup>80</sup>
- (b) The botanical identity of the hemp grown or used in a hemp operation should be documented with as much specificity as appropriate.
  - (1) Many botanists currently consider the genus *Cannabis* to consist of a single species (*Cannabis sativa* L.) with two subspecies (*indica* and *sativa*), although this is the subject of some debate.<sup>81</sup>
  - (2) Other information such as the cultivar or strain may be recorded if applicable and relevant.
- (c) The correct identity of hemp should be confirmed through appropriate tests or examinations to confirm presence of the correct material.
- (d) Additional evidence of identity may be developed by a number of other means.
  - (1) Chemical fingerprinting may be performed using various kinds of chromatography (e.g., TLC, HPTLC, HPLC, GC<sup>82</sup>) to confirm the presence of peaks or bands that are diagnostic of the correct species and/or to confirm any diagnostic relative intensities or ratios between peaks. The fingerprint of an authentic specimen may also be compared to that of the test sample.<sup>83,84</sup>

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<sup>80</sup> Information on taxonomic identification of *Cannabis* spp. can be found in the American Herbal Pharmacopoeia Cannabis Inflorescence monograph.

<sup>81</sup> The currently most-accepted scientific names for hemp species are available from sources such as GRIN Taxonomy (<https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomyquery.aspx>).

<sup>82</sup> TLC = Thin Layer Chromatography  
HPTLC = High Performance Thin Layer Chromatography  
HPLC = High Performance Liquid Chromatography  
GC = Gas Chromatography

<sup>83</sup> For materials purchased from another party, it may be preferable to look at a full fingerprint rather than just a few bands or peaks to avoid inadvertent purchase of a material to which exogenous plant constituents have been added but not disclosed.

<sup>84</sup> It is to be noted that legitimate differences may occur between the fingerprint of an authentic crude botanical sample vs. a sample of the same species that has been processed (as by heating, extracting, etc.). In addition,





Furthermore, fingerprints of the test sample may be used to demonstrate the absence of bands or peaks characteristic of an adulterant or substitute. A printout or photograph of the resulting fingerprint(s) should be maintained on file for future reference.

- (2) DNA analysis may be performed where applicable, such as DNA barcoding or other genomic techniques.<sup>85</sup> A photograph of the resulting DNA barcode or fingerprint should be maintained on file for future reference. Alternately, results may be printed from software that reduces the data to a number that quantifies the degree of similarity or difference from the reference material or expected sequences.
- (3) Analytical testing may be performed for the presence of one or more botanical constituents that are consistent with the target botanical, or for the absence of botanical constituents indicative of a potentially substitute material.<sup>86</sup> The results of the analysis should be maintained on file.
- (4) Infrared testing (e.g., FTIR or NIR<sup>87</sup>) may be performed on the material.<sup>88</sup> A printout of the resulting IR spectrum should be maintained on file. Alternately, results may be printed from software that reduces the spectral data to a pass or fail result based on the degree of similarity or difference between the observed vs. the expected spectrum.
- (e) Voucher specimens of the plant or other archival samples (e.g., of viable seeds or of the crude botanical prior to processing) may also provide evidence of botanical identity.<sup>89</sup> Archival samples of hemp for manufacturing/processing should always be prepared prior to manufacturing/processing, especially before size reduction or extraction as these will destroy or remove important morphologic

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fingerprints may vary due to the natural chemical variation that occurs due to weather, season, soil chemistry, external stressors such as insects, etc. Thus, if the fingerprints of test sample and the authentic sample do not match exactly, this does not necessarily mean the test sample is improperly identified.

<sup>85</sup> Although the layperson might expect DNA to provide definitive identity results, in fact the use of DNA testing in botanical identification is not yet a fully developed science, and is known to produce false negatives and false positives. At the time of this publication, it is often not sufficiently robust and reliable to provide definitive identification and is not generally accepted either by industry or by the scientific community as a replacement for morphologic examinations. Furthermore, usable DNA is not present in many botanical ingredients that have been processed as by heating, extraction, etc.

<sup>86</sup> The constituents used for this purpose should be characteristic of, and preferably unique to, the botanical in question, or to the potential adulterating botanical whose presence is to be excluded. However, it must be kept in mind that testing for individual constituents can be easily fooled by spiking the botanical material with those constituents obtained from an exogenous source.

<sup>87</sup> FTIR = Fourier Transform Infra-Red spectroscopy  
NIR = Near Infra-Red spectroscopy

<sup>88</sup> Where infrared testing is used in conjunction with software that analyzes the spectrum to yield a “pass” or “fail” result, the software must be extensively trained with a sufficient number and diversity of authentic samples; otherwise, false negatives and false positives are likely to be obtained.

<sup>89</sup> Any such voucher or other archival sample is only useful, however, if it is an accurate and positively identified sample of the species; therefore, such samples cannot replace direct examination and/or testing of the actual botanical material itself.



features. Additional information about voucher specimens and archival samples is available in the AHPA GACP-GMP.

- (f) The identity of processed hemp, such as hemp that has been powdered, extracted, and/or blended with other botanicals, often cannot be definitively proven by testing the finished processed material. Microscopy, chemical testing, and/or DNA testing may be used where adequate and scientifically valid methods exist, but these at best provide evidence of identity rather than proof of identity.

### 3.1.3 Physical characteristics

- (a) A variety of physical characteristics may be relevant to the quality of hemp or hemp-derived product. These may include:

- (1) Moisture content. An appropriate specification should be set for the moisture content. Fresh hemp will contain a much higher amount of water than dried. For dried hemp, the moisture content is expected to be 8 to 15% to minimize microbial growth and prevent spoilage; for long-term storage, moisture levels at the lower end of that range are often preferable.
- (2) Particle size. For cut, chopped, or milled materials, specifications for the size of the pieces or particles should be established where relevant. The piece or particle size of hemp materials will affect operations such as steam sterilization, extraction, and encapsulation. In finished products, the particle size may affect mouthfeel, bioavailability, and stability.
- (3) Other relevant tests for powdered materials may include tapped density and bulk density, among others.
- (4) Other relevant tests for liquid materials may include pH, density or specific gravity, viscosity, and total dissolved solids, among others.
- (5) Other relevant tests for products in tablet or capsule form may include disintegration time, dissolution time, friability, and weight variation, among others.

- (b) For crude hemp additional tests may be relevant:

- (1) Soil content. It may be appropriate to set a quantitative limit for the amount of dirt and soil permitted in the material.
- (2) Foreign organic material. It may be appropriate to set a quantitative limit for the amount of non-target plant parts, foreign species, insects, etc. permitted in the material.
- (3) Unacceptable pieces. It may be appropriate to set a quantitative limit for the levels of discolored, damaged, broken, or moldy pieces permitted in the material.

### 3.1.4 Chemical characteristics

- (a) A variety of chemical characteristics may be relevant to the quality of hemp and hemp-derived products. These may include:



- (1) Extractives. In many cases it is desirable to establish a specification for the content of extractable material (“extractives”) in the hemp; this provides a measure of the chemical richness of the material.<sup>90</sup>
- (2) Marker content. Specifications may be established for the levels of one or more botanical constituents in the hemp, such as cannabidiol (CBD). Such tests may provide an indication that the material has been handled and stored properly to maintain freshness; for process control; to monitor shelf life; to limit the presence of illegal constituents, such as  $\Delta^9$ -tetrahydrocannabinol; or, in those cases where a particular constituent or class of constituents is linked to the physiologic effect of the botanical, to control the physiologic activity.<sup>91</sup>

In particular for cultivated hemp, it is required by law to ensure the level of  $\Delta^9$ -THC is at or below the legal limit allowed in hemp. It is strongly recommended to also ensure the level of  $\Delta^9$ -THC is at or below the legal limit allowed in hemp-derived products. For purposes of legal compliance, it is recommended to use validated analytical methods where available to ensure accuracy, precision, and other data quality attributes.<sup>92, 93</sup>

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

### 3.1.5 Contaminants

- (a) Limits should be established for impurities and contaminants that may adulterate the hemp material or adversely affect its quality, as follows.
  - (1) Adulterating substances. Specifications must be established to ensure compliance of the hemp or hemp-derived product with the federal limit for  $\Delta^9$ -THC of not more than 0.3% by dry weight.
  - (2) Adulterating species. Specifications must be established to exclude the presence of known adulterants and substitutes. Depending on the form of the material and the nature of the

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<sup>90</sup> Measuring the content of extractives may be helpful in preventing the inadvertent purchase of material that has previously been extracted (i.e., spent extraction marc). In addition, use of materials containing a consistent level of extractives allows powdered extracts to be made with a reasonably consistent native extract ratio, and liquid extracts to be made with a reasonably consistent content of dissolved solids.

<sup>91</sup> For more complete information about the use of marker compounds, refer to the American Herbal Product Association’s (AHPA’s) “Use of Marker Compounds in Manufacturing and Labeling Botanically Derived Dietary Supplements” and “Standardization of Botanical Products: White Paper,” available at [www.ahpa.org](http://www.ahpa.org).

<sup>92</sup> AOAC International ([www.aoac.org](http://www.aoac.org)) establishes official methods used by FDA and other governmental entities for compliance and enforcement. AOAC and other organizations such as ASTM International are in the process of developing methods for cannabinoids and other quality parameters in cannabis and hemp. USP has also published a document titled “Cannabis Inflorescence for Medical Purposes: USP Considerations for Quality Attributes.”

<sup>93</sup> Recent anecdotal reports to AHPA indicate that variations of 10% or more in reported cannabinoid content is not uncommon amongst current laboratories in the absence of an official AOAC method.



adulterant, such testing may be performed using gross morphology or microscopy, or may involve chemical tests for constituents characteristic of the adulterant.<sup>94</sup>

- (3) Microbiology. Specifications for the microbiological characteristics of the material or product (including indicator organisms, spoilage organisms, and/or potential pathogens) should be established where appropriate.<sup>95,96</sup> Microbiological specifications may not be relevant to raw agricultural commodities, materials intended for further processing, and those intended for use other than as a food or drug. However, microbial limits are often important for hemp-derived products and finished consumer products (especially food products that will not be thoroughly cooked by the end-user prior to consumption).
- (4) Heavy metals. Specifications for the levels of heavy metals are often important in hemp or hemp-derived products intended for use as or in consumer products.<sup>97</sup> If the material will eventually be sold as food in the State of California, due consideration should be given to the Proposition 65 safe-harbor levels for various metals.<sup>98</sup>
- (5) Pesticides. Establishment of pesticide specifications may be appropriate depending on the nature (e.g., conventionally-grown vs. organic) and intended use (e.g., food use vs. other uses) of the hemp or hemp-derived product. Tolerable pesticide levels in botanical crops vary from country to country. In the US, no detectable level of any pesticide is permitted on a food crop (or in food materials derived from that crop) unless a tolerance has been established for that specific pesticide on that specific crop (or for a defined Crop Group that includes the crop). As a result, the *de facto* tolerance for most pesticides and their breakdown products in most food botanicals

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<sup>94</sup> DNA testing might also be used, but since DNA testing cannot provide quantitative results, there is no way to know whether the presence of adulterant DNA indicates significant levels of adulteration or only an insignificant trace, especially when highly sensitive DNA technologies are used (e.g., PCR). Due to its extreme sensitivity, such testing commonly detects “adulterants” consisting merely of airborne pollen, or other stray plant or animal cells that are widespread both in the fields and in processing and laboratory environments.

<sup>95</sup> See AHPA’s “Guidance Policy on Microbiology and Mycotoxins” (2012) at [http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA\\_Microbiology\\_Mycotoxin\\_Guidance.pdf?ver=2016-04-26-121351-030](http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA_Microbiology_Mycotoxin_Guidance.pdf?ver=2016-04-26-121351-030).

<sup>96</sup> It should be noted that microbiological testing of a botanical material cannot, by itself, ensure the microbiological safety of the material, because low levels of pathogenic microorganisms may be missed during sampling and testing. To ensure microbiological safety, it is necessary to either (a) grow the botanical under strict conditions (such as those prescribed in 21 CFR Part 112) to preclude pathogenic contamination, or (b) formulate and/or process the botanical in a manner that destroys pathogens, as by combining with acid, heating, extracting, steam sterilizing, etc.

<sup>97</sup> For reference, see USP Chapters 232 and 233 for elemental impurities.

<sup>98</sup> See AHPA’s “Guidance on California Proposition 65 and Herbal Products” (2018) <https://www.ahpa.org/News/LatestNews/TabId/96/ArtMID/1179/ArticleID/861/AHPA-updates-CA-Prop-65-guidance-for-herbal-products.aspx> and AHPA’s Guidance Policy on Heavy Metals (2012), at [http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA\\_Heavy\\_Metals\\_Guidance.pdf?ver=2016-04-26-121351-157](http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA_Heavy_Metals_Guidance.pdf?ver=2016-04-26-121351-157).



is zero (or more accurately, “not detected” using a highly sensitive analytical test). However, as a practical matter, it is not possible to test a material for residues of every known pesticide; there are simply too many pesticides in use. Therefore, where pesticide specifications are established, consideration must be given to the range of pesticides that will be tested. Depending on the circumstances, it may be appropriate to use a standard pesticide panel (e.g., as per USP<sup>99</sup>) or to create a customized panel to include pesticides employed during the cultivation or collection of the crop, those previously applied to the cultivation site, and/or those applied to neighboring fields.

For purposes of legal compliance, it is recommended to use validated analytical methods where available.<sup>100</sup>

- (6) Radioactivity. A specification for content of radioactivity may be important if the material is sourced from an area known to be contaminated.
- (7) Solvent residues. A specification for solvent residues may be important for hemp-derived ingredients and products produced through solvent extraction processes.<sup>101</sup>
- (7) Other relevant tests may include sulfur dioxide, ethylene oxide residue, aromatic hydrocarbons (PAHs), aflatoxins and other mycotoxins, or presence of genetically modified DNA.

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<sup>99</sup> See USP Chapter 561 Articles of Botanical Origin, General method for pesticides residue analysis.

<sup>100</sup> As of this writing, AOAC and ASTM International are in the process of developing methods for pesticides in cannabis.

<sup>101</sup> For reference, see AHPA’s guidance policy on residual solvents in extracts (accessible at [http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA\\_Residual\\_Solvents\\_Extracts.pdf?ver=2016-04-26-135912-440](http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA_Residual_Solvents_Extracts.pdf?ver=2016-04-26-135912-440)) and USP Chapter 467 Residual solvents. See also NSF/ANSI 173 Dietary supplements (2020) for a list of additional solvents used in the hemp industry.



## 4. General personnel requirements

### 4.1 General personnel training

(a) Hemp operations should:

- (1) Ensure that each person engaged in the operation has the education, training, and experience, or any combination thereof, to enable that person to perform all assigned functions;
- (2) At a minimum, personnel should be familiar with appropriate handling practices for the hemp crop, safety procedures, hygienic procedures (e.g., handwashing, basic first aid to cover minor cuts in the field, etc.), equipment operation, and any tasks relevant to their job function. Ensure personnel handling hemp comply with all gowning, hygiene, and communicable illness procedures set forth in section 4.2; and
- (3) Maintain records of any training provided to employees for the performance of all assigned functions for at least as long as the employee performs work for the hemp operation and hemp cultivated, harvested, or otherwise handled by the employee remains in the marketplace.

(b) Hemp operations should provide all employees with training that includes:

- (1) Instructions regarding regulatory inspection preparedness;
  - (2) Information on applicable local, state, and U.S. federal laws, regulations, and policies relating to the operations and individuals employed in the operations;
  - (3) Hygiene training to prevent microbial contamination, as described in Section 4.2 below;
  - (4) The precautions necessary to maintain the security of the hemp operation and to prevent unauthorized access to controlled access areas (e.g., where hemp and hemp-derived products which exceed the legal limit of  $\Delta^9$ -THC are stored pending disposal or destruction);
  - (5) Implementation of any public health measures necessary for the protection of individual employees, as well as vendors, consumers, and other members of the general public that may interact with hemp operation personnel.
- (5) Other training as appropriate to ensure each employee is able to perform assigned functions.

### 4.2 General personnel hygiene

(a) Procedures should be established to exclude from any operation any person that might be a source of microbial contamination due to a health condition through contact with any material, including components, packaging components, in-process materials, hemp, hemp-derived products, and contact surfaces used in hemp operations, or through contact with other employees. Such measures include the following:

- (1) Excluding from working in any operations that may result in contamination any person who, by medical examination, the person's acknowledgement, or supervisory observation, is shown to have, or appears to have, an illness, infection, open lesion, or any other abnormal source of microbial contamination, that could result in microbial contamination of



components, packaging components, in-process materials, hemp, hemp-derived products, or contact surfaces, or transmission to other employees, until the health condition no longer exists; and

- (2) Instructing personnel to notify their supervisor(s) if they have or if there is a reasonable possibility that they have a health condition described in paragraph (a)(1) of this section that could result in microbial contamination of any components, packaging components, in-process materials, hemp, hemp-derived products, or any contact surface, or transmission to other employees.
- (b) Personnel working in an operation during which contamination or adulteration of components, packaging components, in-process materials, hemp, hemp-derived products, or contact surfaces could occur must use hygienic practices to the extent necessary to protect against such contamination. These hygienic practices include the following:
- (1) Wearing outer garments in a manner that protects against the contamination of components, packaging components, in-process materials, hemp, hemp-derived products, or any contact surface, as appropriate to the operation;
  - (2) Maintaining adequate personal cleanliness;
  - (3) Washing hands thoroughly with soap (and sanitizing if necessary to protect against contamination with microorganisms):
    - (i) Before starting work;
    - (ii) After using the restroom; and
    - (iii) At any other time when the hands may have become soiled or contaminated.

### 4.3 Personnel safety

- (a) Hemp operations must implement safety policies and procedures and provide all personnel with adequate safety training relevant to their specific job functions, as appropriate to the size of the operation. These may include:
- (1) Emergency action response planning as necessary;
  - (2) Personnel accident reporting and investigation procedures;
  - (3) Fire prevention and response plans;
  - (4) Materials handling and hazard communication procedures, including maintenance of safety data sheets (SDS);
  - (5) Materials handling, spill, and disposal procedures;
  - (6) Job hazard analyses; and
  - (7) Personal protective equipment policies, including but not limited to use of eye protection, respiratory protection, and ergonomic supports such as back braces.
- (b) Ensure personnel wear appropriate work clothing and shoes. Provide additional garments as needed, such as water-proof boots or raingear.



- (c) Protect personnel from adverse environmental exposures to the extent possible, such as extreme heat or cold, noxious plants, harmful insects or animals, excessive noise or dust, etc.
- (d) Hemp operations where there is a risk of eye contamination (e.g., from pesticides, solvents, powders, etc.) must provide and maintain a suitable number of emergency eye flushing stations, and access to adequate eye flushing water for each employee working in field operations.
- (e) Hemp operations must visibly post and maintain an emergency contact list which includes at a minimum:
  - (1) Operation manager contacts;
  - (2) Emergency responder contacts;
  - (3) Poison control contacts;
  - (4) Fire department contacts; and
  - (5) Spill response team contacts.
- (f) Hemp operations must comply with all other applicable standards of the federal Occupational Safety and Health Administration (OSHA) and any applicable state or local worker safety requirements, as applicable to the size and scope of the operation.





## 5. Cultivation

Many factors must be considered and controlled in the cultivation of hemp, from the choice of cultivation area through the applications of pesticides and fertilizer. These factors can significantly influence both the quality of the hemp grown and the economics of the cultivation operation. This chapter outlines recommended practices to ensure the quality and freedom from contamination of the hemp produced.

Cultivation operations that grow and harvest hemp food crops are defined under U.S. regulations as “farms.” Cultivators of hemp human food crops may be (depending on certain exemptions) subject to specific agricultural practice requirements established in 21 CFR Part 112, which go beyond the recommendations included here. Certain elements of 21 CFR Part 112 require more stringent, more specific, or more extensive standards than what is suggested herein, for example with respect to agricultural water quality, exclusion of animals, etc.

In addition, cultivation operations that grow and harvest hemp food crops may be subject to the food GMPs in 21 CFR Part 117 if the activities performed at the operation fall outside FDA’s definition of “farm.”

### 5.1 General

Cultivation operations should implement the recommendations of this section as applicable to the scope of their operation. Buyers of hemp must evaluate any consumer safety hazards that may be present and take appropriate steps to mitigate the risks they present.

#### 5.1.1 Regulatory considerations

- (a) Cultivation operations that grow and harvest hemp must operate in compliance with the hemp production regulations that are applicable to the jurisdiction in which the cultivation operation is located. This may be a hemp production program operated by a state or tribal government or a USDA hemp production plan.
- (b) Cultivation operations that grow and/or harvest human food that is “covered produce” are required to comply with 21 CFR Part 112 unless the farm qualifies for one of the exemptions in Part 112.<sup>102</sup> In general terms, “covered produce” refers to food that is:
  - (1) A fruit (e.g., apples, bananas, blueberries, etc.).
  - (2) A vegetable that is not always cooked prior to consumption (e.g., kale, mushrooms, radishes, etc.).
  - (3) A culinary herb (e.g., mint, oregano, cilantro, etc.).

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<sup>102</sup> See Appendix 2 to the AHPA GACP-GMP for more information.



- (4) Other herbaceous plants from which parts other than the fruit are harvested for food use.<sup>103</sup>
- (5) Sprouts, mushrooms, and nuts.
- (b) The distinction between covered produce and other food crops is based on food safety considerations.
- (1) Special regulations apply to the growing and harvesting of covered produce because these crops may be consumed raw and without further processing. In the absence of proper agricultural standards, a significant public health risk may exist due to potential contamination of the produce with pathogenic microorganisms. The agricultural standards in 21 CFR Part 112 are intended to prevent such contamination.
- (2) Crops other than covered produce are either not used for food, or almost exclusively are used for further processing or cooked by the consumer prior to consumption. Cooking destroys microorganisms, and food processors are required to implement procedures to mitigate the risk of microbial contamination. As a result, crops that are not covered produce do not require the same strict growing, harvesting, and handling practices to prevent microbial contamination that produce crops do.
- (c) As of this writing, it is unclear whether or not FDA will consider hemp to fall within the scope of covered produce. If FDA decides that it does, cultivation operations that grow food and are subject to 21 CFR Part 112 must consult the full text of 21 CFR Part 112 to determine the applicable requirements for their operations.

## 5.2 Propagation materials

- (a) Propagation materials used in cultivation operations should be appropriate for use in agricultural food production, even if the hemp will eventually be used not for food but for topical products.
- (b) Cultivation operations should follow the vendor's usage, storage, and disposal recommendations for the propagation material.

## 5.3 Hemp planting materials

- (a) Planting materials must be compliant with all requirements of the hemp production plan in the jurisdiction of the cultivation operation.
- (b) Seeds and other planting material (vegetative cuttings, tissue culture explants, etc.) should be obtained from reliable sources such as reputable vendors, seed banks, or harvest from existing plants.

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<sup>103</sup> According to a strict reading of the definition of "produce," many crops that are not actually used as fresh fruits and vegetables are covered by Part 112, such as orris, goldenseal, and marshmallow. It is unclear to what extent FDA will prioritize enforcement of Part 112 for these crops.



- (c) Planting material should be clearly labeled and recorded with the identity, origin, date of collection or harvest, lot number, and other relevant information as applicable (such as “organic” or “biodynamic”). The cultivation operation should be aware of whether it is receiving male and/or female hemp planting material.
- (d) Cultivation operations should take steps to ensure the correct botanical identity of seeds and other planting material (e.g., through examination of documentation provided by the vendor and/or by morphologic examination of the crop once mature).
- (e) Cultivation operations should ensure that hemp seed lots are of appropriate sex, purity, health, and cleanliness, either by performing seed testing, by having an outside laboratory perform seed testing, or by requiring vendors to provide appropriate analytical reports for each lot of purchased seed. Additional information is available in AHPA’s GACP-GMP, which is hereby incorporated by reference.
- (f) For each lot of planting material used, records should be kept of the following:
  - (1) Botanical identity of the lot, with as much specificity as appropriate. See Section 3.1.2 Identity and Quality for detailed information on botanical identity.
  - (2) Other relevant information such as certified seed status, organic status, genetically modified status, or applicable patent number, if any.
  - (3) Source from which the lot was obtained (even if produced on-site).
  - (4) A copy of any guarantee, certification, analytical report, or other documentation provided by the vendor (where applicable).
  - (5) Results from any testing performed by the cultivation operation or an independent laboratory or consultant hired by the cultivation operation.
  - (6) Information regarding any treatments applied to seed by the vendor or cultivation operation to maximize germination, reduce pests or diseases, and improve yield.<sup>104</sup>
- (g) Cultivation operations should maintain a retention sample of each lot of planting material, for future reference if needed. Retention samples should be stored in a manner to protect against insects, microbial growth, moisture, excessive heat, and other sources of degradation. Where fresh plant material is used for propagation, samples should be stored in a frozen or dried state.

## 5.4 Cultivation site

- (a) Location of cultivation operations:

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<sup>104</sup> Seed treatments are used to initiate germination, promote good seedling establishment, minimize yield loss, maintain and improve quality, and avoid the spread of harmful organisms. Seed treatments may be chemical or physical.



- (1) Outdoor cultivation operations and indoor cultivation operations may be located on any property that is zoned for such use.
  - (2) Outdoor cultivation operations and indoor cultivation operations must be located within any setbacks that pertain to the property where the cultivation is taking place.
  - (3) Indoor cultivation structures must be fully permitted and built to code at the time of construction.
- (b) The field or other setting in which hemp is to be planted should be evaluated to ensure it is suitable for cultivation of food or other consumer products, and for cultivation of hemp. Climatic conditions such as the length of day, sun intensity, rainfall (or irrigation) and humidity, air temperatures, and daily temperature cycles will significantly influence the physical, chemical and biological qualities of the hemp.
  - (c) Soil characteristics. Soil should be sampled in accordance with appropriate sampling plans,<sup>105</sup> and tested as appropriate; information regarding previous and neighboring land use may help identify relevant tests. Records should be maintained for at least several years of any soil testing performed. Additional information is available in AHPA's GACP-GMP, which is hereby incorporated by reference.
  - (d) Water quality. Water should be tested as appropriate to evaluate its suitability for use in cultivation of food or other consumer products; its suitability for hemp; and the extent to which it may require treatment prior to use.<sup>106</sup> Information regarding previous and neighboring land use, or (where municipal water is used) from annual municipal testing, may help identify relevant tests. Maintain records for at least several years of any water testing performed. Additional information is available in AHPA's GACP-GMP for botanicals doc, which is hereby incorporated by reference.
  - (e) Site location and setting. Information relevant to either improving or damaging the crop or the site itself should be recorded and maintained for at least several years, if not permanently. Agricultural activity at adjacent sites that may impact the hemp crop, such as the presence of male hemp plants that may result in unwanted pollen drift, should be evaluated. Additional information is available in AHPA's GACP-GMP, which is hereby incorporated by reference.
  - (f) Site history. A thorough history of prior uses of the crop area should be prepared and maintained to the extent possible. Such records should be maintained for at least several years, if not permanently. Additional information is available in AHPA's GACP-GMP, which is hereby incorporated by reference.

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<sup>105</sup> Information on soil sampling can be found from various organizations, such as <http://www.fao.org/docrep/003/t0234e/t0234e01.htm> and <http://animalrangeextension.montana.edu/forage/documents/soil%20sampling%20stratgeies.pdf>; an example plan is available at [http://www.waterboards.ca.gov/rwqcb4/water\\_issues/programs/401\\_water\\_quality\\_certification/Newhall/Wor\\_kplan%20Soil%20Sampling%20for%20Pesticides%20March%202013.pdf](http://www.waterboards.ca.gov/rwqcb4/water_issues/programs/401_water_quality_certification/Newhall/Wor_kplan%20Soil%20Sampling%20for%20Pesticides%20March%202013.pdf).

<sup>106</sup> Procedures for various testing methods and parameters to test are available at <https://www.epa.gov/cwa-methods> and <http://www.fao.org/docrep/003/t0234e/t0234e01.htm>.



## 5.5 Fertilizer use

- (a) Fertilizers used in cultivation operations should be appropriate for use in agricultural food production, even if the hemp will eventually be used for non-food purposes.
- (b) Fertilizer use should generally be guided by soil sample analysis to determine what fertilizers may be needed, and what ratios of nutrients are required.
- (c) Consideration should be given to the value of fertilizer use in producing better and larger yields, as well as the effects such use may have in the environment.
- (d) Federal, state and local regulations may apply to some of the chemical fertilizers used on hemp. Furthermore, organic cultivation operations must refrain from using chemical fertilizers; instead they should use naturally-sourced amendments when needed.
- (e) Fertilizer stocks should be kept away from water supplies and harvested crop materials.
- (f) For chemical fertilizers:
  - (1) Apply in accordance with federal, state and local regulations that are applicable to the specific fertilizer, if any.
  - (2) Use in accordance with all label directions (e.g., application rates, safe handling, proper disposal, etc.).
  - (3) Store chemical fertilizers properly according to label instructions. Nitrate-based and other oxidizing fertilizers must be stored away from solvents, fuels and pesticides.
- (g) For manure- and/or compost-based fertilizers:
  - (1) Apply in accordance with organic and other regulations as applicable.
  - (2) Do not use manure- or compost-based fertilizers produced with sewage sludge or human feces; these present risks not only to the eventual users or consumers of the crop, but also to personnel at the cultivation operation.
  - (3) Similarly, do not use untreated manure of any kind for crop fertilization. Use only fertilizers that have been adequately treated through an aerobic process.
  - (4) Monitor for undesirable microbial pathogens using appropriate test procedures. Testing may be performed periodically during composting or may be performed on finished batches of compost. Maintain records of such monitoring for several years.
  - (5) For manure- and/or compost-based fertilizers that are produced or openly stored on-site:
    - (i) Follow proper composting procedures (e.g., balanced carbon to nitrogen ratio; appropriate moisture levels; etc.).<sup>107</sup>

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<sup>107</sup> Additional information on composting procedures can be found at North Carolina State University extension services <https://content.ces.ncsu.edu/large-scale-organic-materials-composting>; USDA Alternative Farming



- (ii) Monitor runoff from composting and storage sites. Maintain records of such monitoring for several years.
  - (iii) Do not include sewage sludge or human feces in compost.
  - (iv) Where possible, avoid composting the seed heads of weedy plants unless the seeds will be killed by the heating of the compost pile.
- (h) For all fertilizers:
- (1) Ensure that packaged fertilizers and containers of diluted or prepared fertilizer are properly labeled at all times.
  - (2) Ensure that only properly trained personnel apply crop fertilizers.
  - (3) Provide adequate safety protection for personnel.
  - (4) Ensure that appropriately clean equipment and supplies are used. Ensure that fertilization equipment and supplies are appropriately decontaminated and/or disposed after use.
  - (5) Apply fertilizers at a sufficiently early phase in the crop's cycle to optimally promote growth and to ensure the fertilizer has appropriately broken down before harvest.
  - (6) Apply water-soluble foliar fertilizers within 24 hours of preparation. Prompt use optimizes the effectiveness of the application and prevents microbial contamination of the solution.
  - (7) Do not return unused rooting hormone to the source container.
  - (8) Ensure that water used for mixing any soluble fertilizer is potable or meets established criteria for agricultural irrigation water.
  - (9) Apply fertilizers in a manner that does not contribute to contamination of water supplies.
  - (10) When growing hemp 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.
  - (11) Maintain records of fertilizers used, including:
    - Fertilizer name or description.
    - Chemical name where applicable.
    - Vendor or other origin.
    - Date applied and by whom.
    - Quantity and/or concentration applied.

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Systems Information Center <https://www.nal.usda.gov/afsic/compost-and-composting>; and from organizations such as the Composting Council (<http://compostingcouncil.org/>).



## 5.6 Irrigation

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

- (a) The following steps should be implemented to assure water quality and efficient use in hemp cultivation operations.
- (1) Water source. Identify the source of all water used in crop production (for example, on-site well(s), open irrigation canal(s), reservoir(s), a municipal supply, or other sources).
  - (2) Water monitoring. Establish and follow testing procedures to monitor for contaminants of concern. This may include pathogenic microbes that may be present in water supplies (e.g., *E. coli* and other coliforms), heavy metals, pesticide residues or other contaminants.<sup>108</sup> The frequency of such procedures should take into account the water source(s) and results of previous tests. Analytical reports should be maintained on file for several years.
  - (3) Irrigation type. Choose the irrigation type (e.g., drip system, sprinkler, subsurface, overhead, etc.) based on considerations of cost, water conservation, plant health, and the risk of increased vector-borne diseases (e.g., from snails or mosquitoes).
  - (4) Irrigation systems. Do not use irrigation systems or equipment that may contaminate water or crops, such as those with lead pipes or fittings. Maintain irrigation systems in good working condition (i.e., no leaks or drips) to prevent water waste and to avoid high soil moisture levels that may contribute to mold and fungal problems.
  - (5) Application of irrigation. Apply irrigation according to the needs of the species and in a manner that adequately avoids runoff.
  - (6) Legal conformity. Conform to all rules that are applicable to the local or state water district.
- (b) Maintain irrigation-related records for at least several years, including:
- Records of water sources used in irrigation.
  - Records of water quality testing.
  - Records of irrigation system design, construction, maintenance, and repair.
  - Any records needed to establish conformity with any applicable regulations.

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<sup>108</sup> Procedures for various testing methods and parameters to test are available at <https://www.epa.gov/cwa-methods> and <http://www.fao.org/docrep/003/t0234e/t0234e01.htm>.



## 5.7 Crop maintenance and protection

The growth and development characteristics of hemp, 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.

- (a) Cultivation techniques. Adapt tilling, mulching, and other cultivation practices to the requirements of hemp and to minimize weeds. Consider use of no-till farming to reduce overhead costs (labor, equipment, and inputs such as fuel and irrigation), reduce soil erosion, and improve soil moisture and fertility which can improve yields.
- (b) Growth controls. The timely application of measures such as thinning, topping, bud nipping, pruning and shading may be used to control the growth and development of the hemp, thereby improving the quality and/or quantity of the plant material being produced.
- (c) Crop rotation. Consider adjusting crop rotation plans to maintain soil fertility (e.g., through periodic planting with nitrogen-fixing crops) and to minimize pest and disease problems.
- (d) Companion plants. Consider companion planting strategies such as interplanting with crops that repel damaging insects or attract predatory insects; separately planting trap crops to attract insects away from the target crop; or interplanting to provide necessary shade, support, or humidity. Certain combinations of companion plants are reported to improve flavor and/or vigor. Conversely, some combinations of plants are known to stunt growth and should be avoided.
- (e) Weeds. During hemp growth and immediately prior to harvest, monitor fields for undesirable weeds and control them as appropriate. Any weeds containing tropane or pyrrolizidine alkaloids should be appropriately eliminated before harvesting.
- (f) Integrated pest management.<sup>109</sup> Minimize pest and disease infestations through appropriate selection of resistant varieties, appropriate choice of sowing time, appropriate seed treatments, removal of dead or diseased plants or tissues, applications of beneficial bacteria and fungi (e.g., mycorrhizae; compost tea), etc. Where insects reach unacceptable levels, evaluate alternatives to insecticides such as use of beneficial insects, physical insect barriers and traps, vacuuming, etc. Check with state agricultural agencies for guidance.
- (g) Pesticide use. Pesticides (insecticides, herbicides, fungicides, etc.) from either natural or synthetic sources must be carefully controlled.
  - (1) Pesticides used in cultivation operations must be approved by the jurisdiction in which they will be used, or in the absence of an approved pesticide list, must be one of the following:

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<sup>109</sup> Integrated pest management (IPM) involves the careful consideration of all available pest control techniques and the use of appropriate measures to discourage the development of pest populations and to reduce the use of pesticides to the extent possible. IPM emphasizes the growth of a healthy crop with the least possible disruption to ecosystems by encouraging the use of natural pest control mechanisms.





- (i) Subject to a tolerance established for application to hemp by the U.S. Environmental Protection Agency (EPA)<sup>110</sup>;
  - (ii) Identified by EPA regulation as exempted from tolerance<sup>4</sup>;
  - (iii) Subject to a Section 18 emergency exemption under FIFRA<sup>111</sup>;
- (2) Pesticides should be applied to hemp at the minimum effective rates, and only by properly trained personnel with the proper application equipment and personal protective equipment. Cultivation operations must follow the EPA Worker Protection Standard<sup>112</sup> when preparing and applying pesticides.
  - (3) Application, storage, and disposal of pesticides must be in accordance with label instructions and all regulations.
  - (4) Keep pesticide stocks away from water supplies and harvested crop materials.
  - (5) Pesticides must be applied sufficiently in advance of harvest to comply with label instructions and any relevant regulations. Application of pesticides should be avoided following the flowering of hemp plants, if the flower head will be harvested.
  - (6) Records of pesticide use should be kept for at least several years, including:
    - Pesticide name or description.
    - Chemical name where applicable.
    - Vendor or other origin.
    - Date applied and by whom.
    - Quantity and/or concentration applied.
- (h) Cultivation records.
- (1) In addition to the pesticide-related records discussed above, maintain other records of crop planting, cultivation, maintenance, and protection as appropriate. Activities may be recorded in a Daily Farm Log that combines all this data into the same document, or in activity-specific documents such as a Fertilizer Application Log, Pesticide Application Log, etc.<sup>113</sup>

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<sup>110</sup> See the list of EPA approved pesticides for use on hemp at <https://www.epa.gov/pesticide-registration/pesticide-products-registered-use-hemp>.

<sup>111</sup> Section 18 of the [Federal Insecticide, Fungicide, and Rodenticide Act \(FIFRA\)](#) authorizes EPA to allow an unregistered use of a pesticide for a limited time if EPA determines that an emergency condition exists.

<sup>112</sup> The EPA Worker Protection Standard can be accessed at the following website - <https://www.epa.gov/pesticide-worker-safety/pesticide-worker-protection-standard-how-comply-manual>.

<sup>113</sup> An example of such a log is available at <https://www.ccof.org/documents/sample-farm-activity-log>. Alternately, software is available to manage and record farm activities.



- (2) All records with relevance to a particular cycle of cultivation and harvest should preferably be retained past the time when the harvested crop is no longer in the marketplace, which may be several years or more.<sup>114</sup>

## 5.8 Other considerations

- (a) Organic materials. If the crop is intended to be certified organic per the USDA National Organic Program,<sup>115</sup> conform to all relevant federal and state regulations governing organic certification. Disclose the organic status of the hemp in records and labeling to ensure that downstream recipients of materials produced from the hemp are informed of the organic status.
- (b) Environmental stewardship. Cultivation operations should take steps to protect and improve the stability and quality of the topsoil that is essential to their cultivation area's longevity. 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, cultivation operations should maintain and enhance the biodiversity of their land, and minimize the deleterious effects of fertilizers and pesticides on groundwater and surrounding areas.

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<sup>114</sup> Even when the harvested crop is sold in fresh form (i.e., a perishable form that might be expected to leave the marketplace quickly), downstream companies may process (e.g., by drying or extracting) the material into a shelf stable form that remains in the marketplace for years.

<sup>115</sup> In the US, only crops grown and certified under the USDA National Organic Program or that are recognized as organic crops through USDA international agreements are permitted to be called "organic." See <https://www.ams.usda.gov/services/organic-certification/international-trade>.



## 6. Harvest

Harvesting procedures require proper attention in order to ensure hemp 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 cultivation operations in general; it does not include any specialized requirements established in 21 CFR Part 112 for covered produce farms, nor does it provide detailed, comprehensive recommendations for particular types of hemp.

### 6.1 Harvest conditions

Harvest season and harvest time are important factors in the production of good quality hemp. 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.

- (a) Crop condition. Schedule the harvest, both in terms of time of year and time of day, when the hemp is in the proper condition to meet established quality requirements. Consider such factors as the maturity of the plants or degree of ripeness, size, color, moisture levels, and other characteristics, as well as measured constituent levels if applicable. Also consider the timing of any required preharvest sampling for acceptable hemp THC level compliance testing.<sup>116</sup>
- (b) Weather conditions.
  - (1) Evaluate weather conditions at the actual time of harvest. Depending on the circumstances, it may be preferable to avoid harvesting when rain, dew, or excessive humidity are present; alternately it may be preferable to expedite the harvest and move the material to a dry area. It may also be preferable to avoid harvesting in hot weather, especially if the hemp is susceptible to wilting (e.g., leaves).
  - (2) Consider weather forecasts for several days immediately following harvest if rain, heat, or other weather could adversely affect the quality of the harvested material.
  - (3) Wet weather may pose greater problems with delicate plant parts such as leaves and buds and fewer problems for harvest of sturdy plant parts, such as stalks. However, splashing from rain or hail may contribute to excessive levels of dirt in the harvested material, which will need to be removed.
  - (4) If harvest must occur under wet conditions, take care where necessary to dry the material promptly and properly to avoid damage and spoilage from mold or soil bacteria.
- (c) Harvest timing. The following guidelines may assist in determining the best time to harvest hemp plant parts. However, these are only general in nature; the optimal harvest time will vary depending on the purpose and specifications established for the hemp crop.

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<sup>116</sup> For hemp production in the US, hemp cultivators must comply with the USDA Domestic Hemp Production Program Final Rule for preharvest testing requirements and the applicable State or Tribal requirements. Hemp cultivators outside of the US should comply with any pre-harvest testing requirements in the jurisdiction of the hemp production location.



- (1) Consider the scheduling of any pre-harvest compliance testing in relation to the expected harvest time.
- (2) Always take into account any plant maturity or harvest season specifications that have been set by the material's buyer.
- (3) Review harvest research that has been conducted to evaluate the optimal harvest times or degree of maturity.
- (4) Consider the timing of harvest in light of other needs, such as allowing seed to mature for the next season's planting.
- (5) It may be preferable for above-ground parts of the plants to be collected early in the day but after any dew has evaporated.
- (6) Leaves. Leaves for food use are generally harvested when young, tender, and mild.
- (7) Flower heads. Hemp flower heads are often harvested by hand. Flower heads should be handled carefully to ensure the flower heads are kept intact and the resin glands (trichomes) are not disturbed.
- (8) Seeds. Seed hemp is harvested when the seeds begin to shatter. Determining the optimal time to harvest can be tricky, since the seeds lower in the head will mature and split open earlier than seeds near the top. In addition, seeds mature at different rates on different plants. Generally, hemp seed is harvested when 70-80% of the seeds are ripe and seed samples have a moisture content of 10-20%.
- (9) Stalks. Hemp stalks are generally cut well before the seeds are ripe. Immediately after cutting, stalks intended for fiber production are left in the field to ret before eventually being baled.

## 6.2 Harvest quality

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

- (a) To the extent possible, avoid harvesting plant materials that are broken or moldy, exhibit insect damage or excessive insect infestation, or are otherwise undesirable.
- (b) For flower heads that will be used for resin, handle the material carefully to prevent release and degradation of the resin. Resin commonly occurs in glands on the surface of the plant, and the more the glands are disturbed the more resin will be lost.
- (c) Conduct the harvest in a manner that minimizes the presence of foreign matter in the harvested crop, such as soil, weeds, insects, bird nests, spider webs, trash, plant parts other than the desired part, etc. Remove foreign matter at the time of harvest or prior to transporting the harvest from the field, if practical.



- (d) Examine the harvest carefully and remove damaged, degraded, moldy, off-color, or otherwise undesirable plant material, and remove non-target plant parts where they occur.<sup>117</sup> Also remove any contaminant species that may have been inadvertently collected with the harvested crop, with special attention to any local species that are toxic or potentially toxic. During this inspection, remove as much dirt as possible.
- (e) Ensure that harvested materials are kept clean and isolated from contaminants such as dirt, dung, smoke, and exhaust.<sup>118</sup> Where the harvest is stored on the ground temporarily, consider using plastic sheeting or another clean material between the harvest and the soil; however, this is not appropriate for all crops, especially large-volume crops that are cut and left in the field (e.g., fiber hemp).
- (f) In general, avoid compaction of the harvested material as this may cause physical damage as well as temperature build-up and overheating.
- (g) Protect the harvested crop from moisture where necessary to minimize growth of bacteria, yeast, and mold. Unless fermentation is desired, ensure adequate air circulation around the harvested material, especially if stored in containers or under a cover.
- (h) Protect the harvested crop from contact with birds, rodents, insects, and other animals.
- (i) Control exposure of the harvest to the elements (sunlight, heat, wind, etc.) as appropriate. In many cases, the harvested material should be protected from the elements in order to preserve freshness. In other cases (e.g., where sun-drying is desired) such exposure may be beneficial.
- (j) Transfer the crop to an appropriate receiving station. Ensure that the harvest is not inappropriately fumigated during transport.

## 6.3 Harvest documentation and samples

- (a) A lot number should be assigned to harvested materials on an appropriate basis (e.g., one day's harvest is one lot; one field's harvest is one lot; etc.).<sup>119</sup> Whichever criteria are used, ensure the material in one lot can reasonably be expected to be uniform and consistent.
- (b) Records.

(1) Records should be kept of the following:

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<sup>117</sup> The process of separating the target plant material from unusable or undesirable material is known as "garbling."

<sup>118</sup> Smoke and exhaust contain polycyclic aromatic hydrocarbons (PAHs), which are known carcinogens. Many governments have imposed limits on the permissible content of PAHs in foods and other products.

<sup>119</sup> AHPA strongly recommends use of lot numbers for both food and non-food crops in order to facilitate quality assurance.



- Botanical identity of the harvested crop, including plant part.
  - Lot number(s).
  - Harvest date(s).
  - Harvest quantity(s).
  - Harvest location(s) (e.g., field numbers, GPS coordinates).
  - The identity of personnel involved (e.g., harvesters and supervisors).
  - The age and/or life stage of the crop at the time it is harvested, where necessary for clarity.
  - Field conditions at the time of harvest, where relevant.
  - Results of any compliance testing performed on the harvested material.
  - Other information as needed.
- (2) Consider making other types of records, such as photographs or videos of the cultivation site, plant population(s), and individual plant specimens.
- (3) All records with relevance to a particular cycle of harvest should preferably be retained past the time when the harvested crop is no longer in the marketplace, which may be several years or more.<sup>120</sup>
- (c) Labeling. Label harvested materials as appropriate to prevent the possibility of mix-ups. Include the lot number. Include the presence of any allergens and the grade such as organic, especially when needed to distinguish between similar crops on the same cultivation site.
- (d) Keep a retention sample of each lot of harvested material.
- (1) The sample may be taken either immediately after harvest, after washing and cleaning the harvest (if performed), and/or after drying (if performed). In any case, at least one retention sample should be taken before the harvested material is subject to any additional processing.
- (2) Label the retention sample with the botanical identity, lot number, and any other relevant information.
- (3) Store the sample in a manner to protect against insects, microbial growth, moisture, excessive heat, and other sources of degradation. If the sample consists of fresh plant material, store the samples in a frozen or dried state.
- (4) Maintain the retention sample in storage for several years or as long as the records associated with the lot are retained.

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<sup>120</sup> Even when the harvested crop is sold in fresh form (i.e., a perishable form that might be expected to leave the marketplace quickly), downstream companies may process (e.g., by drying or extracting) the material into a shelf stable form that remains in the marketplace for years.



## 7. Post-harvest handling

Post-harvest activities are critical to ensuring hemp meets appropriate quality specifications. Temporary storage, inspection, grading, cleaning, drying, and packing 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 at hemp operations engaged in the cultivation, inspection, grading, cleaning, drying, and packing of hemp. It does not include any specialized requirements established in 21 CFR Part 112 for covered produce farms, nor does it provide detailed, comprehensive recommendations for particular types of hemp.

For hemp food crops, most of these operations fall within the scope of farm activities permitted by FDA, so long as they are performed on the same farm where the hemp was grown or another farm under the same management. If they are performed by a business separate from the farm then these activities are food manufacturing/processing activities subject to facility registration and food GMPs. In addition, drying is an activity which, depending on various details as explained at greater length below, may be defined by FDA as food manufacturing/processing even if it occurs on the same farm where the hemp was grown.

### 7.1 Location

- (a) Post-harvest handling may be located on any property zoned for such use.
- (b) Post-harvest handling operations must be located within any setbacks that pertain to the property where the operations occur.

### 7.2 Handling immediately after harvest

- (a) The harvested crop should be handled, stored, and consolidated in a manner that ensures that the harvested material does not degrade.
- (b) Avoidance of compaction. In general, do not fill or stack sacks or other harvest containers to levels that will result in compacting of harvested materials, as this may cause physical damage as well as temperature build-up and overheating.
- (c) Protection from external sources of contamination. Protect the harvested material from contact with birds, rodents, insects, and other animals, as well as dirt, dung, smoke, and exhaust.
- (d) Protection from the elements. Protect the harvested material from exposure to the elements as appropriate. In most cases the material should be protected from direct sunlight, rainfall, freezing, etc., except where such exposure is required for a specific purpose such as sun-drying or retting.
- (e) Timing. Where applicable, minimize the transit time from the point of harvest to the location used for consolidation and cleaning. (However, this may not apply where additional steps are required to



prepare the crop for use, such as sun-drying.) Plant materials should be promptly unloaded and unpacked upon arrival.

- (f) Examination. If harvested materials are brought from diverse locations or harvesters to one location for consolidation and further processing, examine the harvested material upon arrival to determine whether the material appears to be generally uniform and acceptable.
- (g) Consolidation. If multiple harvest lots are consolidated together, assign a new lot number to the combined harvest. Maintain records of the individual lot numbers and quantities combined together.
- (h) Temperature and moisture control. Ensure that both the temperature and moisture of the harvested material are controlled throughout post-harvest handling as appropriate to prevent degradation. Use of refrigeration or other cooling steps may be used when needed and appropriate (e.g., for hemp leaves that will be used fresh).

## 7.3 Separating the desired plant part

- (a) Depending on the hemp crop and the harvest procedures used, additional steps may be necessary to separate the target plant part from other parts present in the material.
- (b) For food crops, such steps that serve to isolate the desired plant part are generally defined by U.S. regulation as farm activities (rather than food manufacturing/processing activities).<sup>121</sup>

## 7.4 Washing and cleaning

Washing and cleaning may be necessary after harvest to remove dirt, soil, and foreign items or materials.

- (a) Washing with water. Many hemp crops do not require washing, but if washing is performed, use only potable water.<sup>122</sup> Additional recommendations are provided in the AHPA GACP-GMP.

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<sup>121</sup> In the preamble to the proposed rule (78 FR 3540, 2013, Table 1), FDA designates “Activities designed only to isolate or separate the commodity from...other parts of the plant” as activities that do not transform a raw agricultural commodity into a processed food. When performed on a farm or farm mixed-type facility, these activities are part of “harvesting” rather than “manufacturing/processing.” FDA has adopted the general principle that manufacturing/processing operations are ones that alter the general state of the commodity, while non-manufacturing/processing operations, like harvesting, are designed only to isolate or separate the commodity from foreign objects or other parts of the plant. (See also the 1998 Joint EPA/ FDA Policy Interpretation (63 FR 54532, 1998) and the 1999 FDA [Guidance for Industry: Antimicrobial Food Additives](#), July 1999.)

<sup>122</sup> EPA’s primary drinking water standards can be found at <https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations>.





- (b) Cleaning areas should be isolated from areas where other steps are performed.
- (c) Either before or after washing, inspect for and remove all visible foreign matter and sub-standard material.
  - (1) Ensure the hemp is sufficiently well displayed for ready visibility (e.g., on a conveyor, or spread out on tables, screens, or tarps).
  - (2) 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.
  - (3) Sub-standard material includes, for example, discolored leaves or flower heads, or any material that would cause the hemp not to meet its specifications.
  - (4) Where appropriate, equipment such as a de-stoner, gravity separator, or metal detector may be used.
- (d) Records.
  - (1) Records should be kept of the washing and cleaning performed, including the identity, lot number, and the quantity of hemp before and after cleaning; the location, date, and person(s) involved; the equipment used; and other information as appropriate.
  - (2) Records should be kept of the water source and water quality used for washing and cleaning.
  - (3) Records should be kept of general cleaning procedures and also any crop-specific cleaning procedures.
  - (4) Maintain these records for at least several years, or as required by regulation.

## 7.5 Drying

For most hemp crops the harvested material must be properly dried prior to packing and distribution. 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 drying conditions is therefore essential when drying is performed.

### 7.5.1 Regulatory considerations for drying hemp food crops

If a hemp crop is intended for use as or in food (as opposed to non-food uses such as for biofuels, pharmaceuticals, clothing, household products, cosmetics, etc.), FDA food GMPs may apply to the drying process.



(a) Classification of drying as a farm activity vs. manufacturing/processing.

- (1) Drying of a raw agricultural commodity that results in creation of a distinct food commodity is considered “manufacturing/processing.” For example, drying grapes into raisins, apricots into dried apricots, fresh peas into dried peas, and fresh chilis into dried chilis are all food manufacturing/processing operations.<sup>123</sup>
- (2) Drying accompanied by another activity that is itself defined as a manufacturing/processing operation, such as slicing or chopping, is a food manufacturing/processing operation rather than a farm activity.
- (3) Drying of a raw agricultural commodity on a farm that does not result in the creation of a distinct food commodity and does not involve other manufacturing/processing operations is considered a farm activity.<sup>124</sup> For example, the drying of hay, cinnamon bark, or ginkgo leaf on a farm is a farm activity.
- (4) AHPA believes that drying of hemp generally does not create a new commodity and does not involve other manufacturing/processing operations such as chopping, slicing, artificial ripening, etc. and is, therefore, within the definition of a farm activity when it is conducted by the cultivation operation. However, hemp operators are advised to consult a lawyer regarding the details of their circumstances.

(b) Classification of hemp operations that perform drying.

- (1) If a cultivation operation performs only drying that does not create a new commodity, then FDA considers the operation to be a “farm.” As such, the drying performed on the farm is generally not subject to FDA food GMPs such as 21 CFR Part 117 or 21 CFR Part 111.<sup>125</sup>
- (2) If a cultivation operation performs drying that does create a new commodity, but performs no other manufacturing/processing activities that are outside the farm definition, the farm is not required to register with FDA as a food facility and is generally exempt from the GMPs established in 21 CFR Part 117.<sup>126</sup>

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<sup>123</sup> Although such drying that creates a new commodity is considered “manufacturing/processing,” it does not create a requirement for the farm to register as a “farm mixed-type facility” unless other manufacturing/processing is performed that is outside the farm definition. Drying by itself remains fully within the definition of “farm” whether or not a new commodity is created by the drying. See the definition of “primary production farm.”

<sup>124</sup> Specifically, such drying is defined as “holding” by the farm, because the drying is necessary for proper storage of the food. See the definition of “holding.”

<sup>125</sup> However, if the farm dries and sells hemp to a customer that simply packages and markets the hemp as a dietary supplement, without any other manufacturing/processing steps performed by the customer, the farm may be considered a manufacturer of dietary supplements and therefore subject to 21 CFR Part 111.

<sup>126</sup> However, if the farm mixed-type facility dries and sells hemp to a customer that simply packages and markets the hemp as a dietary supplement, without any other manufacturing/processing steps performed by the customer,



- (3) If cultivation operation performs drying that does create a new commodity, and also performs other manufacturing/processing activities that are outside the farm definition, then FDA considers the operation to be a “farm mixed-type facility.” Such a facility is generally (subject to certain exemptions) required to register with FDA as a food manufacturing/processing facility, and is generally (subject to certain exemptions) required to comply with the GMPs established in 21 CFR Parts 111 or 117<sup>127</sup> as well as other relevant FDA regulations, at least for those activities that are outside the farm definition.
- (4) If drying is performed by a hemp operation other than the cultivation operation, then the drying is a manufacturing/processing activity. The drying facility is generally (subject to certain exemptions) required to register with FDA as a food manufacturing/processing facility, and is generally (subject to certain exemptions) required to comply with the GMPs established in 21 CFR Parts 111 and 117<sup>110</sup> as well as other relevant FDA regulations.

### 7.5.2 Recommended drying practices

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

- (1) Timing. Conduct the drying process as quickly as possible after the harvested crop is ready for drying. This is often immediately after harvest.
- (2) Sunlight. Hemp flower heads should generally be protected from sunlight to minimize degradation of the resin. Direct sunlight is appropriate in other circumstances, such as for fiber hemp.
- (3) Temperature control. The optimal drying temperature differs for various hemp crops. Drying should be completed quickly enough to minimize growth of spoilage organisms and (where relevant) pathogens. 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 hemp itself to exceed the range at which damage to the quality of the crop may occur.
- (4) Airflow control. The drying area should be well-ventilated and have sufficient airflow control for the amount of hemp plant material being dried.

(b) Air drying. Operations may conduct drying processes in open air, either outdoors or in enclosed areas, and may use ambient heat or may also use artificial heat. The following practices are essential to all such operations.

- (1) Design outdoor drying operations with sufficient covering over the drying hemp (e.g., a net, tarp or roof) to protect against contamination from birds and other flying animals, especially if the crop is intended for use as or in food, inhalable, or personal care products. Also, establish

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the farm mixed-type facility may be considered a manufacturer of dietary supplements and therefore subject to 21 CFR Part 111.

<sup>127</sup> See Section 10 “Food and Farm-Mixed Type Facility Requirements” for more information.



- procedures to rapidly provide cover in case of rain or other events that could interrupt the drying process or contaminate the in-process material.
- (2) Design indoor drying operations to ensure that there is sufficient ventilation for airborne moisture to escape.
  - (3) In both outdoor and indoor settings, provide adequate air circulation throughout the drying area, for example by installing fans as needed or by monitoring natural air circulation.
  - (4) Place material to be dried in thin layers on clean surfaces that afford adequate air circulation. Use food-grade surfaces if the crop is a food crop. Alternately, hang the material to facilitate drying.
  - (5) Carefully turn the drying material as needed to facilitate rapid and complete drying.
  - (6) If heaters or other sources of artificially generated heat are used in the drying operation, provide adequate ventilation of the heating equipment, and use only fuels that will not result in smoke or other combustion products coming into contact with the crop and thereby contaminating the material.<sup>128</sup>
- (c) 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 hemp is maintained.
- (d) Finished moisture content. Ensure that the moisture content of the material after drying conforms to any established specifications. If a moisture specification is expressed quantitatively (e.g., “not more than 12 percent”), use adequate analytical tests to accurately measure moisture content.
- (e) Keep a retention sample of each lot of dehydrated material.
- (1) Label the retention sample with the botanical identity, lot number, and any other relevant information.
  - (2) Store the sample in a manner to protect against insects, microbial growth, moisture, excessive heat, and other sources of degradation.
  - (3) Maintain the retention sample in storage for several years or as long as the records associated with the lot are retained.
- (f) Records.
- (1) Records should be kept of the drying performed, including the identity, lot number, and quantities of fresh and dried hemp; the location where drying occurs; the dates (and where applicable the times) when drying begins and ends; the person(s) involved; the equipment used; the temperature used, especially if a controlled temperature is specified; and other information

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<sup>128</sup> As mentioned previously, smoke may contaminate the material with hazardous PAHs, which are often an undesirable contaminant in botanical materials. Many governments have established limits for PAHs in food and other products.



as appropriate. The moisture content of the dried material should also be recorded if a quantitative moisture limit has been established.

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

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

## 7.6 Packing and storage

Proper packing and storage are important to protect and maintain the quality of the finished hemp or hemp-derived product. With respect to hemp food crops, packing and storage (“holding”) performed by a cultivation operation fall within the FDA definition of farm activities.

(a) Hemp intended to be packaged for short or long-term storage must be adequately dried prior to packaging.

(b) The following practices are relevant to packing and storage operations for hemp and hemp-derived products in bulk.

(c) Packing materials. Drums, boxes, bags, liners, etc. should be constructed of appropriate materials that pose no risk of introducing contamination to the hemp or hemp-derived product.

(1) Packing materials that directly contact hemp or a hemp-derived product intended for food use should be made of materials that are suitable for contact with foods and/or drugs.

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

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

(4) Where the hemp or hemp-derived product will eventually be distributed into the State of California, it may be appropriate to avoid the use of packing materials that contain bisphenol A (BPA), which is regulated under California Proposition 65.<sup>129</sup>

(d) Tamper evidence. Where appropriate, ensure packs are equipped with tamper-evident features. This is particularly important if the hemp is for food use.

(e) Suitability. Use only packing materials that are appropriate for its intended use.

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

(2) Dried hemp and hemp-derived products should be protected from excessive humidity. Use of packing materials that form an adequate moisture barrier may be necessary, especially if the

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<sup>129</sup> See California Office of Environmental Health Hazard Assessment (OEHHA) website <https://www.p65warnings.ca.gov/fact-sheets/bisphenol-bpa> for more information regarding bisphenol A and Proposition 65.



- finished material is hygroscopic (e.g., powdered extracts). Use of desiccants inside the containers may also be appropriate.
- (3) Some hemp and hemp-derived products (such as those intended to contain oil, resin or CBD) may require protection from light. Such materials should be packed in amber-colored or opaque containers.
- (4) Some hemp and hemp-derived products (such as those intended to contain oil, resin or CBD) may require protection from oxygen. Such materials should be packed with an appropriate oxygen barrier, such as glass or foil containers. Use of oxygen-absorbers inside the containers may also be appropriate.
- (f) Labeling. Labels must be clearly printed, permanently affixed, and conform to any applicable labeling regulations. Labels or labeling of bulk hemp or hemp-derived products should include the following information as applicable:
- (1) Botanical identity (including variety, cultivar, etc. as applicable);
  - (2) The part of the plant;
  - (3) The form of the material (e.g., whole, powder, extract, etc.);
  - (4) The grade or certification, where applicable (e.g., organic, biodynamic, Kosher, AHP, etc.);
  - (5) Other descriptive information, where applicable (e.g., steam-sterilized; content of CBD; etc.);
  - (6) The batch or lot number;
  - (7) The name and contact information of the cultivation operation, manufacturer/processor, packager, and/or distributor;
  - (8) The location of harvest;
  - (9) The date of harvest, manufacturing/processing, packaging, and/or expiration;
  - (10) The net quantity by weight, volume, or count;
  - (11) The seller's and/or buyer's item number, if any;
  - (12) The identity of substances added to the material, if any.
- (g) Storage. Store hemp and hemp-derived products in cool, dry areas away from direct sunlight and off the ground. Storage facilities should be dry, well ventilated, and have sufficient insulation or other temperature-control features to avoid extreme temperature fluctuations. Storage facilities should be appropriately designed and maintained to exclude insects and other pests from the facility. Ensure storage facilities are not inappropriately fumigated with chemicals that may contaminate the botanical material.
- (h) Separation from non-food storage. Segregate storage of hemp and hemp-derived products from storage of chemicals and other non-food items.



- (i) Control of odor absorption. Where necessary, segregate botanical materials that are high in essential oils so that other materials do not inadvertently absorb their odors. For example, peppermint leaf should not be stored in close proximity to hemp unless it is in well-sealed, airtight containers.
- (j) Records.
  - (1) Appropriate records should be kept of the packing performed, including the identity, batch or lot number, and quantity of hemp or hemp-derived product; the packing materials used, including any associated lot numbers; a sample of the label used; the location, date(s), and person(s) involved; any equipment used; and other information as appropriate.
  - (2) Records should be kept of general procedures for packing and any crop-specific packing procedures.
  - (3) Maintain these records for at least several years, or as required by regulation.

## 7.7 Storage and disposal of non-compliant hemp and hemp-derived products

Hemp operations should establish written procedures for the secure storage of any hemp or hemp-derived product that exceeds the acceptable hemp THC level allowed by law.

Hemp operations must establish written procedures for the disposal or destruction of such non-compliant hemp in accordance with the applicable federal, state, or tribal hemp plan. Such disposal or destruction should be documented in writing and witnessed by two employees.

## 7.8 Shipping

The quality of hemp and hemp-derived products must be maintained through the shipping process, which should be designed and carried out to minimize damage and degradation.

- (a) Hemp and hemp-derived products that are represented as conforming to various certifications (e.g., acceptable hemp THC level, 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.
- (b) Secondary shipping containers and pallets. Ensure that the secondary shipping containers into which hemp or hemp-derived products are placed are suitable for transporting food products, where applicable, and are designed to meet any special needs of the material. Ensure secondary containers and pallets are clean and dry and are not inappropriately fumigated with chemicals that may contaminate the botanical material.



- (c) Carriers. Ship hemp and hemp-derived products via carriers that are suitable for transportation of food products, if applicable. Special emphasis should be placed on temperature control and ventilation where necessary, such as for shipments of fresh materials. Ensure hemp and hemp-derived products intended for food use (including both conventional foods and dietary supplements) are not shipped in the same conveyance with hazardous materials or poisons. Ensure conveyances are clean and free of insects and other pests. Ensure conveyances are not inappropriately fumigated with chemicals that may contaminate the botanical material.
- (d) Classification. Specify on bills of lading the accurate freight classifications or, for international shipments, the appropriate Harmonized Tariff System code. Ensure hemp and hemp-derived products intended for food use (including both conventional foods and dietary supplements) are designated as “food.”
- (e) Regulations. Ensure hemp and hemp-derived products used for food that originate in, or will be distributed within, the U.S. are shipped in accordance with 21 CFR Part 1 Subpart O, Sanitary Transportation of Human and Animal Food.<sup>130</sup>
- (f) Records.
  - (1) Appropriate records should be kept of the shipping performed, including the identity, batch or lot number, acceptable hemp THC level, and quantity of hemp or hemp-derived product shipped; the carrier used; the date; tracking number if used; the destination company and address; and other information as appropriate.
  - (2) Records should be kept of general shipping procedures and any crop-specific shipping procedures.
  - (3) Maintain these records for at least several years, or as required by regulation.

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<sup>130</sup> These regulations can be found at <https://www.accessdata.fda.gov/scripts/cdrh/Cfdocs/cfCFR/CFRSearch.cfm?CFRPart=1&showFR=1&subpartNode=21:1.0.1.1.1.14>.





## 8. Buildings, equipment, and personnel for cultivation, harvest, and post-harvest handling

Cultivation and post-harvest operations that do not require food facility registration and compliance with food manufacturing/processing GMPs should meet the following minimum standards.

### 8.1 Buildings

- (a) Buildings must be fully permitted and constructed in compliance with local building codes. Buildings should be of suitable design and sound construction, and should be maintained in good repair.
- (b) Location. Buildings should preferably be located in areas that are not subject to flooding and that are away from objectionable odors, smoke, dust, pests, or other contaminants.
- (c) Light. Buildings should provide sufficient space and light to accomplish the activities performed in the building.
- (d) Pest control. Design, manage, and monitor buildings to keep out pests, including insects, rodents, and other animals. Maintain records of pest control, including any chemical pest control measures used, for at least several years. Where the harvested crop is intended for food use, ensure all pest control chemicals used inside the buildings or in proximity to the harvested materials are permitted for use around food, and use them strictly in accordance with the label instructions.<sup>131</sup>
- (e) Order and cleanliness. Design and maintain buildings with sufficient order and cleanliness to prevent contamination of crops handled in these locations, including cross-contact with allergens where applicable. Consider segregating the storage of organic from non-organic materials. Maintain records of building cleaning for at least several years.
- (f) Grounds. Minimize the presence of trash, landscape plants, pooling water, and other harborage for pests around the exterior of buildings.
- (g) Waste. Provide adequate storage for waste, recycling, and unusable materials prior to removal from the premises. Ensure waste is stored and removed properly to avoid attracting animals, releasing mold spores, or otherwise creating contamination.
- (h) Non-compliant hemp storage. A secure controlled access area must be provided for storage of hemp or hemp-derived product that exceeds the acceptable hemp THC level, pending appropriate destruction or disposal in accordance with the applicable federal, state, or tribal hemp plan.

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<sup>131</sup> Any pest control chemicals applied directly to the harvested crop must comply with the pesticide requirements discussed in “Cultivation” Section 5.7(g).



## 8.2 Equipment

- (a) Equipment should be suitable for its purpose and properly functioning. This includes mechanical equipment, wagons, buckets and other containers, tarps, hand tools, brooms and brushes, etc.
- (b) Design and installation. Design and install equipment in a manner that permits easy access for cleaning and maintenance.
- (c) Construction. Use only equipment made of non-toxic and non-corrosive materials, especially for those parts that come in contact with the hemp. Avoid equipment having parts that contact the hemp that are difficult to easily and thoroughly clean, such as parts made of absorbent materials or parts that are not physically accessible. If absorbent materials are used (e.g., wood), ensure such use does not present a risk of unacceptable contamination. Avoid use of glass, brittle plastic, and other such materials that may introduce physical contaminants.
- (d) Maintenance. Examine all equipment and maintain in proper working order; repair as necessary. Maintain records of equipment maintenance for at least several years.
- (e) Measuring equipment. Equipment used for measuring, regulating, or recording temperatures, pH, humidity, or other conditions related to the cultivation and post-harvest handling of hemp should be accurate and adequately maintained, and should be calibrated on an appropriate schedule. Scales used for the weighing of hemp should be calibrated at regular intervals. Maintain records of equipment calibrations for at least several years.
- (f) Cleanliness. Maintain all equipment in clean condition. Pay particular attention to ensuring that those parts of equipment that come in direct contact with hemp are clean and free of potential contaminants (e.g., chipping paint, lubricants, insects or other pests, etc.). Cultivation and processing tools that come in direct contact with hemp plants should be cleaned and disinfected as needed to protect plant health. Store clean equipment away from sources of contamination, and keep equipment properly labeled as to cleaning status (clean vs. dirty). Maintain records of equipment cleaning for at least several years.
- (g) Absence of cross-contamination. Remove remnants of any prior botanical material from equipment to prevent cross-contamination. Where cross-contact with allergens is possible (e.g., where equipment has been used with a gluten-containing grain), ensure the equipment is thoroughly cleaned prior to use for the hemp; or consider use of dedicated equipment for the allergen-containing crop.
- (h) Storage containers. Do not use hemp containers to hold or contain non-plant materials, such as tools or chemicals. Where cross-contact with allergens is possible, consider using separate containers that are dedicated to the allergen-containing crop. Ensure containers provide adequate protection for the hemp during storage, and are labeled appropriately as to the contents (e.g., with identity of the hemp; lot number; grade such as organic, especially when needed to distinguish between similar crops on the same farm; presence of any allergens; etc.).
- (i) Toilets. Provide appropriate toilet facilities in buildings and provide portable toilets at field locations. Ensure toilet facilities comply in number, location, installation, and function (including effluence,



drainage, and sewage functions) with applicable local, state, and federal regulations. Ensure toilets are stocked with toilet paper and single-use paper towels and are maintained in clean and functioning condition.

- (j) Hand wash facilities. Provide hand washing facilities with soap and running water (preferably hot water) in buildings and at field locations.
- (k) Safety equipment. Provide personal protective equipment or other safety equipment as appropriate.
- (l) First aid kit. Have a first aid kit available to workers, including bandages, hydrogen peroxide, antibiotic ointment, gloves, and other wound protecting material.
- (m) Transport equipment. Provide suitable conveyances to transport tools and other equipment, supplies, personnel, and hemp.
- (n) Training. Ensure that all personnel are properly trained in the use of the equipment, especially mechanized equipment, and that equipment is operated in a manner that ensures the safety of the operators and avoids or minimizes damage to the hemp.

## 8.3 Records

- (a) In addition to specific records mentioned elsewhere in this document, accurate records should be prepared for each stage of site selection, planting, cultivation, harvest, and post-harvest handling as applicable.
- (b) All records with relevance to a particular cycle of hemp cultivation and/or harvest should preferably be retained past the time when the hemp is no longer in the marketplace, which may be several years or more.<sup>132</sup>

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<sup>132</sup> Even when the hemp is sold in fresh form (i.e., a perishable form that might be expected to leave the marketplace quickly), downstream companies may process (e.g., by drying or extracting) the hemp into a shelf stable form that remains in the marketplace for years.



## 9. Further processing

After post-harvest handling, including drying, the hemp may be packed and held for distribution, or it may first be subject to additional processing such as size reduction and extraction. As with other activities, these steps should be optimized appropriately in order to prevent degradation or contamination.

With respect to hemp food crops, FDA classifies these activities as manufacturing/processing that is subject to food GMPs. Therefore, any cultivation operation that performs these activities on a hemp food crop is a “farm mixed-type facility” under FDA regulations, and is generally (subject to certain exemptions) required to register with FDA as a food manufacturing/processing facility and to comply with food GMPs if the material will be distributed in the US. This applies even if the farm is located outside the US.

If these activities are conducted by a hemp operation other than a cultivation operation, the operation is a food manufacturing/processing facility and is subject to food GMPs.

### 9.1 Size reduction

- (a) Size reduction (comminution) includes cutting, chopping, slicing, milling, and other activities which reduce the material to a smaller size.
- (b) Cutting or chopping of hemp can occur either before or after drying, 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.
- (c) Timing. Where possible, size reduction operations are preferably performed as close to the time of manufacture of finished products as possible, in order to reduce quality degradation that may be associated with storage of cut or powdered forms.
- (d) Advance cleaning and preparation. Before size reduction, perform any necessary cleaning and screening steps. These may include, for example, use of a de-stoner, a gravity separator, or a metal detector. The material should also be inspected as appropriate to remove foreign or otherwise unacceptable material, such as foreign plant parts, foreign species, foreign objects, moldy pieces, etc.
- (e) Protection of operators. Provide adequate ventilation in the size reduction facility to protect operators’ health. Also provide any needed protective gear, such as dust masks or respirators, eye protection, and ear plugs.
- (f) Dust control. Ensure milling facilities are equipped with suitable dust control equipment to minimize the chance of explosion (airborne botanical dust is highly combustible) and to minimize the spread of cross-contamination and allergens. Milling should be performed in a separate room or building from other process steps.
- (g) Temperature control. Do not allow the temperature in milling equipment to rise above the temperature at which damage to the quality of the hemp may occur.



- (h) Size requirements. Ensure that the material after size reduction meets all established specifications with regard to particle size, length, and/or density requirements.
- (i) Metal detection. After size reduction, it may be prudent to pass the material through a magnet bank or metal detector to ensure that any metal fragments from the equipment or screens are removed.<sup>133</sup>
- (j) Records.
  - (1) Records should be kept of the size reduction performed, including the identity, batch or lot number, and quantities of botanical material and of cut or milled product; the identity, lot number, and quantity of any processing aids or excipients used; the location, date, and person(s) involved; the equipment used; the size after processing; and other information as appropriate.
  - (2) Records should be kept of general size reduction procedures and any crop-specific size reduction procedures.
  - (3) Maintain these records for at least several years, or as required by regulation.
- (k) Keep a retention sample of each batch or lot of material after size reduction.<sup>134</sup>
  - (1) Label the retention sample with the botanical identity, batch or lot number, and any other relevant information.
  - (2) Store the sample in a manner to protect against insects, microbial growth, moisture, excessive heat, and other sources of degradation. If the sample consists of fresh plant material, store the samples in a frozen or dried state.
  - (3) Maintain the retention sample in storage for several years, or as long as the records associated with the batch or lot are retained, or as required by regulation.

## 9.2 Extraction

- (a) Hemp may be extracted using various solvents and various extraction technologies.<sup>135</sup>
- (b) The extraction process and conditions should be chosen based on the desired characteristics of the final ingredient or finished product (e.g., flavor, content of marker substances, etc.).

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<sup>133</sup> If additional processing will be performed, it may be appropriate to delay the final metal detection step until after all other processing is complete.

<sup>134</sup> If the size reduction is a preliminary step for further processing such as extraction, it may be preferable to take the retention sample at a later point in the process.

<sup>135</sup> Refer to AHPA's "Guidance Documents for the Manufacture and Sale of Botanical Extracts," including "Use of Marker Compounds in Manufacturing and Labeling Botanically Derived Dietary Supplements," and "White paper: Standardization of botanical products" for more extensive discussions.



- (c) Preparatory steps. Prior to extraction, perform any necessary cleaning and screening and if necessary, cut, chop, or mill the cleaned material to a defined particle size. Perform other preparatory steps as appropriate.
- (d) Extraction. Extract the prepared material using a specified extraction technology (e.g., maceration, percolation, steam distillation, etc.) and a defined solvent or mixture of solvents (e.g., water, aqueous ethanol, supercritical carbon dioxide, etc.). Extraction conditions should be defined to the extent necessary for the applicable technology; these may include temperature, pressure, agitation, extraction time, ratio of solvent to crude botanical material, number of repeated extractions of the same crude material, etc.
- (e) Post-extraction processing for liquid extracts. After extraction, separate the liquid extract from the spent hemp through decanting, filtering, pressing, or centrifuging, then concentrate the liquid to remove the solvent as appropriate. Perform any additional processing appropriate for the extract, such as:
  - (1) Decarboxylation.
  - (2) Concentration of desirable constituents.
  - (3) Removal of undesirable constituents.
  - (4) Pasteurization.
  - (5) Addition of excipients.
  - (6) Drying to a solid.
  - (7) Milling to a powder.
  - (8) Metal detection.
- (f) Protection of operators. Provide adequate ventilation in the extraction facility to protect operators' health and prevent the buildup of combustible or explosive vapors. Also provide any needed personal protective equipment, and provide hazardous material training for any solvents or other chemicals used.
- (g) Records.
  - (1) Appropriate records should be kept of the extraction performed, including the identity, lot number, and quantity of hemp extracted; the identity, lot number, and quantity of any processing aids or excipients used; the identity, batch or lot number, and quantity of final extract; the location, dates, and person(s) involved; the equipment used; the equipment settings used and actual readings obtained; and other information as appropriate.
  - (2) Records should be kept of general procedures for each manufacturing process and any crop-specific manufacturing procedures.
  - (3) Maintain these records for at least several years, or as required by regulation.
- (h) Keep a retention sample of each batch or lot of material after extraction.



- (1) Label the retention sample with the botanical identity, batch or lot number, and any other relevant information.
- (2) Store the sample in a manner to protect against insects, microbial growth, moisture, excessive heat, and other sources of degradation. If the sample consists of liquid extract that is not shelf stable, store the samples in a frozen state.
- (3) Maintain the retention sample in storage for several years, or as long as the records associated with the batch or lot are retained, or as required by regulation.

## 9.3 Packaging

Proper packaging is important to protect and maintain the quality of the finished hemp or hemp-derived product. Recommendations for packaging hemp are generally the same as those provided in Section 7 Post-Harvest Handling for the packing of hemp.

- (a) If the hemp or hemp-derived product is packaged in retail form, keep a retention sample of each packaged batch or lot.
- (b) Label the retention sample with the product name, batch or lot number, and any other relevant information.
- (c) Store the sample in a manner to protect against insects, microbial growth, moisture, excessive heat, and other sources of degradation. If the product is not shelf stable, store the sample in a frozen state.
- (d) Maintain the retention sample in storage for several years, or as long as the records associated with the batch or lot are retained, or as required by regulation.

## 10. Food facility and farm mixed-type facility requirements

Hemp operations that perform size reduction, extraction, compounding, heating, or other manufacturing/packaging activities on foods, or which pack or hold hemp foods that are processed foods, are subject to registration with FDA as a food facility and are subject to food GMP regulations.

Cultivation operations must register with FDA as a food facility (a “farm mixed-type facility”) and comply with food GMPs if they perform manufacturing/processing that falls outside the farm definition (unless the operation qualifies for an exemption).

The following recommendations and regulations apply to these hemp operations.

### 10.1 Storage and disposal of non-compliant hemp and hemp-derived products

Food and farm-mixed type facilities must provide a secure controlled access area for storage of hemp or hemp-derived product that exceeds the legal limit of  $\Delta^9$ -THC, pending appropriate destruction or disposal in accordance with the applicable federal, state, or tribal hemp plan.

Food and farm-mixed type facilities must establish written procedures for the secure storage of any hemp or hemp-derived product whose  $\Delta^9$ -THC content exceeds the level allowed by law.

Food and farm-mixed type facilities must establish written procedures for the disposal or destruction of such non-compliant hemp in accordance with the applicable federal, state, or tribal hemp plan. Such disposal or destruction should be documented in writing and witnessed by two employees.

### 10.2 Human foods

The regulations in 21 CFR Part 117 Subpart B apply to all human food manufacturing/processing, packing, and holding facilities (including dietary supplement facilities). In addition, 21 CFR Part 117 Subpart C applies to most human food manufacturing/processing facilities subject to certain exemptions. All hemp operations that manufacture/process, pack, or hold hemp or hemp-derived products that will be used as or in human food, must comply with these GMP regulations.

More information about general requirements for food manufacturing/processing, packing, and holding facilities, and various exemptions from food GMPs, are available in AHPA’s GACP-GMP and in the applicable parts of the CFR.

### 10.3 Dietary supplements

Facilities that manufacture, package, label, or hold dietary supplements are subject to the regulations in 21 CFR Part 111 and 21 CFR Part 117 Subpart B.

If a hemp operation sells hemp or a hemp-derived product to a customer that simply packages and markets the item as a dietary supplement, without any other manufacturing/processing steps





performed by the customer, then the hemp operation is considered a dietary supplement manufacturer and therefore is subject to 21 CFR Part 111.

## **10.4 Dietary ingredients**

Facilities that manufacture/process, pack, or hold dietary ingredients are technically subject only to the requirements of 21 CFR Part 117. However, in order to ensure their own compliance with the requirements of 21 CFR Part 111, dietary supplement manufacturers often expect their ingredient suppliers to go above and beyond the basic requirements set forth in 21 CFR Part 117, particularly with respect to component and ingredient controls, process controls, recordkeeping, and general quality systems management. Therefore, AHPA has established additional recommended practices for dietary ingredient manufacturers which are set forth in the AHPA GACP-GMP, which are hereby incorporated by reference.

## Appendix 1: Sources of specifications and test methods

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

### **Compendia**

#### **American Herbal Pharmacopoeia**

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

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

#### **British Herbal Compendium**

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

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

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

#### **British Herbal Pharmacopoeia (1996)**

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

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

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



### **European Pharmacopoeia**

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

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

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

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

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

### **Food Chemicals Codex**

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

More information about the FCC is available at <https://www.foodchemicalscodex.org/>.

### **Official Methods of Analysis of AOAC International**

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

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

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

Compiled by the Pharmacopoeia Commission of the Ministry of Public Health, the Chinese Pharmacopoeia (CP) covers 784 medicinal herbs, plant oils, and Chinese formulated medicines and 967 western medicines and preparations. The 2015 edition of CP was adopted at the plenary session of the Executive Committee of the Tenth Chinese Pharmacopoeia Commission. On June 5, 2015, China Food



and Drug Administration (CFDA) promulgated the 2015 edition of Chinese Pharmacopoeia, which went into effect on December 1, 2015.

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

### **Books**

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

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

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

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

### **Online resources**

#### **AHPA's Botanical ID References Compendium**

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

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

<https://www.ahpa.org/AHPAResources/BotanicalIDReferencesCompendium.aspx>



## Appendix 2: Other good agricultural practice guidelines

Other documents that have been valuable in the process of preparing and reviewing this work or that have relevance to agricultural practices for hemp are referenced here.

### Health Canada

#### Industrial Hemp Technical Manual

[https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/hc-ps/alt\\_formats/hecs-sesc/pdf/pubs/precurs/hemp-indus-chanvre/tech-man/hemp-tech-manual-eng.pdf](https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/hc-ps/alt_formats/hecs-sesc/pdf/pubs/precurs/hemp-indus-chanvre/tech-man/hemp-tech-manual-eng.pdf)

### U.S. Hemp Authority®

#### Certification Program 3.0

<https://ushempauthority.org/assets/uploads/USHA-Standard-v3.0-final.pdf>

### European Herb Growers Association (EUROPAM)

*Guidelines for Good Agricultural and Wild Collection Practices for Medicinal and Aromatic Plants (GACP-MAP), No. 7.3 (2019)*

<https://www.europam.net/documents/>

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

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

[https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-agricultural-collection-practice-gacp-starting-materials-herbal-origin\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-agricultural-collection-practice-gacp-starting-materials-herbal-origin_en.pdf).

### Global G.A.P.

*General Regulations – Part 1, General Rules (2012)*

[https://www.globalgap.org/.content/.galleries/documents/190201\\_GG\\_GR\\_Part-I\\_V5\\_2\\_en.pdf](https://www.globalgap.org/.content/.galleries/documents/190201_GG_GR_Part-I_V5_2_en.pdf)

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

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

[https://thie-online.eu/files/thie/docs/2018-09\\_PU\\_GAHP\\_Version\\_9.pdf](https://thie-online.eu/files/thie/docs/2018-09_PU_GAHP_Version_9.pdf).

### World Health Organization

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

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

