Publication Date: May 27th, 2022

U.S. Hemp Authority® Releases Certification Program Standard Version 4.0 Draft; Request for Public Comment by June 15th, 2022

The U.S. Hemp Authority® has released a draft Version 4.0 of the standard for its Certification Program for public comment to better serve the evolving hemp and CBD industries. The U.S. Hemp Authority Program® Standard v4.0 include clarifications on glossary terms, intoxicating cannabinoid products and manufacturing requirements.

Version 4.0 does not represent a substantial change from the previous version 3.0 which has been operating effectively over the past year. However, there are some key changes that deserve public attention and input:

- Most prominently, the definitions provided in the Standard's glossary were completely overhauled to reflect the greater understanding of the science and policy behind the hemp plant and hemp products. Of note, other organizations and state regulators have been looking to U.S. Hemp Authority's definitions for their guidance, so public attention is critical to ensure that they are sound and accurate.
- With the rise of intoxicating products being marketed as hemp, such as Delta-8 THC, sections outlining the prohibitions on intoxicating compounds being certified by U.S. Hemp Authority were strengthened in 4.0.
- Given that many different certification bodies may in the short and long term be involved with the program, we deleted mention of any particular firm or company,
- The category that was originally labeled "Manufacturer/Processor" has been renamed "Manufacturer" to provide more clarity and precision.

The U.S. Hemp Authority® Standard, through its Certification Program and seal aims to assure all interested parties with production practices meet legal requirements for quality of hemp and hemp-derived ingredients and products, that ingredients and products are handled to maintain product integrity, and are labeled to represent their contents truthfully and clearly. Certified operators are held accountable for demonstrating compliance with all applicable requirements of the Standard, including providing for adequate worker training and safety, and documentation of practices to verify product quality, authenticity, and traceability.

Over the past few years, thousands of industry experts have answered the U.S. Hemp Authority's calls to help develop industry standards in what they have termed Guidance Plan 1.0, Guidance 2.0, Standard 3.0, and the latest, Standard 4.0 – previous iterations demonstrate the industry's professionalism and promote confidence among consumers that hemp products can be trusted, and among government officials that hemp products meet clear standards.

Once again, the U.S. Hemp Authority® is calling on the hemp industry – farmers, manufacturers, brand owners, retailers and consumers – to weigh in on how they can make the Standard even stronger, and how they can make the U.S. Hemp Authority® Certification Seal an even prouder symbol of confidence, trust, truth in labeling, and transparency of process.

The draft version of the U.S. Hemp Authority® Certification Program Standard v4.0 is available below for review and public comment through June 15th, 2022. All comments can be submitted via email to info@ushempauthority.org.

U.S. HEMP AUTHORITY®
CERTIFICATION PROGRAM

PROGRAM STANDARD 4.0

GROWERS
MANUFACTURERS
BRAND OWNERS

Disclaimer: *The U.S. Hemp Authority® is a tax-exempt organization, legally independent of other hemp organizations and companies and is not a governmental body or regulatory agency.*

1 INTRODUCTION & OBJECTIVES

1.1 BACKGROUND

Cannabis spp. (hemp) has been valued by cultures around the world for its many and varied uses since time immemorial, including as a part of farming systems, food, medicine, fiber, and for other purposes. In recent years a resurgence of public awareness of the value of and consumer interest in hemp and hemp-derived products has led to increased demand in the marketplace, along with increased field production and product development in countries where its cultivation has been legalized. With the passage of the United States Agricultural Improvement Act of 2018, hemp became legal again for cultivation in the United States, adding to an already widespread resurgence in production and consumption of hemp-based products.

The early stages of this resurgence of hemp have raised exciting opportunities for producers and consumers. A myriad of products has been released into the marketplace, teeming with innovations stemming from the nature and potential of the plant itself and entrepreneurial ingenuity. As an agricultural crop, hemp affords the grower a valuable addition to crop rotation and soil stewardship, and the potential for a new income stream. Even so, significant challenges have arisen along with these opportunities: market volatility in these early stages of rapid sector evolution mean instability in sales contracts and supply chains, and potential economic risks; product claims are many, varied, and sometimes unsubstantiated; product quality is variable; and state laws and governmental regulations are inconsistent across jurisdictions and still in a rapid state of flux.

The U.S. Hemp Authority was launched in 2019 as an initiative to serve this burgeoning sector. As a multi-stakeholder platform, it coalesces a balance of interests into a Standard and Certification Program aimed at demonstrating the willingness and ability of the private sector to be self-regulating and an effective and reliable voice in a public-private partnership with regulatory agencies. This unified approach by the sector affords an assurance to consumers and regulators that products certified under the U.S. Hemp Authority are consistently trustworthy. Furthermore, the ongoing evolution of this Standard serves as a convening for interested parties to develop best practices, leadership, and continuously improve production practices and inform the most practical ways forward for the whole sector.

1.2 PROGRAM SCOPE & OBJECTIVES

The U.S. Hemp Authority Certification Standard encompasses the entire production chain from seed to finished product. Certification is awarded to three categories of operations: Growers, Manufacturers, and Brand Owners. Compliance with applicable sections of the Standard is required for each of these stages of the supply chain. U.S. Hemp Authority certification can be attained for hemp and hemp products such as raw and dried biomass for direct sale or further processing[1], and the constituents and extracts found in hemp, for food, dietary supplements, personal care products, pet supplements[2] and products based on hemp fiber. The U.S. Hemp

[1] U.S. Hemp Authority does not yet certify smokable or vaping products due to current regulatory uncertainty/inconsistency, and/or product safety concerns expressed by FDA.

[2] U.S. Hemp Authority does not certify animal feed, single source nutrition products, or other pet products carrying a nutrition facts panel.

Authority will not however certify products that are promoted/marketed to encourage consumers to use them for their intoxicating benefits or THC content.

Hemp Growers, Manufacturers, and Brand Owners operate in a broader market context, and are thereby subject to regulations and practice expectations that are common to all kinds of operations within their respective category of activities. It is therefore not the intention of the U.S. Hemp Authority Standard to explicitly repeat in detail all such common requirements, but rather contains provisions to assure that operators have systems in place to adhere to relevant industry norms. For example, any manufacturer of dietary supplements in the United States is required per 21 CFR 111 to follow current Good Manufacturing Practices (cGMPs); similarly, food manufacturers are expected to follow food safety guidelines as delineated in 21 CFR 117.

With the expectation that operators must employ these baseline or minimum practices simply in order to be in business anyway, this Standard focuses on the specific characteristics and attributes of hemp with respect to production practices, legal compliance, product quality, and labeling. While the importance of these baseline good and necessary production practices cannot be forsaken, it is the hemp-specific features that are not covered by other assurance schemes that provide the most salient added value of the U.S. Hemp Authority Certification Program.

This Standard is organized such that terms and requirements applicable to all operations seeking certification appear first, namely a Glossary and a statement of prohibited practices and inputs. Following these are sections specific to certification of each successive supply chain link category, ie requirements for Growers, Manufacturers, and Brand Owners. The U.S. Hemp Authority Standard, through its Certification Program aims to assure all interested parties that production practices meet legal requirements for quality of hemp and hemp-derived ingredients and products, that ingredients and products are handled to maintain product integrity, and are labeled to represent their contents truthfully and clearly. Certified operators are held accountable for demonstrating compliance with all applicable requirements of the Standard, including providing for adequate worker training and safety, and documentation of practices to verify product quality, authenticity, and traceability.

The Standard is crafted such that requirements are directly verifiable via physical inspection and/or document audit. Certain clauses also are followed by Guidance notes; these are explicitly noted as such and serve as recommendations but are not absolute requirements.

2 GLOSSARY

2.1 GLOSSARY

The following definitions and interpretations apply to these terms when used in this standard:

Acceptance Criteria means predetermined limits (e.g., number, numerical ranges, or other suitable measures) for acceptance of examination or test results

Adequate means an item/area/system/knowledge that meets basic minimum requirements that are needed to accomplish intended purpose.

Adulteration means any hemp product that contains any poisonous or deleterious substance; or if it consists of any filthy, putrid, or decomposed substance; or if it is otherwise unfit for use; or if it has been prepared, packed or held under insanitary conditions; or if its container is composed of any poisonous or deleterious substance which may render the contents injurious to health; or if it has been intentionally subjected to radiation; or if the contents have been altered; or if damage or inferiority has been concealed; or if it contains a color additive which is unsafe; or if it contains an ingredient that presents a significant or unreasonable risk of illness or injury; or if it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations; or if it has not been transported in compliance with regulations.

Adverse event means any undesirable experience associated with the use of a hemp product in a person.

Allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug and Cosmetic Act (FFDCA), means any of the following: (1) milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans; (2) a food ingredient that contains protein derived from a food specified in (1), except (A) any highly refined oil derived from a food specified in (1) and any ingredient derived from such highly refined oil, and (B) a food ingredient that is exempt under paragraph (6) and (7) of section 403(w) of the FFDCA.

Artificial cannabinoid: Any cannabimimetic compound whose molecular structure is not found in nature.[3]

Audit means a planned, systematic, objective, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited firm, and, as appropriate, sampling and laboratory analysis) to assess whether agreed upon requirements are being met.

Batch means a specific quantity of material that is intended to be uniform, that is intended to meet specifications for identity, purity, strength, and composition, and that is produced during a specified time period according to a single manufacturing record during the same cycle of manufacture.

Batch Number, or Lot Number means any distinctive group of letters, or numbers, or symbols, or any combination of them, from which the complete history of the manufacturing, packaging, labeling, and/or holding of a batch or lot of hemp product can be determined.

Bioengineered Substance, as defined in 7 CFR Part 66, means a substance that contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.

[3] Note that under current US laws and regulations, all artificial cannabinoids are illegal drugs.

Brand Owner means a manufacturer or a retailer with private label products.

Broad Spectrum Hemp Extract means an extract derived from hemp that is comprised of naturally-occurring cannabinoids in which intoxicating tetrahydrocannabinols have been removed to non-detectable levels using a compliant laboratory and fit-for-purpose methods with a limit of quantification of less than 0.01%. In addition, broad spectrum extract must not be formulated with the addition of one or more isolated cannabinoids. If isolated cannabinoids are added, see "fortified broad spectrum hemp extract."

Broad Spectrum Hemp Finished Product means a hemp retail product labeled to indicate that it contains an extract derived from hemp that is comprised of multiple cannabinoids in which intoxicating tetrahydrocannabinols have been removed to non-detectable levels using a compliant laboratory and fit-for-purpose methods with a limit of quantification of less than 0.01%. In addition, broad spectrum finished products must not be formulated with the addition of multiple isolated cannabinoids. If isolated cannabinoids are added, see "fortified broad spectrum hemp finished product."

Calibration means the demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a reference or traceable standard over an appropriate range of measurements.

Can is used to indicate a possibility or a capability.

Cannabimimetic Compound means any substance that is not structurally a cannabinoid, but which can elicit a biological response similar to those produced by structural cannabinoids by acting directly or indirectly on endocannabinoid system. *See also* AHPA's Hemp Lexicon for the following terms which are considered to be cannabimimetic compounds: “Artificial Cannabinoid,” “Nature-identical Cannabinoid,” and “Synthesized Cannabinoid.”

Cannabinoids means a diverse class of C_{21} or C_{22} terpenophenolic compounds found in *Cannabis* spp., their carboxylic acids, analogs, and transformation products. The term is also used in the scientific literature to represent structurally unrelated cannabimimetic compounds. For the purposes of consumer product labeling, the term "cannabinoid" and variations such as "phytocannabinoid" is limited to the structural cannabinoids produced by *Cannabis* spp. and their carboxylic acids, analogs, and transformation products.

***Cannabis* spp.** means any species of the plant genus *Cannabis*, including *Cannabis sativa*, *Cannabis indica*, hemp, etc.

Certification Body means the organization assigned by the U.S. Hemp Authority to inspect, audit, and otherwise evaluate an operation’s compliance with this Standard.

Composition means the aggregate mixture of constituents in an ingredient, or the aggregate mixture of ingredients in a hemp product.

Component means any ingredient used in the manufacture of a hemp product including those that may not appear in the finished batch of the hemp product.

Confidence Level means the probability that the value of a parameter falls within a specified range of values.

Contamination means the undesired introduction of a chemical or microbiological nature, or of foreign matter, into or onto a component, in-process material, or hemp product during production, sampling, packaging, repackaging, storage or transport.

Contract Manufacturer means a manufacturer performing some aspect of manufacturing on behalf of the brand owner.

Corrective Action means an action that is developed and implemented to ensure that any identified root cause of a nonconformity does not recur.

Critical describes a manufacturing process step, process condition, test requirement, or other relevant parameter or item that must be controlled within predetermined criteria to ensure the hemp product meets its specification.

Decarboxylation means a process of treating a hemp material or product to remove carboxyl groups from the cannabinoids native in the plant, to form transformation products such as THC and CBD. Decarboxylation is commonly accomplished by application of heat. Decarboxylation is a not considered to be a synthetic process.

Delta-9 Tetrahydrocannabinol (D9THC) means the cannabinoid having the formula $C_{21}H_{30}O_2$. It is a chemical found in Cannabis responsible for intoxicating effects.

Delta-9 Tetrahydrocannabinolic Acid (D9THCA) means the cannabinoid having the formula $C_{22}H_{30}O_4$; it is the precursor (acidified form) to delta-9 tetrahydrocannabinol.

Deviation means any departure from written procedures (e.g., standard operating procedures (SOPs), protocols, test methods, etc.).

Dietary Ingredient is an ingredient intended for use or used in a dietary supplement that is: a vitamin; a mineral; an herb or other botanical; an 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 a combination of the aforementioned ingredients.

Dietary Supplement is a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total daily intake; or a concentrate, metabolite, constituent, extract or combination of the aforementioned ingredients; that is intended for ingestion in a tablet, capsule, powder, softgel, gelcap, or liquid form; that 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; and does include

an article approved as a new drug, certified antibiotic, or licensed biologic, and was prior to such approval, certification, or license, marketed as a dietary supplement or food unless the Secretary of Health and Human Services has issued a regulation finding that the article , when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement is unlawful.

Disposition Decision means a decision to approve or reject material based on a scientifically valid reason. Disposition decisions can be made regarding release of components, in-process materials, hemp products, packaging materials, labels, returned hemp products, based on a determination of whether or not established specifications are met and whether or not a deviation or unanticipated occurrence during the production and in-process control system could lead to adulteration of a hemp product.

Equipment means a device used to manufacture, package or hold hemp products, or to maintain or clean the physical plant and devices.

Facility means a place, amenity, utility, or piece of equipment provided for a particular purpose, such as manufacturing, packaging, labeling, or holding of hemp ingredients or hemp consumer products.

Finished Product means a retail product or a product labeled for retail use.

Fortified Broad Spectrum Hemp Extract means an extract derived from hemp that is comprised of naturally-occurring cannabinoids in which intoxicating tetrahydrocannabinols have been removed to non-detectable levels using a compliant laboratory and fit-for-purpose methods with a limit of quantification of less than 0.01%. In addition, fortified broad spectrum extract may be formulated with the addition of one or more isolated cannabinoids, a distillate, resin, or other such hemp ingredients. If isolated cannabinoids, a distillate, resin, or other such hemp ingredients are added, the quantitative amount of the isolated cannabinoids, distillate, resin, or other such hemp ingredients must be listed on the ingredient label. Note: the extract does not need to be labeled as a “fortified broad spectrum hemp extract.”

Fortified Broad Spectrum Hemp Finished Product means a hemp retail product labeled to indicate that it contains an extract derived from hemp that is comprised of multiple cannabinoids in which intoxicating tetrahydrocannabinols have been removed to non-detectable levels using a compliant laboratory and fit-for-purpose methods with a limit of quantification of less than 0.01%. In addition, broad spectrum finished products may be formulated with the addition of multiple isolated cannabinoids, distillate, resin, or other such hemp ingredients. If isolated cannabinoids, a distillate, resin, or other such hemp ingredients are added, the quantitative amount of the isolated cannabinoids, distillate, resin, or other such hemp ingredients must be listed on the product label. Note: the finished product does not need to be labeled as a “fortified broad spectrum hemp finished product.”

Fortified Full Spectrum Hemp Extract means an extract derived from hemp that is comprised of naturally-occurring cannabinoids and other compounds with a total intoxicating tetrahydrocannabinols quantitative amount of not greater than 0.3% using a compliant laboratory and fit-for-purpose method. In addition, fortified full spectrum extract may be formulated with the addition of one or more isolated cannabinoids, distillate, resin, or other such hemp ingredients. If isolated cannabinoids, distillate, resin, or other such hemp ingredients are

added, the quantitative amount of the isolated cannabinoids, distillate, resin, or other such hemp ingredients must be listed on the ingredient label. Note: the finished product does not need to be labeled as a "fortified full spectrum hemp extract."

Fortified Full Spectrum Hemp Finished Product means a hemp retail product labeled to indicate that it contains an extract derived from hemp that is comprised of naturally-occurring cannabinoids and other compounds with a total intoxicating tetrahydrocannabinols quantitative amount of not greater than 0.3% using a compliant laboratory and fit-for-purpose method. In addition, a fortified full spectrum finished product may be formulated with the addition of one or more isolated cannabinoids, distillate, resin, or other such hemp ingredients. If isolated cannabinoids, distillate, resin, or other such hemp ingredients are added, the quantitative amount of the isolated cannabinoids, distillate, resin, or other such hemp ingredients needs to be listed on the product label. Note: the finished product does not need to be labeled as a "fortified full spectrum hemp finished product."

Full Spectrum Hemp Extract means an extract derived from hemp that is comprised of naturally-occurring cannabinoids and other compounds with a total intoxicating tetrahydrocannabinols quantitative amount of not greater than 0.3% using a compliant laboratory and fit-for-purpose method. In addition, full spectrum extract must not be formulated with the addition of one or more isolated cannabinoids. If isolated cannabinoids are added, see "fortified full spectrum hemp extract."

Full Spectrum Hemp Finished Product means a hemp retail product labeled to indicate that it contains an extract derived from hemp that is comprised of naturally-occurring cannabinoids and other compounds with a total intoxicating tetrahydrocannabinols quantitative amount of not greater than 0.3% using a compliant laboratory and fit-for-purpose method. In addition, a full spectrum finished product must not be formulated with the addition of one or more isolated cannabinoids. If isolated cannabinoids are added, see "fortified full spectrum hemp finished product."

Genetically Engineered means produced from an organism or organisms in which the genetic material has been altered through the application of (a) vector-based recombinant deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) techniques; direct introduction of DNA or RNA into cells, protoplasts, or organelles; or other in vitro nucleic acid techniques; (b) methods of fusing cells or protoplasts beyond the taxonomic family that overcome natural physiological, reproductive barriers; and (c) does not include techniques used in traditional breeding and selection, such as selective breeding and hybridization. The terms "bioengineering," "bioengineered," "genetic engineering," "recombinant DNA (rDNA),"and "modern biotechnology" are terms that may be used interchangeably by industry, federal agencies, and international bodies.

Good Agricultural Practices (GAP) are a set of guidelines covering areas of cultivation (from seeds and propagation material), collection, harvest, processing, packaging, personnel, equipment, documentation and other matters for the purpose of satisfying the minimum required quality assurance in plant cultivation.

Good Manufacturing Practices (GMPs) are the principles for the methods to be used in, and the facilities and controls to be used for, the manufacture, packaging, labeling, holding and distribution of drugs, dietary supplements, foods and cosmetics. The principles are set forth to ensure that such products meet the

requirements of safety, have the identity and strength, and meet the quality and purity characteristics that they are purported to possess. The U.S. Food and Drug Administration (US FDA) has established regulations for Current GMPs (CGMPS) in the Code of Federal Regulations (CFR) for drugs (21 CFR 210/211), dietary supplements (21 CFR 111), foods for humans (21 CFR 117), and foods for animals (21 CFR 507). The US FDA has a draft guidance for cosmetic GMPs (current as of 11/14/2018) as well as Guidelines/Inspection Checklist for Cosmetics (current as of 02/25/2022).

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[4].

Hemp Biomass means total mass of hemp botanical material in given mass or volume from which consumable hemp ingredients and products can be made.

Hemp Extract means a mixture of constituents obtained from some or all of the aerial parts of hemp by using a solvent or physical process.

Hemp Isolate means an extract derived from hemp that has been processed to intentionally yield a high percentage of a single molecular constituent (such as CBD or another cannabinoid). Isolates may contain trace amounts of other constituents, moisture, etc.

Hemp Product means hemp, an ingredient derived from hemp, or a product which contains hemp or an ingredient derived from hemp and is intended for oral ingestion or topical application

Hempseed Oil means a fixed oil obtained by the pressing or by some other means of extraction of hemp seeds.

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 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.

In-Process Controls means checks performed during production in order to monitor and, if appropriate, to adjust the process and/or to ensure the hemp product conforms to its specification

In-Process Hemp Extract means hemp extract that is processed for use in the manufacture of a hemp product and has not yet been packaged as a finished product and is not intended for sale to consumers.

[4] The term hemp is consistent with the definition established by the Agricultural Marketing Act of 1946, section 297A.

Instrument or Instrumentation means a sophisticated measuring device or tool used for analytical or scientific work.

Intoxicating tetrahydrocannabinols means naturally occurring, synthetically derived, or synthetically converted tetrahydrocannabinols which, when consumed, have the potential to induce disturbances in nervous system function and may result in changes in cognition, perception, judgement, mood, consciousness, or behavior, that resolve with time.

Label means a display of written, printed, or graphic matter upon the immediate container of a hemp product.

Labeling includes all labels and other written, printed, or graphic matter upon any hemp product or any of its containers, or wrappers, or accompanying such hemp product at any time while the hemp product is held for sale after shipment or delivery for shipment in commerce. The term “accompanying” is interpreted liberally to mean more than physical association with the hemp product. It extends to marketing materials, online publications and postings, posters, tags, pamphlets, circulars, booklets, brochures, fillers, etc.

Lot means a batch, or a specific identified portion of a batch, that is intended to be uniform and that is intended to meet specifications for identity, purity, strength, and composition.

Manufacture means all operations and related controls of receipt of components, production, packaging, labeling, quality control testing, release, holding and distribution of hemp products. Production may include manufacturing material that is grown, fabricated, compounded, blended, ground, extracted, sifted, sterilized, derived by chemical reaction, or processed in any other way for use in the manufacture of a finished product.

Material is a general term used to denote components, in-process materials, hemp products, and packaging and labeling material.

May is used to indicate a permission.

Must is used to state a requirement. "Shall" means the same as "must."

Nonconformance means an event that occurs when a specified requirement is not met or results from an undesirable situation or defect. This covers departure from a procedure, standard or requirement, or the absence of dependability. This typically arises from a deviation from or the inability to meet documented procedures, expectations or specifications

Packaging Material means a container and/or closure for components, in-process material and hemp products.

Pest means any objectionable insect or other animal including but not limited to birds, rodents, flies, mites, and larvae.

Pesticide means 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 any nitrogen stabilizers. Pesticides include herbicides, fungicides, and insecticides as well as other substances. Pesticides include herbicides, fungicides, and insecticides as well as other substances. (See 7 U.S.C. 136 for additional terms related to pesticides.)

Procedure means a documented description of the operations to be performed, the precautions to be taken, and measures to be applied directly or indirectly related to the manufacture of a hemp product.

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 removed later in processing.

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, harvesting, manufacture, packaging/packing, labeling, holding, or related operations. Product complaints may include reports of adverse events or serious adverse events.

Proprietary Blend means a blend of two or more ingredients, which is identified by the term "proprietary blend" or other appropriately descriptive term, for which only the total quantity of all ingredients in the blend is provided and the ingredients in the blend are provided in order of predominance by weight (for solids) or volume (for liquids).

Purity means the identity and amount of a substance that is the intended substance, typically expressed in units of percentage, and determined using tests for assay or content.

Qualification means the action of proving and documenting that equipment or ancillary systems are proper, work correctly, and actually lead to the expected results.

Quality means that components, in-process materials, packaging materials, labeling and hemp products meet established specifications for identity, purity, strength and composition, and limits on contaminants, and that the finished product has been manufactured, packaged, labeled, and held under conditions to prevent adulteration

Quality Assurance means the sum total of the organized arrangements made with the goal of ensuring that all hemp products are of the quality required for their intended use and that quality systems are maintained.

Quality Control means a planned and systematic operation or procedure necessary to ensure the quality of the hemp product, by checking and testing that specifications are met.

Quarantine means the status of materials isolated physically or by other effective means pending a decision on their subsequent disposition determination.

Regulatory Authority means the local, tribal, state, or federal enforcement body or authorized representative having jurisdiction over a hemp product manufacturer's operation. Federal enforcement agencies may include the U.S. Food and Drug Administration, (US FDA), the U.S. Federal Trade Commission (FTC), the U.S. Department of Agriculture (USDA), and the U.S. Environmental Protection Agency (EPA).

Retail means the sale of labeled goods to the public in relatively small quantities for use or consumption rather than for resale.

Representative Sample means a sample that consists of an adequate number of units that are drawn based on rational criteria, such as random sampling,and that is intended to ensure that the sample accurately portrays the material being sampled. The sample may be a particular plant part (e.g., inflorescence (flower), leaf, stalk or seed) or it may be processed material (e.g., oil, powder, extract, in-process blend, tablet).

Scientifically Valid Method means an analytical test method or test procedure that is based on scientifically legitimate principles, theat meets proper standards of accuracy and precision, and is appropriate for its intended use (i.e., is fit for purpose).

Serious Adverse Event means an event that results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect; or requires based on a reasonable medical judgement, a medical or surgical intervention to prevent an outcome previously described.

Should is used to indicate a recommendation.

Specification means a list of tests, references to test procedures, and appropriate acceptance criteria for the tests described. It establishes the set of criteria to which a material should conform to be considered acceptable for its intended use. “Conformance to specifications” means that the component, in-process material and/or hemp product, when tested according to the listed test procedures, will meet the listed acceptance criteria. Specifications are critical quality standards that are proposed, justified and approved by the manufacturer. Material specifications include test specifications for identity, purity, strength, limits on contaminants and/or performance that define a standard of quality for the material.

Standardized Extract means an extract produced through control of agricultural practices, raw material specifications, and manufacturing processes to optimize batch to batch reproducibility of an extract, which may include controlling the amount of one or more botanical constituents in the extract (i.e., marker, active and/or co-active compounds). The amount of such constituents may be adjusted by the addition of fillers and/or by mixing two or more lots of extracts with different amounts of such constituents, whereby the lots of extract were made using the same manufacturing process.

Strength means the concentration or amount of an ingredient per unit serving of a finished product. Strength only applies to a finished product.

NOTE: In the hemp extract 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. 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.

Synthetic cannabinoid: A cannabinoid synthesized in a laboratory or by industry using directed synthetic or biosynthetic chemistry rather than traditional food preparation techniques such as heating or extracting. They may be nature-identical or artificial since this definition refers only to the process of their creation.

Terpenes means a class of unsaturated hydrocarbons produced predominately in plants built up from isoprene (C_5H_8)n units. Terpenes are classified by the number of isoprene units or carbons 5 units: monoterpenes (C_{10}), sesquiterpenes (C_{15}), diterpenes (C_{20}), sesterterpenes (C_{25}),triterpenes (C_{30}), sesquarterpenes (C_{35}), tetrterpenes (C_{40}), etc. **Terpenoids** are modified terpenes containing different functional groups and oxidized methyl groups.

Validation means a documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting pre-determined acceptance criteria.

2.2 ADDITIONAL TERMINOLOGY

Definitions for the following terms when used in this standard may be obtained from the current version of the American Herbal Product Association (AHPA) *Hemp Lexicon*. See https://www.ahpa.org/Portals/0/PDFs/HempLexicon/21_0325_AHPA_Hemp_Lexicon_Final.pdf

Artificial Cannabinoid
Botanical Compounds, Types of: Active Compound
Botanical Compounds, Types of: Co-Active Compound
Botanical Compounds, Types of: Marker Compound
Cannabidiol (CBD)
Cannabidiolic Acid (CBDA)
Cannabigerol (CBG)
Cannabinol (CBN)
Extract
Fixed Oil
Fortified Extract
Microorganisms
Mycotoxins
Nature-Identical Cannabinoid
Phytocannabinoid
Synthesized Cannabinoid
Tincture

3 REQUIREMENTS FOR ALL CERTIFIED OPERATORS

3.1 COMPLIANCE WITH APPLICABLE LAWS

3.1.1 Any operation certified under this Standard must be in compliance with all applicable laws, including holding relevant permits and licenses required by federal, state, tribal, or other jurisdictional authorities as applicable to the location and nature of their business. This also includes appropriate permits for importation and exportation of seed, hemp biomass or processed products.

3.1.2 Operators must demonstrate to the certification body how they stay informed of the legal requirements that apply to their operations, and how they follow such requirements on an ongoing basis.

3.1.3 Operators must keep on file a record of any violations of applicable laws and corrective actions for which they have been cited by relevant regulatory authorities.

3.2 PROHIBITIONS

3.2.1 Only products containing cannabinoids derived from the hemp plant *(Cannabis* spp*.)* are eligible for U.S. Hemp Authority Certification. Products with artificial cannabinoids, synthetic cannabinoids, biosynthetic cannabinoids, cannabimimetic phytochemicals, bioengineered hemp, and/or genetically engineered hemp may not be used in any stage of production.

3.2.2 . The U.S. Hemp Authority will NOT certify products that are promoted or marketed to encourage consumers to use them for their intoxicating effects or THC content. These products include, but are not limited to those marketed for intoxicating cannabinoids: delta-8 THC, delta-9 THC, delta-10 THC, THCO, HCH, exo-THC.

4 REQUIREMENTS FOR GROWERS

4.1 PRODUCTION PLANS AND RECORDS

All certified Growers must have a plan for production that at least includes the practices and corresponding records noted in this section, to show that the plan being routinely implemented.

Guidance: Growers can expect that their use of Good Agricultural Practices (GAP) will fulfill baseline requirements delineated in this section, but that additional considerations are needed as described below to address the specific characteristics of hemp.

The American Herbal Products Association AHPA also publishes a Guidance document on Good Agricultural Collection Practices and Good Manufacturing Practices (GACP-GMP) for botanical materials, available at http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Documents/AHPA_Good_Agricultural_Collection_Practices_Good_Manufacturing_Practices_Botanical_Materials.pdf?ver=2017-03-30-190312-060.

4.1.1 All growers must be duly licensed in accordance with USDA regulations for hemp production, as noted in 7 CFR 990[5].

4.1.2 Actual acreage and/or number of hemp plants grown, by variety must be declared to the certification body. Maps of all growing parcels must be kept on file.

Guidance: Farm Service Agency (FSA) crop reporting records may support compliance this requirement.

4.1.3 Employee qualification and training records relevant to hemp production must be kept updated and on file.

4.1.4 All sources of hemp seed used, by source, variety, and amount, and all related purchases must be recorded and on file.

Guidance: With respect to imported seed, the U.S. Department of Agriculture (USDA) regulates the importation of all seeds for planting to ensure safe agricultural trade. USDA guidelines for the import of hemp seeds and hemp plants can be found at https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/hemp.

4.1.5 All production input materials used, including purchase records, material data sheets and labels must be noted to the certification body. Input use should be specific to the part(s) of the growing operation affected (ie per field, greenhouse, etc.) and include dates and amounts used.

4.1.6 All amounts harvested by field and/or structure (eg greenhouse, indoor grow room, etc.) must be duly recorded and maintained on file.

4.1.7 Copies of all analyses done on seed, soil, crop, and product must be duly recorded and maintained on file.

[5] 7 CFR 990 is the USDA Domestic Hemp Production Program outlines provision for the USDA to approve plans submitted by States and Indian Tribes for the domestic production of hemp. It also established a Federal plan for producers in States or territories or Indian Tribes that do not have their own USDA-approved plan.

4.1.7.1 Analyses on harvested crop must at least attest to THC levels being 0.3% or less on a dry weight basis.

4.1.8 All post-harvest handling activities and other treatments of crop, including but not limited to drying, cleaning, cutting, grinding, packing, and storage must be duly recorded and maintained on file.

4.1.9 All amounts sold, by variety, quantity, and customer must be duly recorded and maintained on file. Any amounts otherwise disposed shall also be specified and recorded.

4.1.10 Records must be retained for a minimum of 5 years from the date on which certification is first granted.

4.2 Personnel Training, Hygiene and Safety

Employees who grow, manufacture, package, or label hemp shall be qualified to do so, and must have the education, training, or experience to perform the assigned functions. Supervisors shall be qualified by education, training, or experience to supervise.

4.2.1 All persons involved in activities related to compliance with this Standard must be trained in the relevant requirements that pertain to their specific role. Training must be updated at least annually and any time otherwise as changes are made to this Standard and/or to the operation itself.

4.2.2 All Grower operations must ensure proper sanitation measures by and for employees. This includes adequate personal hygiene and washing facilities, appropriate clothing and tools to prevent contamination of crop, and guidelines about exclusion from work when personal health poses a risk to other workers or certified product.

4.2.3 All workers must be provided with appropriate training and personal protection equipment (PPE) to assure their safety with respect to use of equipment, contact with the crop (and contamination avoidance of it), and materials used during production, harvest, and/or post-harvest handling.

4.2.4 Applicable laws regarding minimum wage, labor laws, child labor, forced labor, and human rights must be followed.

4.3 Soil and Water Management and Related Hemp Production Practices

4.3.1 Growers must control waste, erosion and protect wetlands, waterways and other non-cropped areas from degradation by cropping techniques and/or use of input materials including but not limited to synthetic fertilizers and pesticides, manures and other biological preparations.

4.3.2 Soils must be sampled for laboratory analysis in preparation for certified growing under this Standard. Samples must be taken for heavy metal concentration (at a minimum, for arsenic, cadmium, mercury, and lead), pH, pesticide residues, and soil nutrient profile in order to establish a baseline measurement. Subsequent analyses may be required by the certification body dependent on the Grower's risk due to materials use and potential for contamination from sources outside the farm.

Guidance:

For proper soil sampling, see the International Plant Nutrition Institute's Grid Soil Testing at http://www.ipni.net/publication/bettercrops.nsf/0/CDD207A2ADFB855385257D310068B14C/$FILE/BC-1994-4%20p6.pdf.

This Standard does not mandate an additional requirement for THC testing at the Grower's operation since U.S. regulations (7 CFR 990) already require such sampling and testing by an authorized government agent. USDA publishes the following guidelines about hemp sampling on its website:

https://www.ams.usda.gov/sites/default/files/media/SamplingGuidelinesforHemp.pdf

https://www.ams.usda.gov/sites/default/files/media/GuidelinesforSamplingAgents.pdf

https://www.ams.usda.gov/sites/default/files/media/USDAHempSamplingTraining112719.pdf

4.3.3 Laboratories conducting analyses included in 4.3.2 must be accredited to ISO 17025 for the specific tests involved.

4.3.4 Growers must have a soil nutrient management program that addresses the needs of their hemp crop(s) and optimizes use of fertility input materials. Fertility recommendations may be obtained from any source the Grower deems reputable. In any case, Growers must have their own rationale and method to evaluate the effectiveness of their program.

4.3.5 Growers must employ a system of integrated pest management that guides their use of pesticides (which includes fungicides, herbicides, and any other crop protection materials) so as to mitigate associated environmental damage and contamination of the crop with chemical residues. All materials used must be in accordance with their specific label restrictions for the jurisdiction where they are used, handled and stored in a manner that prevents acute toxic exposure to humans, animals, or the environment.

4.3.6 Sowing and production techniques must be done with equipment that is properly cleaned so as to avoid contamination of the crop by unintended materials.

4.3.7 Harvest must be done in a manner that does not contaminate the crop with chemicals and enables the maximum practical traceability back to the field.

4.4 Post-Harvest Handling, Storage and Shipping

4.4.1 Harvested hemp should be cleaned of non-hemp related matter (foreign material) and dried or otherwise maintained under conditions of preservation (eg cold storage) as soon as possible following harvest.

> 4.4.1.1 Any water used during harvesting, post-harvest handling, or storage of hemp must meet the requirements of the Safe Drinking Water Act.

Guidance: Drying can be done in an oven or dehydrator as necessary, especially in more humid climates. Drying temperatures should be low enough that negative effects on quality are minimized.

4.4.2 Storage of hemp shall be under appropriate conditions of temperature, humidity, and light so that the identity, purity, strength, and other relevant qualities of the hemp are not affected as appropriate for the variety and purpose(s) for which the crop shall be used. Storage of hemp shall also be done in a manner that protects it from infestation by pests.

4.4.3 Transportation of hemp shall be under conditions that will protect the hemp against contamination, adulteration, and/or deterioration of desired quality. Growers must verify and document that transport vehicles are clean and protect certified inputs from damage or contamination.

4.4.4 Packaging must not be coated with or otherwise contain any materials (eg fungicides, mold inhibitors, etc.) that may contaminate the hemp.

4.4.5 All package labels should at a minimum state variety, lot number and/or harvest date, and Grower name.

4.4.6 Growers must regularly monitor off-site storage units and document their monitoring activities to assure compliance with these standards.

4.4.7 Exported goods must be accompanied by permits and declarations as required by the operator's legal jurisdictional authorities, as well as all other applicable requirements of this Standard to ensure the quality and identity of the certified products. Operators are responsible for demonstrating their knowledge of applicable legal requirements and their methods for keeping up to date on them.

5 REQUIREMENTS FOR MANUFACTURING

5.1 PRODUCT SAFETY

5.1.1 Operators must demonstrate their awareness of product quality, safety and production practices, applicable regulatory requirements, and their methods for adhering to those requirements. Operators must establish and maintain documentation that reflects ongoing adherence to such requirements. The following main objectives must be considered:

- All inputs and finished products must meet established specifications and be free from adulteration or the inadvertent introduction of unintended materials, from receipt of inputs to packaging of finished product.
- All products must be labeled in accordance with the requirements of this Standard and any other applicable federal, state, or tribal laws.

Guidance:

Manufacturers subject to imminent FDA regulation for their respective areas of activity related to hemp products must comply with the Federal Food, Drug and Cosmetic Act -- as amended by the Food Safety and Modernization Act -- as a baseline in addition to the requirements in this Standard.

5.1.2 Facilities producing dietary supplements must demonstrate how they follow current Good Manufacturing Practices (cGMPs) as specified in 21 CFR 111.

5.1.3 Facilities producing human and animal food products must show how they follow applicable food safety measures as specified in 21 CFR 117 and 21 CFR 507, respectively.

Guidance: The FDA provides information on Current Good Manufacturing Practices (CGMP) for foods and supplements on their website at this link: https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/current-good-manufacturing-practices-cgmps

Examples of evidence to demonstrate compliance may include but are not limited to a GMP certificate and corresponding report with corrective action plans and/or a recognized FSMA training acknowledgement.

5.1.4 Facilities producing cosmetics and other personal care products must show how they follow applicable measures to ensure products are manufactured consistent with Good Manufacturing Practices (GMP).

*Guidance: The FDA provides guidance for the industry on Cosmetic Good Manufacturing Practices at this link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-cosmetic-good-manufacturing-practices*5.1.5 Facilities manufacturing over-the-counter (OTC) drug products officially registered in the FDA's National Drug Code (NDC) Directory must provide their NDC number and demonstrate compliance with relevant Good Manufacturing Practices for drugs pursuant to 21 CFR 210.

Guidance: The FDA provides guidance for the industry on Good Manufacturing Practices for over-the-counter topical drugs, which can be searched for at this link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

5.1.6 Facilities manufacturing hemp-derived products not subject to clauses 5.1.2 through 5.1.5 (for example textiles, other hemp fiber-based products, construction materials, other durable goods) must conduct a risk analysis of all activities pertaining to the handling of all inputs used in the manufacturing of such products to be certified under this Standard. They must identify all critical control points to assure that the finished products meet specifications for contaminants and are free of unspecified materials of any kind.

5.2 SANITATION, HYGIENE & PEST CONTROL

5.2.1 All facility spaces, equipment, and tools must be free of physical, chemical, and biological contaminants prior to and during their use in making certified products. Exterior and interior spaces must have sufficient room to enable their ongoing cleaning, monitoring, and maintenance.
5.2.2 Personnel involved with manufacturing of certified products must employ personal hygiene and disease control practices and have adequate facilities to do so.
5.2.3 Personal protection equipment (PPE) must be used as necessary so that workers are protected and do not act as vectors for contaminants, foreign matter, or pathogens.
5.2.4 Water used in processing, as an input or in sanitation, must meet applicable legal potability requirements.
5.2.5 All cleansers, sanitizers, and disinfectants that may affect certified production and products in any way must be specified as to their storage and method of use.
5.2.6 Sanitation Standard Operating Procedures (SSOPs) and/or associated records must document practices as necessary to show compliance with section 5.1.
5.2.7 Routine sanitation measures must be logged as to the materials used, amounts, timing, methods, and persons doing the task. Documentation must include a validation step to affirm the process was effective as intended.
5.2.8 All materials used for pest control at the facility (exterior and interior spaces) must be specified as to their storage, method, and frequency of use. Measures must be taken to assure compliance with clause 5.2.1, as well as avoid contamination of all inputs and packaging materials used in the manufacture of certified products. All such ongoing activities must be documented.

5.3 INPUT SOURCING & SUPPLIER QUALIFICATION

5.3.1 The operation must provide written specifications for each kind of component (hemp and hemp-based materials, other ingredients, and processing aids) it uses to manufacture certified products. Specifications for each hemp-based input must at least reflect legal compliance requirements with respect to applicable federal, state, or tribal licensing to grow hemp and maximum allowable THC content.

> 5.3.1.1 A hazard or risk analysis with associated approval procedures must be documented for each kind of component used in certified products, including but not limited to biological, chemical, physical, irradiation and/or economically-motivated safety hazards (including adulteration or other fraudulent activity).

5.3.2 Operators must establish a qualification procedure for all suppliers of ingredients used in certified products, as well as for contract manufacturers of finished goods. This procedure must be followed and documented for each approved supplier, and a current list of approved suppliers maintained. Suppliers of hemp inputs must be re-qualified on an annual basis as part of their certification renewal. Suppliers of other inputs must be evaluated and if necessary re-qualified on an annual basis as part of their certification renewal.

Guidance: Qualification procedures should at a minimum use this Standard's applicable requirements as a baseline guideline (or checklist) to verify suppliers' competence.

5.3.3 Operators must always either receive hemp inputs with relevant valid analyses already done to address their own established specifications or must conduct such analyses themselves. Parameters for analyses must be specified per input. If relying on suppliers' analyses, operators must verify the sampling and testing program of their supplier.

5.3.4 Non-hemp inputs may be sourced according to specifications as delineated in clause 5.3.1.

Guidance: 5.3.1 presumes necessities pertinent to section 5.1 are also followed.

5.3.5 Any inputs, packaging or other materials received for activities under this Standard must be documented. All documents issued by the supplier as well as those kept the receiving operation as required by this Standard must be on file.

5.3.6 Imported inputs must be accompanied by permits and declarations as required by the operator's legal jurisdictional authorities. Operators are responsible for demonstrating their knowledge of applicable legal requirements and their methods for keeping up to date on them.

5.3.7 Operators must identify any inputs found to be non-conforming and document their disposition.

5.4 SAMPLING AND TESTING OF INPUTS AND PRODUCTS

5.4.1 Manufacturers must implement sampling and testing plans for hemp and hemp derivatives in a manner that is statistically significant, yields a statistically representative sample for analysis and yields a result with a minimum confidence level of 95%. Operators must specify their sampling procedure, which must be evaluated and approved by the certification body.

Guidance: If a Manufacturer wishes to composite samples, this may be done in a manner that ensures that any composite sample exceeding specification limits produces a positive result for the composite sample as a whole and each single component included in the composite would need to be re-tested.

5.4.2 Sampling procedures must retain enough of the sample to enable at least one repetition of the analysis in case questionable results are obtained. Samples must be retained for at least the stated shelf life of the certified product as well as the hemp-derived inputs that were used to make it.

5.4.3 Laboratories conducting analyses on hemp ingredients and finished product must be accredited to ISO 17025 for the specific tests involved, or proficiency testing in cases where ISO protocols have not been established.

5.4.4 Cannabinoid quantification methods must be able to determine the concentration of target cannabinoids and must effectively distinguish *Cannabis* as either legal hemp or marijuana.

5.4.4.1 Methods must be accurate and precise at concentrations that bracket 0.3% THC[6] on a dry weight basis. Laboratories must adopt fit for purpose validated analytical methods that meet AOAC[7] SMPR

[6] 7 CFR 990.3(a)(3) states" … testing methodology must consider the potential conversion of delta-9 tetrahydrocannabinolic *acid* (THC-A) in hemp into THC and the test result measures total available THC derived from the sum of the THC and THC-A content."

[7] AOAC International (formerly Association of Analytical Chemists); SMPR is standard method performance requirements.

2019.003, such as AOAC Official Method of Analysis 2018.11, or use equivalent official methods. (See also https://www.aoac.org/wp-content/uploads/2019/10/SMPR-2019_003.pdf).

5.4.5 Testing of hemp and hemp derivatives for contaminants (heavy metals, pesticides, residual solvents, microbiology and mycotoxins), as required by the Manufacturer's specifications and in line with the intended use and clause 5.3.1.1, must follow guidance as listed in the American Herbal Pharmacopoeia *Cannabis* Monograph, "Standards of Identity, Analysis and Quality Control" and the following AHPA Guidance Documents, unless said testing is determined by the certification body to be equivalent or better than those cited here:

Guidance: Testing for contaminants prior to processing is recommended to reduce the potential for finished products to test above legal or otherwise specified limits.

5.4.5.1 For pesticides, limits of quantitiation for foods are listed in AOAC Official Method 2007.1, "Pesticide Residues in Foods" at http://www.weber.hu/Downloads/SPE/QuEChERS/AOAC_2007_01.pdf. Tolerances for pesticides (EPA) may be found at https://www.epa.gov/pesticide-registration/pesticide-products-registered-use-hemp. Alternatively, the limits set by the California Bureau of Cannabis Control may be used; please see https://bcc.ca.gov/law_regs/cannabis_order_of_adoption.pdf.

Guidance: Note that most pesticide testing panels do not include glyphosate; thus, if glyphosate testing is desired, that request must generally be specifically and separately made to the lab.

5.4.5.2 For heavy metals:

http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA_Heavy_Metals_Guidance.pdf

Guidance: AHPA guidance does not include the stricter limits for lead consumption required in the state of California under Proposition 65.

5.4.5.3 For microbiology and mycotoxins: The manufacturer shall establish the microbiological and mycotoxin levels taking into consideration the intended consumer use of the finished product.

Guidance: microbiology limits are based on products consumed orally. Extraction processes should remediate the mycotoxin presence in the extracted material. It is advisable to test for mycotoxins/aflatoxins in raw biomass.

For further reference please see:

- *USP General Chapters 2021/2022 or 2061/2062*
- *AHPA Guidance Document, "Microbiology & Mycotoxins," found at: http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA_Microbiology___Mycotoxin_Guidance.pdf?ver=2016-04-26-121351-030*
- *FDA Bacteriological Analytical Manual (BAM), https://www.fda.gov/food/laboratory-methods-food/bacteriological-analytical-manual-bam*

5.4.5.4 For residual solvents: USP General Chapter 467.

5.4.6 Analytical specifications must be established for all finished products, including quantitative limits on contaminants including pesticides and heavy metals, residual solvents, microbiological pathogens and toxins, target quantities of cannabinoids, and THC.

5.4.6.1 Analysis must show that degradation of cannabinoids within shelf-life of product does not result in amount of active ingredients being lower than that which the label declares.

5.4.7 Each finished batch of product must be sampled and tested to assure that it meets specifications. Sampling and testing must be done in accordance with clauses 5.4.1 through 5.4.6.

5.5 PRODUCTION & PROCESS CONTROLS

5.5.1 Inputs must be received in a manner that prevents contamination, affirms the integrity of the packaging, follows the facility's established procedure for sampling and sample retention per section 5.4 and distinguishes between accepted and rejected lots. In the case of rejected lots, the disposition of those lots must be recorded.
5.5.2 All inputs must be properly labeled at all times and must include identity of material and lot number.

5.5.3 Inputs and finished products must be traceable by batch or lot back to the source(s) from which they each are obtained. All transfer and use of inputs must be reflected in documentation**.**
5.5.4 All approved inputs must be received, stored, and processed during all stages of handling and processing to keep them separate from commingling with non-approved inputs**.**
5.5.5 All formulation components must meet the requirements of this Standard for a given product to be certified.
5.5.6 All movements and transformations of inputs into finished products must be duly recorded as to the equipment used, the exact amounts and lot numbers of each input used, the final output of product, specific by-products created and their disposition, and quantity wasted or lost during the process.
5.5.7 All work-in-progress must be clearly labeled to maintain its product and lot identity.
5.5.8 Packaging materials must be received, stored, and used in a manner that prevents contamination of finished products by any unapproved substances, whether from the surrounding environment or from the packaging material itself.
5.5.9 Non-retail containers of finished goods must at least be labeled to indicate the product name and lot number.
5.5.10 Retail containers of finished goods must comply with section 6.2 of this Standard.

5.6 STORAGE, TRANSPORTATION & DISTRIBUTION

5.6.1 All stored products must be clearly labeled to enable their identification.

5.6.2 Operators must have an inventory tracking system in place that updates all quantities of stock as changes occur.

Guidance: For larger facilities, it is advisable that the inventory system also indicate the exact locations of different kinds of stock.

5.6.3 Storage areas and distribution centers must protect the quality of goods stored by providing adequate space, environmental conditions (including but not limited to temperature and humidity), and protection from the elements, pests, and potential contaminants (physical, chemical, or biological).

5.6.4 Operators must regularly monitor off-site storage units as relevant and document their monitoring activities to assure compliance with these standards.

5.6.5 Operators must verify and document that transport vehicles are clean and protect certified inputs from damage or contamination.

Guidance: Special attention should be paid to goods shipped in permeable containers (eg raw hemp biomass).

5.6.6 Up-to-date records must be maintained for amounts of hemp-based ingredients and finished products sold, discarded, or otherwise used (eg as samples).

5.6.7 Exported goods must be accompanied by permits and declarations as required by the operator's legal jurisdictional authorities, as well as other relevant requirements of this Standard. Operators are responsible for demonstrating their knowledge of applicable legal requirements and their methods for keeping up to date on them.

5.7 QUALITY CONTROL

5.7.1 Record Keeping – Operators must maintain records to demonstrate compliance with this Standard and have them readily available to certification body personnel. Records must be retained for at least five (5) years, or longer if required by the regulatory authority having jurisdiction. Records must be stored in such a way that they remain legible and retrievable.

Guidance: Electronic records should be backed up regularly to assure that redundant copies exist. Hard-copy documents must be stored so that they are protected from degradation by the elements.

5.7.2 Document control – A system must be in place to assure that all personnel use the most current version of any given document involved with certified production.

5.7.3 Employee training – All personnel undertaking any activity involved with certified production under this Standard must be trained and competent in the operation's specified procedures for complying with this Standard. Personnel must be able to demonstrate their knowledge of their related responsibilities. Training must be effectively documented and updated as changes are needed.

5.7.4 Equipment calibration – All equipment used in certified production must be regularly and appropriately calibrated to assure that processes and measurements are controlled and accurate. Operators must document how such calibration has been done.

5.7.5 Sample retention – Samples of hemp-specific inputs and finished products must be retained for each production lot and held under environmental conditions that mitigate degradation for at least the stated shelf-life of the product in question.

Guidance: It is recommended to retain samples for longer than the minimum specified above. Such samples may be retained directly by the Brand Owner, or by the manufacturer of the finished product, but in the latter case they must be available to the Brand Owner as necessary to comply with certification requirements.

5.7.6 Hold and release – Operators must have a system in place to hold (quarantine) and segregate all finished products for final inspection and quality control measures before they are released for distribution outside the facility.

5.7.7 Non-conforming materials – Products or inputs failing to conform with internal specifications or those of this Standard must not be used or distributed for certified production. Their disposition must be documented and approved by authorized quality assurance personnel. A root-cause analysis of the reason for the nonconformance must be undertaken and documented along with corrective actions to prevent recurrence.

Guidance: Non-conforming materials in some cases may be re-worked in order to make them usable for certified production; the operation must have specific written guidelines, procedures, and documentation to reflect compliance with this Standard.

5.7.8 Recalls – A product recall system must be in place and verified at least annually to assure its effectiveness, and all such actions (real or mock) documented as to when they occurred and the results, including the degree of effectiveness (% recovery and amount of time elapsed).

Guidance: The recall must be achievable within 4 hours.

5.7.9 Complaints – Operators must have a system in place to receive, log, respond to and resolve any complaints received about its products or operations. At a minimum documentation must include the original complaint in the form received, the date, the nature of the complaint, the response, and the resolution. Complaints received only verbally must be documented by the manufacturer.

5.7.9.1 For complaints about dietary supplements, adverse event reporting as legally required pursuant to 21 CFR 111, Subpart O – Product Complaints must also occur.

Guidance for adverse event reporting for dietary supplements is available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-adverse-event-reporting-and-recordkeeping-dietary.

5.7.10 Internal audit – Operators must at least annually conduct an internal audit of its physical operations and record keeping in conformance with this Standard, with the results documented along with any corrective actions and timelines for achieving them.

6 REQUIREMENTS FOR BRAND OWNERS & LABELING RETAIL PRODUCTS

6.1 BRAND OWNERS' PRODUCTS & SOURCING

6.1.1 The Brand Owner must maintain written specifications of its own requirements for each product it sells under this Standard, which shall also explicitly refer to compliance with the U.S. Hemp Authority Standard. Specifications for each product must include the formulation such that label declarations at least reflect legal compliance with respect to applicable federal, state, or tribal licensing to grow hemp and ingredient content and maximum allowed contaminants for their product category, as well as for THC content.

6.1.2 Brand Owners must establish a qualification procedure for all suppliers of products included in their U.S. Hemp Authority certification, adhering to the requirements of this Standard. This procedure must be documented as having been followed for each approved supplier, and a current list of approved suppliers maintained. Non-U.S. Hemp Authority-certified contract manufacturers of Brand Owner finished consumer products may be subject to direct inspection and audit by the certification body in instances where Brand

Owner's supplier qualification program is not able to obtain full disclosure of information necessary to show compliance with this Standard.

6.1.2.1 If a GMP, food safety, or similar third-party audit is a necessary component of the supplier qualification procedure, the audit report and any related corrective action plan/resolution must be made available to the certification body, to assure accordance with sections 5.1 and 5.3 of this Standard.

Guidance: Qualification procedures should at a minimum use this Standard's applicable requirements as a baseline guideline (or checklist) to verify suppliers' competence.

6.1.3 Brand Owners must always either have relevant valid analyses already done by the final manufacturer to address their own established specifications or must conduct such analyses themselves. Parameters for analyses must be specified per product. If relying on suppliers' analyses, operators must first validate the testing program of their supplier through a method that both (i) evaluates the supplier's sampling and testing procedure, and (ii) validates the analyses presented on each product by conducting their own analysis in order to reproduce the results.

6.2 LABELING

6.2.1 With respect to all claims relating to hemp and hemp-derived ingredients, all products for consumer use must be labeled according to applicable parts of Title 21 of the Code of Federal Regulations for foods and dietary supplements, the Food Drug & Cosmetic Act for cosmetics as applicable, as well as any additional state or tribal government requirements. Brand Owners are responsible for demonstrating how they stay informed of what legal labeling requirements apply to their operations regardless of the type of product(s), and how they keep up to date regarding such requirements on an ongoing basis.

Guidance: Federal regulations that merit attention in particular include:

- *21 CFR §§ 101.1-101.108, 190.6—Food Labeling (including Dietary Supplements)*
- *21 CFR §§ 111.1-111.610—Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements*
- *21 CFR §§ 117.1-117.475—Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food*
- *21 CFR §§ 701.1-701.30—Cosmetics Labeling*
- *21 CFR §§ 740.1-740.19—Cosmetic Product Warning Statements*

6.2.2 All labels for products certified under this Standard must be approved in writing by the certification body.

6.2.3 For hemp ingredients grown outside the United States, a country-of-origin statement must be included on the label. Country abbreviations other than for the United States of America are not acceptable.

6.2.4 Certified products under this Standard may not include any bioengineered substance unless duly disclosed on the product label in accordance with 7 CFR 66 (National Bioengineered Food Disclosure Standard).

6.2.5 Use of the terms “broad spectrum,” “full spectrum,” and “isolate” on labels shall be consistent with the definitions of these terms in Section 1 of this Standard. Any use of isolate(s) shall be disclosed on the supplement facts panel, nutrition facts panel, or ingredients list, as required under federal labeling regulation.

6.2.6 Nutrition Facts panels and allergen statements must be included on food and beverage products, supplement fact panels must be included on dietary supplement products, and drug facts panels for OTC drugs.

Guidance:

Food and beverage nutrition fact panels should also follow FDA guidelines that are outlined in the FDA Food Labeling Guide, found at:

https://secure.in.gov/isdh/files/Food_Labeling_Guide(1).pdf

Supplement fact panels should also follow FDA guidelines that are outlined in the FDA’s Dietary Supplement Guide, found at: https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/dietary-supplement-labeling-guide

Cosmetics should be labeled consistent with the FDA’s Cosmetic Labeling Guide, found at:

https://www.fda.gov/media/88234/download

6.2.7 Claims must be truthful and not misleading. In particular, claims of products being “free from” or having “zero” content (eg “zero GMOs” or “zero pesticides”) are not considered realistic given the limits of analytical detection methods. Claims about being “free” of certain materials (eg THC, heavy metals, pesticides) are only allowed if accompanied by a clear statement, immediately adjacent to the “free” claim that the “free” claim means that analysis has shown no detection at the most sensitive practical analytical limit available (typically 0.01%).

6.2.8 No products may have labels or marketing that claim to diagnose, treat, prevent or cure any disease or have therapeutic effects.

6.2.9 All dietary supplements intended to support the structure or function of the body must include a disclaimer such as: “This product is not intended to diagnose, treat, cure or prevent any disease.”

Guidance: products containing measurable amounts of cannabinoids should include proper warnings and cautions, such as the following:

- *This product should be used with caution when driving motor vehicles or operating heavy machinery.*
- *Use this product under the guidance of a physician if you have a medical condition, are pregnant or lactating[8].*
- *Keep out of the reach of children.*
- *This product was manufactured from hemp material that meets federal requirements for hemp products; however, consumption may be flagged by some drug tests.*

[8] Note: FDA strongly advises against the use of CBD in any form during pregnancy or while breastfeeding.

- *Use with caution if subject to urinalysis.*

6.2.10 All finished product packages labels must include a lot code that may be used to trace the product back to the manufacturer and thereby to its activities and the inputs used to make the product.

Guidance: The code can include a "best by", manufacturing date or expiration date as long as that can be used to trace to the relevant manufacturing data.

6.2.11 Use of the U.S. Hemp Authority seal may must be in accordance with the U.S. Hemp Authority's related Licensing Agreement and its Trademark and Branding Guidelines.

ANNEX A – CERTIFICATION PROCESS

U.S. Hemp Authority certification happens on an annual cycle, subject to annual update and renewal. The process is as follows:

APPLICATION

Operations wishing to become certified must submit an application, through a form provided by the U.S. Hemp Authority's certification service provider, certifying body. The application is made in 2 parts, the first to gauge the scope of the certification request and generate a Service Agreement, followed by a second part that includes more details about the operation and allows for a deeper technical review prior to inspection. The certifying body may request additional information and/or system corrections prior to releasing the case for audit.

SERVICE PROPOSAL

A Service Agreement is provided for certification which will set out the terms, conditions, and fee structure of the proposed certification. The Organization returns the signed agreement and proposal, agreeing to the audit and to commit to compliance with the Standard once certified. Details of fees are provided with the certification proposal and agreement.

AUDIT AND ON-SITE INSPECTIONS

The certifying body will assign a trained auditor to complete the certification audit. Auditors will:

- Confirm intentions set forth in the application;
- Audit operations to determine compliance;
- Present overall findings of the audit; and
- Provide a list of findings

On-site inspections (audits) may be required for any operation that physically handles, packages, or labels certified product. Operations such as Brand Owners who do not physically handle product may be certified through a desk review only. The certifying body reserves the right however to conduct on-site audits in any case.

AUDIT REPORT, REVIEW, AND CORRECTIVE ACTIONS

The auditor will produce and submit a written report of the audit to the certifying body, who reviews the report and its findings and issues a letter to the applicant identifying any nonconformities that require correction prior to being granted certified status. The certifying body will send the applicant a copy of the report once the technical review of the report has been completed. Operations must demonstrate to the certifying body that any corrective actions imposed have been duly implemented as a condition for granting or renewing certification. Corrective action plans must be submitted by the operation within 30 days of receipt of the certifying body letter of findings, and then approved by the certifying body. Where the number or nature of any nonconformance(s) raises doubt as to the effectiveness of systems or procedures, the certifying body may conduct a further on-site visit to verify corrective actions have been met.

CERTIFICATION

A certification decision will be made by the certifying body based on the report, corrective actions and closeout of non-conformance(s). If the decision is that certification is granted, a certificate will be issued to the applicant with an annual expiration date.

LICENSING AGREEMENT TO USE THE U.S. HEMP AUTHORITY SEAL AND NAME

Once certified, an operation has the right to use the U.S. Hemp Authority certification seal and name on its products and marketing materials by executing the U.S. Hemp Authority's Licensing Agreement. Execution of this Agreement is facilitated by the certifying body between the operation and the U.S. Hemp Authority Secretariat. The certified operation agrees not to use its certification in such a manner to discredit the U.S. Hemp Authority or make statements regarding its product certification that the U.S. Hemp Authority may consider false or misleading or otherwise unauthorized. Use of the U.S. Hemp Authority reference includes any media including but not limited to websites or electronic or hardcopy marketing materials, specifications, and datasheets.

MAINTENANCE OF CERTIFICATION

The U.S. Hemp Authority or certifying body will contact the certified operation prior to annual expiry. This is generally 3 months before the expiration date of the current certification certificate. It is the responsibility of the certified operation to assure that it undertakes all necessary steps to maintain certification. If recertification is not sought, the use of the U.S. Hemp Authority certificate and seal, as applicable, shall cease on its annual expiry date and no new claims related to the certified status is allowed.

SUSPENSION OF CERTIFICATION

If the certified operation cannot provide satisfactory objective evidence of corrective actions to discharge non-conformances, certification may be suspended or withdrawn. If the certifying body or the U.S. Hemp Authority becomes aware of circumstances that raise doubt as to the ability of the certified operation to meet the

responsibilities and requirements of the Standard, it may ask the operation for further information to clarify the situation. If no satisfactory explanation or assurances are received, the certifying body may revoke, suspend or withdraw certification. Operations may also choose to withdraw from the program through a formal withdrawal request in writing.

COMPLAINTS

Operations have the right to file a complaint. Complaints should be submitted in writing to the certifying body, detailing the nature of the issue, the personnel involved, and any relevant dates. Complaints will be handled according to the certifying body's written complaint procedure.

APPEALS AND ADJUDICATION

Should an operation disagree with the certification decision, it has the right to appeal per the certifying body's Appeals and Adjudication Procedure for the U.S. Hemp Authority Certification Program. An Adjudication Committee will be assigned to adjudicate the matter. The decision of the committee will be final. In circumstances of suspension, withdrawal, complaint, or appeal, the operation will be informed in writing of the action taken/decisions made. The certifying body will not reimburse any fees incurred.