US Hemp Authority - Request for Comment

Keeping pace with the rapid evolution of the hemp sector, the U.S. Hemp Authority is undertaking a revision of its Standard (known currently as its "Guidance Procedures v2.0"). The rationale for this revision is described in a Terms of Reference adopted by the Board of Directors in early 2020.

An initial draft of a new version 3.0 of the U.S. Hemp Authority Standard is now available for broad stakeholder feedback. Your participation in this process is highly encouraged. Comments for this initial round of stakeholder feedback may be submitted until October 15, 2020. Please submit comments using this form.

Thank you for your interest! Any additional questions may be directed to USHAcert@foodchainid.com.
Note: Please write "USHA Standard Revision" in the subject line of your email.

We thank you for your participation in this process.

U.S. Hemp Authority

1 INTRODUCTION & OBJECTIVES

1.1 BACKGROUND

Cannabis sativa (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 Farm Bill in 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 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 final product. Certification is awarded to three categories of operations: Growers, Processor/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 biomass, food, dietary supplements, personal care products, and products based on hemp fiber.

Hemp Growers, Processor/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" 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, Processor/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 attest to 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

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

Adulteration refers to a food, dietary supplement, or personal care product that may be considered adulterated if it (1) contains any poisonous or deleterious substance which may render it injurious to health, or if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; or (5) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption. In the event the substance is not an added substance, such food shall not be considered adulterated if the quantity of such substance in such food does not ordinarily render it injurious to health.

Authority having jurisdiction usually means the state, but it could be FDA,[1] FTC,[2] USDA,[3] EPA,[4] tribal government, county or city.

[1] U.S. Food & Drug Administration.
[2] U.S. Federal Trade Commission.
[3] U.S. Department of Agriculture.
[4] U.S. Environmental Protection Agency.

Batch means a specific quantity of a hemp product that is uniform, that is intended to meet specifications for identity, purity, strength, and composition, and that is produced during a specified period of time 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 any combination of them, from which the complete history of the processing, packaging, labeling, and/or storage of a batch or lot of hemp product can be determined.

Bioengineered has the same definition as found in 7 CFR Part 66, , namely 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."

Brand owner means a company that owns a hemp product brand.

Broad Spectrum Extract is hemp extract that has been processed to remove THC such that the quantified THC has been deemed non-detectable by a compliant laboratory using a fit-for-purpose method with a limit of quantification of less than 0.01%.

Cannabinoids means a group of 22-carbon compounds produced by plants in the genus *Cannabis,* including their analogs and transformation products, in particular 21-carbon compounds resulting from decarboxylation during processing.

Cannabimimetic phytochemical means any substance not derived from the genus *Cannabis* with similar pharmacological effects to those of the genus *Cannabis* in that it acts directly or indirectly on cannabinoid receptors in the body.

Certification body means the organization assigned to inspect, audit, and otherwise evaluate an operation's compliance with this Standard.

Component means any ingredient, additive, processing aid used in the manufacture of a hemp product.

Confidence level means the probability or percentage chance that a result will be reliable.

Facility means all or any part of a building or location used for or in connection with manufacturing, processing, packaging, labeling, or storage of hemp products or ingredients.

Full Spectrum Extract is hemp extract including any naturally-occurring THC and other cannabinoids, terpenes, and other naturally occurring compounds, that has been processed without intentional complete removal of any compounds, and has a final THC quantification of not greater than 0.3%.

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

does not include techniques used in traditional breeding and selection, such as selective breeding and hybridization.

Genetically engineered ingredient means an ingredient in dietary supplements or as an additive to food and beverages that is derived from or produced by a genetically engineered organism regardless of whether the ingredient contains detectable DNA or protein from a genetically engineered organism.

Genetically modified organism (GMO) is a term used that often relates to bioengineering and/or genetic engineering. This Standard instead use the terms "bioengineered" and "genetically engineered," which are terms and definitions used by US and foreign government authorities respectively, and by private sector standards and other organizations that address these issues.

Good Agricultural Practices (GAP) are a collection of recommended principles and practices to apply for on-farm production and post-production processes..

Good Manufacturing Practice (GMP, or cGMP for current Good Manufacturing Practice) means a system for ensuring that products are consistently produced and controlled according to current quality standards. cGMP for food, animal food, dietary supplements, and over-the-counter (OTC) drugs are regulated by the FDA within the Code of Federal Regulations (CFR) (*i.e.*, 21 CFR 117, 21 CFR 507, 21 CFR 111, and 21 CFR 210 respectively), and for over-the-counter (OTC) drugs. The FDA also has provided voluntary (non-binding) GMPs for cosmetics.

Growth medium means soil, or the solid, liquid or semi-solid substance used to support the growth of the plant.

Hemp means cultivars of the plant species *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.[5]

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

Hemp product means any product manufactured or produced with hemp or containing or comprised of hemp or parts of the hemp plant, or hemp extract(s).

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

Input means any material that is used to grow a crop or is an ingredient or processing aid in the manufacture of a processed product.

Isolate means a hemp extract that has been processed to intentionally yield a high percentage of a single molecular constituent (such as CBD or another cannabinoid).

[5] 7 CFR 990

Lot means a batch, or a specific identified portion of a batch, or, in the case of a hemp 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 for identity, purity, strength, and composition.

Must is used herein to state a requirement. “Shall” means the same as must.

Non-retail means any product that is meant to be further transformed, packaged or labeled before being made available to the final consumer.

Personal Protective Equipment (PPE) means protective clothing, helmets, goggles, or other garments or equipment designed to protect the wearer's body from injury or infection. The hazards addressed by protective equipment include physical, electrical, heat, chemicals, biohazards, and airborne particulate matter.

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

Processing means making a transformative change to the hemp plant or product following harvest; converting an agricultural commodity into a marketable form.

Processing aid means (i) A substance that is added during the processing but is removed in some manner before a product it is packaged in its finished form; (ii) a substance that is added during processing, is converted into constituents normally present in the final product, and does not significantly increase the amount of the constituents naturally found in the final product; and (iii) a substance that is added for its technical or functional effect in the processing but is present in the finished product at insignificant levels and does not have any technical or functional effect in that final product.

Quality means that the hemp product meets the established specifications for identity, purity, strength, and composition, and limits on contaminants, and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration.

Retail means any product labeled for final consumer use.

Sample means a sufficient amount of material that is statistically representative of the population from which it is taken. A sample may be a particular plant part, including inflorescence (flower), leaf, stalk or seed, or it may be a processed product (oil, extract, powder, etc.).

Sanitize means to adequately treat cleaned equipment, containers, utensils, etc. 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.

Synthetic cannabinoid means a cannabinoid that is not derived from the genus *Cannabis*.

Tetrahydrocannabinol (THC) is an intoxicating crystalline compound found in the genus *Cannabis*. U.S. federal law mandates that hemp plants may only contain trace amounts of THC (not more than 0.3% on a dry weight basis).

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 how they stay informed of what legal requirements 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 for which they have been cited by relevant authorities.

3.2 PROHIBITIONS

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

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 Actual acreage and/or number of hemp plants grown, by variety. Maps of all growing parcels must be kept on file.

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

4.1.2 Employee qualification and training records relevant to hemp production.

4.1.3 All sources of hemp seed used, by source, variety, and amount, and all related purchases.

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.

4.1.4 All production input materials used, including purchase records, material data sheets and labels. 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.

4.1.5 All amounts harvested by field and/or structure (eg greenhouse, indoor grow room, etc.)

4.1.6 Copies of all analyses done on seed, soil, crop, and product.

4.1.7 All post-harvest handling activities and other treatments of crop, including but not limited to drying, cleaning, cutting, grinding, packing, and storage.

4.1.8 All amounts sold, by variety, quantity, and customer. Any amounts otherwise disposed shall also be specified and recorded.

4.1.9 Records must be retained for a minimum of 5 years.

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 as changes are made to this Standard and/or to the operation itself.

4.2.2 All Grower operations must assure 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 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 erosion and protect wetlands, waterways and other non-cropped areas from degradation due to 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 production under this Standard. Samples must be taken for heavy metal concentration, 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.

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

Guidance: 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 does publish 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

4.3.4 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.

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.

Guidance: Drying can be done in an oven or dehydrator as necessary, especially in more humid climates. Drying temperatures should not be low enough that negative effects on quality is minimized.

4.4.2 Storage of hemp shall be under appropriate conditions of temperature, humidity, and light so that the identity, purity, strength, and composition of the components and hemp are not affected as appropriate for the variety and purpose(s) from 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 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 REQUIREMENTS FOR PROCESSOR/MANUFACTURERS

5.1 PRODUCT SAFETY

5.1.1 Operators must demonstrate their awareness of product quality and 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.

Guidance: Processor/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 comprehensive 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 non-ingestible 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 Directory must 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, inhalable products) must conduct a risk analysis of all activities pertaining to 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 final products meet specifications for contaminants and are free of unspecified materials of any kind.

5.2 Sanitation & Hygiene

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 processing and manufacturing of certified products must employ personal hygiene 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, 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 specify its own requirements for each kind of input (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 maximum allowable THC content.

> 5.3.1.1 A risk analysis or specifications and associated approval procedures must be documented for each kind of input used in certified products, including but not limited to potential 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. This procedure must be followed and documented for each approved supplier, and a current list of approved suppliers maintained.
5.3.3 Sources of approved hemp and hemp-derived inputs must either be (i) certified under the U.S. Hemp Authority Certification Program, with valid certificates maintained on file; or (ii) be verified fully compliant with the U.S. Hemp Authority Standard through the operator's own due diligence, which must be documented.
5.3.4 Operators must always either receive 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.
5.3.5 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.

5.3.6 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.
5.3.7 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.
5.3.8 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 Processor/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 Processor wishes to composite samples, this may be done in a manner that ensures that any single sample exceeding specification limits produces a positive result for the composite sample as a whole.

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.

5.4.3 Laboratories conducting analyses must be accredited to ISO 17025 for the specific tests involved.

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, microbiology and mycotoxins), as required by the Processor/Manufacturer's specifications and in line with 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) are published in the CFR. https://www.ecfr.gov/cgi-bin/ECFR?page=browse. 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/News/LatestNews/tabid/96/ArtMID/1179/ArticleID/226/Default.aspx

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: Extraction processes should remediate the mycotoxin presence in the extracted material. The processor/manufacturer shall establish the microbiological and mycotoxin levels taking into consideration the intended consumer use of the finished product. For guidance, please see 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

Guidance: microbiology limits are based on products consumed orally.

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.

5.4.7 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 5.4.4.

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 final 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 be labeled to at least indicate the product 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 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.

5.6.2 Storage areas 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).

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

5.6.4 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).

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

5.6.6 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 these Guidance Procedures 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 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 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 maintained 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.

5.7.6 Hold and release – Operators must have a system in place to hold (quarantine) 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. 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.

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 processor/manufacturer.

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 BRAND OWNERS

6.1 PRODUCT SOURCING

6.1.1 The Brand Owner must specify its own requirements for each product it sells under this Standard. Specifications for each product must include the full formulation such that label declarations at least reflect legal compliance requirements with respect to ingredient content and maximum allowed contaminants for their product category, as well as for THC content.

Guidance: It is advisable for written specifications to refer to compliance with the U.S. Hemp Authority Standard.

6.1.2 Brand Owners must establish a qualification procedure for all suppliers of certified products. This procedure must be documented as having been followed for each approved supplier, and a current list maintained of approved suppliers.

6.1.3 Sources of approved products must either be (i) from operations certified under the U.S. Hemp Authority Certification Program; or (ii) be verified fully compliant with the U.S. Hemp Authority Standard through the Brand Owner's own due diligence, which must be duly documented.

6.1.4 Brand Owners must receive products with relevant valid analyses already done and documented in accordance with this Standard or must conduct such analyses themselves. The parameters for analyses must be specified per product.

6.2 LABELING

6.2.1 All products labeled 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 follow such requirements on an ongoing basis.

Guidance: Federal regulations that merit compliance 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*

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

6.2.2 For hemp ingredients grown outside the United States, a country-of-origin statement must be included on the label, conspicuous and in close proximity to the name and address of the firm responsible for processing,

manufacturing or distribution of the product, and at least comparable in size of lettering. Country abbreviations are not acceptable.

Guidance: 19 CFR 134 describes country of origin marking requirements. All finished hemp products derived from hemp grown in the United States may be labeled with a statement such as "produced from hemp grown in the U.S."

6.2.3 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).

6.2.4 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.

6.2.5 Nutrition Facts panels and allergen statements must be included on food and beverage products and supplement fact panels must be included on dietary supplement products.

Guidance:

Food and beverage nutrition fact panels should 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 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

6.2.6 Claims must be truthful and not misleading. In particular, claims of products being "free" of certain materials (eg THC, heavy metals, pesticides) or having "zero" content (eg "zero GMOs" or "zero pesticides") are not considered realistic given the limits of analytical detection methods.

6.2.7 No products may have labels or marketing that claim to diagnose, treat, prevent or cure any disease or have therapeutic effects, with the exception of Over-The-Counter topical drug products officially registered in the FDA's National Drug Code Directory.

6.2.8 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.*
- *Use with caution if subject to urinalysis.*

6.2.9 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 be a "best by" or expiration date as long as that can be used to trace to the relevant manufacturing data.

6.2.10 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.

6.3 Storage & Distribution

6.3.1 Brand Owners must have an inventory tracking system in place that updates all stock as changes occur, by storage unit/location.

6.3.2 Storage and distribution units must protect the quality of goods stored by providing adequate space, environmental conditions, and protection from the elements, pests, and potential contaminants (physical, chemical, or biological).

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

6.3.4 Brand Owners must document how they regularly monitor off-site storage units and document their monitoring activities that address compliance with this Standard.

6.3.5 Brand Owners must demonstrate how they verify that transport vehicles are clean and protect certified inputs from damage or contamination.

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

6.4 Quality Control & Records

6.4.1 Brand Owners must maintain records to demonstrate compliance with these Guidance Procedures and have them readily available to certification body personnel. Records must be retained for at least five (5) years,

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

or longer if required by the 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.

6.4.2 Brand Owners' finished products must routinely have had relevant valid analyses already done and documented in accordance with this Standard, in accordance with the requirements for Processor/Manufacturers (refer to sections 5.5 and 5.6). The parameters for analyses must be specified per product.

Guidance: It is recommended that Brand Owners implement a surveillance testing program to reproduce analyses done by the processor/manufacturer.

6.4.3 Samples of inputs and finished products must be maintained 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: Such samples may be retained directly by the Brand Owner, or by the manufacturer of the final product, but in the latter case they must be available to the Brand Owner as necessary to comply with certification requirements.

6.4.4 Complaints – Brand Owners must have a system in place to receive, log, respond to and resolve any complaints received about its products or operations. Minimum components must include the original complaint in the form received, the date, the nature of the complaint, the response, and the resolution. For complaints about dietary supplements, adverse event reporting as legally required pursuant to 21 CFR 111, Subpart O – Product Complaints must also occur. Complaints received only verbally must be documented by the brand owner.

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.