Model Code for Consumable Hemp Products

Co-Authored by

Association of Food and Drug Officials (AFDO) &

Foundation of Cannabis Unified Standards (FOCUS)

FOCUS
Foundation Of
Cannabis Unified Standards

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Introduction

The development of this model code for consumable hemp products is an important milestone for the cannabis industry as it is the result of working with the local, state, tribal, and federal regulators who are taking a proactive interest in how the industry is best served through a sound and effective regulatory framework.

The patchwork of US cannabis regulations at the state level creates enormous challenges for operators and regulators alike, ultimately increasing risks to public health and safety. This standardized regulatory model code is a critical step forward on the path to developing a cohesive regulatory structure for cannabis in the United States and ultimately building better protections for the health and safety of Americans.

By providing regulators guidance, we hope to help the cannabis industry continue its growth through consistent cannabis regulations and safety. The partners believe that in order for cannabis to develop into a federally legal, sustainable industry, there must be a clear understanding of the issues related to safety, quality, and consistency, in conjunction with the importance of effective quality management systems.

About the Association of Food and Drug Officials (AFDO)

Since 1986, AFDO unites high-level regulatory officials, industry representatives, trade associations, academia and consumer organizations. AFDO members strive to foster uniformity in the adoption and enforcement of science-based food, drug, medical device, and cosmetic products safety laws and regulations for improved public health.

About the Foundation of Cannabis Unified Standards (FOCUS)

Established in 2014 as The Cannabis Health and Safety Organization, FOCUS is an independent, unbiased, 501(c)(3) non-profit that addresses the many shortcomings in quality, safety, and consistency that have become evident with the explosive growth of the global cannabis industry. FOCUS exists to help assure the rapidly growing global cannabis industry has the necessary protections in place for the health, safety, success, and welfare of everyone. The autonomy of FOCUS fosters a principled, objective organization that protects end-users, and acts as the much-needed neutral, nonpartisan bridge between industry and regulatory. Since 2016, FOCUS has partnered with AFDO to educate regulators about challenges in the cannabis industry, and the founder of FOCUS has served on the AFDO cannabis committee.

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Preface

The Agricultural Improvement Act of 2018 removed hemp from the Controlled Substances Act. Hemp is defined by the Agricultural Marketing Act of 1946 as "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".

A number of consumable hemp products are being manufactured as food and sold directly to consumers across the United States. Products range from dietary supplements to packaged foods and beverages. Prior to the 2018 legislation, the United States Food and Drug Administration (FDA) has accepted Generally Recognized as Safe Notices for the use in foods of three hemp-derived products, specifically hulled hemp seed (GRN765), hemp seed protein powder (GRN771), and hemp seed oil (GRN778).

At this time, there are no standardized consumable hemp regulations to help guide businesses or regulatory officials in the United States, although some state and local jurisdictions have taken steps toward this common goal by developing their own regulations. Additionally, there is a lack of peer-reviewed literature identifying how the compounds in hemp affect, or are affected by, different food products. With that in mind, the Association of Food and Drug Officials brought together regulatory experts to create this Model Code for consumable hemp products.

This **Model Code for Consumable Hemp Products** focuses on food-safety standards; best efforts were made to base this document on Title 21 of the Code of Federal Regulations and FDA Model Food Code. However, it is apparent that there are some unique challenges that accompany regulating consumable hemp products. As a result, standards developed by Foundation of Cannabis Unified Standards (FOCUS) were also considered.

This Model Code is intended to serve as a minimum standard to support food safety and sanitation concerning consumable hemp products. This document is formatted to be adopted and implemented by any state, local, or tribal jurisdiction, and certain aspects may need additional detail added by some jurisdictions before implementation. For example, the packaging and labeling requirements contained within this document focus mainly on food safety and do not address other specifics that may be required by jurisdictions for consumable hemp products. Restrictions on the content of hemp-derived compounds, like cannabidiol (CBD), in a product were intentionally not

specified. In 2018, the World Health Organization (WHO)'s Expert Committee on Drug Dependence summarized in its *Cannabidiol (CBD) Critical Review Report* that "CBD is generally well tolerated with a good safety profile". (see https://www.who.int/medicines/access/controlled-substances/CannabidiolCriticalReview.pdf)

At this time, peer-reviewed literature identifying therapeutic versus toxic doses of hemp-derived compounds in humans is limited. Additionally, little is known about how the amount of a hemp-derived compound measured in a product translates to an amount absorbed through the gastrointestinal tract and into the circulatory system. There appear to be more than one-hundred cannabinoids, and potentially thousands of phytochemicals in hemp. Due to the potential public health implications, this Model Code was developed to regulate consumable hemp products from a food safety perspective.

Food safety regulation* in the United States is complex, involving more than 2,000 federal, state, and local agencies. Although work at ensuring uniform national food safety law is ongoing, different federal, state, tribal, and local regulations could all apply to a single location intending to manufacture and/or sell consumable hemp products. For that reason, as jurisdictions plan to develop and implement regulations for consumable hemp products, they should be aware of several regulations and resources to avoid conflicts. These include but may not be limited to:

- **9 CFR Parts 300-599** is a federal law relating to the food manufacturing of animal products (specifically meat, poultry, and liquid egg products), enforced by the United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS).
- **21 CFR Parts 1-1299** is a federal law relating to food (other than USDA-regulated products), enforced by the FDA; also called the Food, Drug and Cosmetic Act.
- **FDA 2017 Model Food Code** is a model code that assists food safety jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail and food service segment of the industry (restaurants, grocery stores and institutions such as nursing homes). This document is reviewed every two years by the Conference for Food Protection and updated every four years by the FDA. The latest version is the 2017 Model Food Code, although many state and local jurisdictions still operate under versions based on earlier editions. It is important to check for updates to the Model Food Code to see if there are changes that affect the work being

performed for consumable hemp products at this web address; the 2017 Model Food Code is located here: https://www.fda.gov/media/110822/download.

- **Association of Food and Drug Officials Food Code Pocket Guide** is designed to assist food regulators in the performance of their work (the current version of the pocket guide is based on the 2013 Model Food Code). It is located here: https://www.afdo.org/product/food-code-pocket-guide-for-regulators/
- **Foundation of Cannabis Unified Standards (FOCUS) Standards V.1** are a set of independent, voluntary consensus, cannabis-specific standards designed to create uniformity by addressing all elements related to product quality and safety throughout the cannabis genus supply chain. FOCUS standards are based upon the US Code of Federal Regulations; USDA, FDA, and WHO guidelines for Good Agricultural Practice, Good Manufacturing Practice, and Good Retail Practice; standards of the International Organization for Standardization (ISO) and the Occupational Safety and Health Administration (OSHA); and the Food Safety and Modernization Act (FSMA).
- **Guidance for Industry: Food Labeling Guide** (2013) is the FDA's current thinking on this topic. The Nutrition Labeling and Education Act (NLEA), which amended the Food Drug and Cosmetics Act, requires most foods to bear nutrition labeling and requires food labels that bear nutrient content claims and certain health messages to comply with specific requirements. This document can be located here: https://www.fda.gov/files/food/published/Food-Labeling-Guide-%28PDF%29.pdf
- **Local, State, Tribal, and Federal Regulations**

Historically, preventive food safety measures have proven to be effective when implemented correctly. Regulatory officials at the state, local, and tribal levels should develop regulations for consumable hemp products that are consistent with applicable federal and state regulations. Once the regulations are implemented, regulators should work with industry to educate and implement the new regulations through the development of and compliance with consistent Standard Operating Procedures that support food safety and sanitation.

Note: The Association of Food and Drug Officials does not endorse the use of hemp or consumable hemp products or the incorporation of hemp into foods. This document is solely intended to guide local, state, tribal, and federal regulatory officials if they choose to develop regulations for consumable hemp products.

* *Important Note: The terms "regulation", "law", "ordinance", and "code" are essentially synonyms, and all are used to refer to legal requirements enforced by different jurisdictions. Code can have two meanings: A "model code" such as the FDA's "2017*

Food Code" and this "Model Code for Consumable Hemp Products" refer to a non-regulatory document that is intended to serve as a model for state, local, and tribal jurisdictions as they formulate their own regulations. Once the model code language is incorporated into state, local, and tribal regulation, in whole or in part, with or without edits, by adoption or by reference, the language then becomes binding food safety legal requirements at the state, local, or tribal level.

Model Code for Consumable Hemp Products

1. Scope

The purpose of this Code is to safeguard public health and to provide consumable hemp products that are safe, unadulterated, and honestly presented.

This Code:

A. Provides the minimum safety and sanitation requirements to manufacture, store, or transport consumable hemp products and ingredients intended for human consumption;

B. Provides the minimum safety and sanitation requirements for retailers to receive, store, and distribute consumable hemp products intended for human consumption; and

C. Is only intended to supplement local, state, tribal, and/or federal food safety codes when the finished product will contain hemp or hemp-derived ingredients and is intended to be consumed by mouth.

2. Definitions

A. In this Code, the following terms have the meanings indicated.

B. Terms Defined.
   1) **Adequate**: that which is needed to accomplish the intended purpose in keeping with good health practices.
   2) **Allergen cross-contact**: allergen cross-contact occurs when an allergen is inadvertently transferred from a food containing an allergen to a food that does not contain the allergen. Cooking does not reduce or eliminate the chances of a person with a food allergy having a reaction to the food eaten.
   3) **Approved source**: a source of food ingredients, including hemp or hemp-derived ingredients that is approved, licensed, and regulated by the appropriate authority based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

4) **Batch**: a defined quantity of hemp or hemp material that is intended to have uniform character and quality, within specified limits, and is produced during the same cycle.
5) **Cannabinoid**: any of the various naturally occurring, biologically active, chemical constituents of cannabis such as:
    a. cannabidiol (CBD)
    b. tetrahydrocannabinol (THC).
    c. THC-A
    d. CBD-A
    e. Cannabinol (CBN)
6) **Cannabis**: the Latin name of the plant that, depending on its THC concentration level, is further defined as either “hemp” or “marijuana.” Cannabis is a genus of flowering plants in the family *Cannabaceae* of which *Cannabis sativa* is a species, and *Cannabis indica* and *Cannabis ruderalis* are subspecies thereof. For the purposes of this Model Code, Cannabis refers to any form of the plant where the tetrahydrocannabinol (THC) concentration on a dry weight basis has not yet been determined. This term is important in describing regulations that apply to plant production, sampling or handling prior to determining its THC content.
7) **CBD**: stands for cannabidiol, a naturally occurring, non-psychoactive cannabinoid found in the cannabis plant.
8) **Certificate of Analysis**: documentation supplying evidence and traceability from a verifiable source for a description of the test or examination method(s) used, limits of the test or examinations, and actual results of the tests or examinations for a food ingredient.
9) **Consumable hemp product**: a food, food product, or ingredient that contains hemp, or one or more hemp-derived cannabinoids, including CBD, that is intended for oral consumption by a human.
    a. **Consumable hemp product** does not include any:
        i. Hemp extracts intended for inhalation or injection;
        ii. Hemp-containing products including a wax, an ointment, or a salve intended for topical application and not oral consumption; or
        iii. Cosmetics, suppositories, eye drops, or other products containing hemp that are not intended for oral consumption.
10) **Contamination**: microbiological, chemical, radiological, or physical substances that either develop in or are added to consumable hemp products or ingredients and are capable of causing consumable hemp products or an ingredient to be unsafe for human consumption or in violation of a regulatory standard.

11) **Corrective action**: any action or set of steps to be taken when the results of monitoring a critical control point indicate there may be potential for contamination of a consumable hemp product or hemp-derived ingredient.
12) **Critical control point**: means a point, step, or procedure in a process at which a control measure can be applied and at which control is essential to reduce an identified hazard to an acceptable level.
13) **Critical factor**: a property, characteristic, condition, aspect, or another parameter, which, if varied, may affect an approved scheduled process and the attainment of commercial sterility.
14) **Dry weight basis**: refers to a method of determining the percentage of a chemical in a substance after removing the moisture from the substance.
15) **Employee**: person on the payroll, volunteer, person performing work under contractual agreement, person having supervisory or management duties, or other person working in a consumable hemp facility.
16) **Facility**: a location at which an operator manufactures, produces, or sells consumable hemp products.
17) **Food**: a raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.
18) **Food allergen**: typically naturally-occurring proteins in foods, ingredients, or derivatives of them that cause abnormal immune response. The 8 major food allergen groups are: milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans.
19) **Hazard Analysis and Critical Control Point (HACCP) plan**: a detailed, systematic approach that identifies, evaluates, and controls quality hazards for each that are reasonably likely to occur during processing.
20) **Hemp**: the plant *Cannabis sativa L.* and any part of that plant, including the seeds there-of and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with delta-9 tetrahydrocannabinol concentrations of not more than 0.3 percent on a dry weight basis.
21) **Hemp refuse**: unauthorized, misbranded, contaminated, unused, surplus, returned, post-extraction or out of date hemp plant material, hemp concentrates, consumable hemp products, hemp-infused products, recalled hemp or finished products, and any plant debris, including dead plants, all unused plant parts, and roots.
22) **Ingredient**:
    a. any component of a consumable hemp product including but not limited to:
        i. Hemp in its whole plant form or any parts thereof;

ii. A hemp extract; or
iii. Additives (any substance the intended use of which results or may reasonably be expected to result -- directly or indirectly -- in becoming a component or otherwise affecting the characteristics of any hemp product), including:
    a) Color additives (any dye, pigment or substance which when added or applied to a food is capable [alone or through reactions with other substances] of imparting color).; or
    b) Flavors; or
    c) Preservatives (prevent food spoilage from bacteria, molds, fungi, or yeast; slow or prevent changes in color, flavor, or texture, and delay rancidity; maintains freshness); and

b. must be from an approved source.

23) **Label** or **Labeling**: a display of written or graphic matter on the container, other than the package liner, that is on a:
    i. Consumable hemp product container; or
    ii. Consumable hemp product; and
    a. Accompanies a consumable hemp product; and
    b. Must be attached to any consumable hemp product prior to leaving a facility without exception.
24) **Lot**: a specific identified portion of a batch with uniform character and quality that is intended to meet specifications for identity, purity, strength, and composition.
25) **Manufacturing** or **processing**: as it relates to consumable hemp products, means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing or processing activities include: baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating or extracting raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing.
26) **Non-working area**: an area that is not used for product or raw material processing or storage activities, such as an office or an area intended for employees to store personal items and take their breaks.
27) **Operator**: a company that is manufacturing or selling consumable hemp products that is licensed through a regulatory authority.

28) **Packaging**: any type of container, wrapping, or other type of vessel intended to hold a consumable hemp product.
29) **Pest**: any objectionable animals or insects, including, but not limited to, birds, rodents, and insects.
30) **Recall**: an operator's removal or correction of a marketed consumable hemp product that a regulatory authority considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery.
31) **Recall plan**: a plan for actions taken by a facility to remove a product from the market.
32) **Regulatory authority**: the local, state, tribal, or federal enforcement body or authorized representative having jurisdiction for regulating a food processing facility, hemp processing facility, or hemp growing facility.
33) **Sanitize**: to adequately treat product contact surfaces, equipment, containers, utensils or any other 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 undesirable microorganisms, without adversely affecting the product or its safety to the consumer.
34) **Scheduled process**: a method or set of procedures that takes into account the critical factors that may impact the safety or stability of a consumable hemp product or an ingredient.
35) **Segregated area**: an area within a facility in which consumable hemp products or ingredients that may be contaminated, spoiled, unwholesome, vermin-infested, insect-infested, over the legal limit of THC, or otherwise requiring further action are clearly identified and temporarily stored away from other products and ingredients, prior to disposal or collection.
36) **Standard operating procedure** or **SOP**: an established method to be followed routinely for the performance of designated operations or in designated situations.
37) **TCS food** or **Time/temperature control for safety food**: a consumable hemp product that requires time and temperature control for safety to limit pathogenic microorganism growth or toxin formation. See additional information in the FDA Model Food Code 1-2 Definitions.
38) **Temperature measuring device**: a thermometer, thermocouple, thermistor, or other device that indicates the temperature of products, air, or water.
39) **THC**: tetrahydrocannabinol, is the primary psychoactive compound of cannabis.

3. Licensed Consumable Hemp Product Manufacturers

A. Prior to manufacturing, packaging, or distributing any consumable hemp product, manufacturers shall:
   1) Be licensed by the appropriate regulatory authority;
   2) Ensure all types of consumable hemp products, ingredients, packaging, and labeling meet:
      a. The requirements established within this; and
      b. All applicable local, state, tribal, and federal regulations.

B. The operator shall ensure that compliance with this Code is continuous and not intermittent.

C. The regulatory authority may deny a license to make consumable hemp products based on:
   1) The inability of an operator to meet the standards set forth in this Code and maintain a safe environment for consumable hemp products to be manufactured; and
   2) The operator's inability to demonstrate an understanding of safety and sanitation procedures necessary to prevent contamination of consumable hemp product or ingredients.

D. All standard operating procedures (SOPs) and scheduled processes performed in the facility are limited to those approved by the appropriate regulatory authority upon initial approval to operate and during inspections.

E. The facilities and any equipment associated with the premises shall be designed, operated, and maintained in a good state of repair and in compliance with:
   1) This Code; and
   2) Any other applicable local, state, tribal and federal regulations.

F. Education and training in food handling, personal hygiene, facility sanitation, processing, storage, and transport of consumable hemp products is provided in accordance with approved scheduled processes, in compliance with this Code, and any other applicable state and federal regulations, and as applicable to the employee's job.
   1) Training must be documented;
   2) Training must apply to the employee's actual duties;
   3) Records of employees must be kept for two (2) years or as required by the regulatory authority; and

4) All records must be made available to any regulatory authority upon request.

G. The regulatory authority may deny or revoke a licensed processor's permission to make consumable hemp product products if they:
   1) Violate or fail to meet the requirements of this Code; or
   2) Any other applicable local, state, tribal and federal regulations; or
   3) Fraudulently or deceptively obtain a license; or
   4) Are found to be distributing consumable hemp products other than those approved by the regulatory authority.

4. Process Plan and Facility Requirements

A. The operator shall ensure that a properly prepared process plan and specifications are submitted to the regulatory authority for initial approval to operate and again during each inspection.

B. A process plan shall include the following information:
   1) Intended consumable hemp product to be processed;
   2) Anticipated volume of consumable hemp product to be processed;
   3) Anticipated number of employees and their roles.
   4) A scale drawing that adequately represents the:
      a. Proposed layout and arrangement of work areas;
      b. The flow of all ingredients, packaging/labeling materials, and consumable hemp products from the point of receiving through all steps of the manufacturing, packaging, and labeling processes, including inventory storage procedures, to the point at which finished consumable hemp product leave the premises;
      c. Location of any equipment involved in processing, including, but not limited to:
         i. Exhaust ventilation hoods; and
         ii. Location of plumbing and plumbing fixtures such as water lines, sewer lines, hand sinks, toilets, utility sinks, utensil washing sinks, floor drains, floor sinks, and hose stations; and
   5) Manufacturer and model number of all equipment;
   6) Specifications for the:
      a. Construction materials used inside the building and interior finishes;
      b. Storage and disposal of all refuse materials;
      c. Disposal of sewage;
      d. Provision of potable water;

e. Ventilation of the premises and individual areas within the premises;
f. Processing equipment;
g. Shipping facilities;
h. Lighting.

7) Written SOPs for:
   a. Receiving and storing ingredients;
   b. Repackaging bulk ingredients into smaller quantities to prevent contamination;
   c. Processing all consumable hemp products, which includes, but is not limited to:
      i. A standardized recipe for each type of consumable hemp product;
      ii. All steps in the manufacturing process;
      iii. Packaging;
      iv. Labeling; and
      v. Bulk packaging;
   d. Allergen control and the prevention of allergen cross-contact:
      i. If allergens are used in any product or product component, the operation must implement written procedures to control the purchase, storage, handling and integration of allergens; workers must be trained and demonstrate required controls.
      ii. The operation must document and maintain a current and complete list of all potential allergens and sensitizing chemicals used.
         a. Major allergens include proteins from peanuts, tree nuts, crustacean shellfish, fish, dairy, egg, soy and wheat.
         b. The allergen list should define where and how the allergen is used in the production process.
   e. Prevention and detection of other hazards, i.e., debris and dirt;
   f. Shipping and transport of consumable hemp;
   g. Planned distribution of the finished product;
   h. Scheduled processes for all applicable steps that outline corrective actions;
   i. Employee and facility sanitation; and
   j. Monitoring activities and records to be maintained.
8) A written recall plan;
9) All critical control points and their associated scheduled processes.

C. The regulatory authority shall:

1) Review the process plan and its specifications to ensure compliance with all applicable state, local, tribal, and federal regulations;
2) Inform the operator in writing:
    a. Of additional information that may be required; and
    b. Following the review, whether the plans and specifications are approved or denied; and
    c. If applicable, based on the laws of the jurisdiction, provide the operator with information about how to appeal the decision.

D. The design, construction, maintenance, and operation of the facility and the flow of ingredients, packaging materials, labeling materials, and consumable hemp products through the facility shall minimize the:
1) Potential for contamination with or growth of pathogenic microorganisms;
2) Potential for allergen cross-contact contamination:
    a. Allergens and allergen-containing materials must be handled and stored using methods that avoid cross-contaminating all other materials, raw materials or work-in-process with allergens.
    b. All allergens must be clearly labeled; all allergen-containing products must be labeled as required by the FDA Food Allergen Labeling and Consumer Protection Act of 2004, and
    c. The operation shall maintain a documented allergen validation process to verify sanitary conditions including testing methods.
3) Access by vermin and insects to:
    a. Ingredients;
    b. Consumable hemp product;
    c. The facility; and
4) Harborage of vermin and insects.

E. Equipment needed for effective cleaning of the facility and for cleaning and sanitizing consumable hemp product and ingredient contact or non-contact surfaces must be provided and maintained in a sanitary condition.

F. Ingredients or consumable hemp products are processed or stored in a room or area that shall:
1) Be separated from employee-use rooms (i.e., toilets, locker rooms), non-working areas, refuse storage, mechanical room, or other rooms or areas where potential sources of contamination may occur in the facility by the use of walls, ceilings, and self-closing, tight-fitting doors; and
2) If not refrigerated, be mechanically ventilated using exhaust and supply fans so that:

a. Excessive grease vapors, steam, condensation, heat, and odors are removed;
b. Filtered air is supplied to provide a positive air pressure in the room;
c. Condensation and grease do not accumulate on room surfaces and equipment; and

3) Have a floor, walls, and ceiling that are smooth, washable, easily cleanable, and impervious to water; and
4) Have floor-wall junctures that are:
   a. Coved;
   b. Sealed;
   c. Impervious to water; and
5) Have only the exposed overhead pipes, ducts, conduits, evaporators, and other structures that are needed for proper processing, that:
   a. May not be located over ingredient or consumable hemp product storage, preparation, manufacturing, packaging, or labeling areas; and
   b. Shall be installed so that ingredients and consumable hemp products are protected against leakage or other contamination.

G. Utensils or equipment are cleaned, sanitized, or stored in a clean, protected location and manner to prevent contamination of ingredients or consumable hemp products.

H. Handwashing sinks shall:
1) Be for the sole purpose of handwashing;
2) Be easily accessible to employees;
3) Number at least one and be the number of sinks necessary for their convenient use by employees;
4) Provide warm water under pressure with sufficient volume for effective handwashing procedures; and
5) Be provided with:
   a. Soap
   b. Single use towels and a covered waste receptacle or
   c. Warm air dryers; and
   d. A clearly visible sign or poster that notifies the employees to wash their hands.

I. Rooms must have lighting:
1) That provides a minimum of:
   a. 50 foot-candles of light on all work surfaces used for processing and working with utensils;

b. 20 foot-candles of light at a distance of 30 inches from the floor in areas used for handwashing and ware-washing; and
c. 10 foot-candles of light at a distance of 30 inches from the floor in storage areas.

2) If artificial, lighting must consist of:
   a. Shatter-resistant bulbs; or
   b. Light shields that:
      i. Protect exposed light bulbs or light fixtures that are not shatter-resistant from breakage by potential direct impact; and
      ii. Prevent glass fragments from a bulb or light fixture that breaks or explodes from contacting ingredients, consumable hemp products, or contact surfaces.

J. When a floor receives liquid (such as water) as a result of processing or cleaning, the floor shall be sloped to one or more floor drains at a pitch of 1/8 to 1/4 inch per foot;
   1) The floor drains shall:
      a. Effectively remove all water from the floor;
      b. Be constructed to ensure water will be moved into the floor drains at a frequency that prevents water from pooling at the rate of a minimum of one floor drain for each 400 square feet of floor area;
      c. Receive only refuse water that must be directed to the floor, such as water from:
         i. Cleaning the floor or other room surfaces;
         ii. Cleaning equipment;
         iii. Ice used in processing; and
         iv. Incidental splash from equipment; and
   2) Standing water is not allowed.

K. The operator shall ensure that toilet rooms:
   1) Do not open directly into an area in which:
      a. Ingredients or consumable hemp products are stored, processed, packaged, or labeled; or
      b. Containers, utensils, or equipment are washed or held; and
   2) Are adequately supplied with:
      a. At least one toilet and not fewer than the toilets required by law. If authorized by law and urinals are substituted for toilets, the substitution shall be done as specified in law;
      b. Ventilation having:

i. Mechanical air exhaust and entrance of an equal amount of makeup air at the rate of two cubic feet per minute of air for each square foot of floor area; or
ii. A screened window that allows the entrance of outside air; and

c. Easily cleanable and durable walls and ceiling;
d. A smooth, impervious, and easily cleanable floor;
e. A tight-fitting, self-closing door;
f. A handwashing sink in or immediately adjacent to the toilet room (see previous Section 4, subsection H).

L. The grounds around a facility are:
1) Maintained free of:
a. Unused equipment;
b. Debris;
c. Litter;
d. Refuse;
e. High weeds;
f. Grass that provides an attractant, breeding place, or harborage for vermin and insects; and
2) Adequately drained to:
a. Promote sanitation;
b. Prevent breeding places for insects and vermin.

M. The disposal of all refuse from a facility, including trash, hemp refuse, hazardous refuse, and liquid refuse shall be performed in a manner consistent with local, state, tribal, and federal laws. (see Section 19 -- Refuse and Refuse Disposal, all subsections)

5. Critical Control Points

A. A facility that either manufactures, stores, or distributes consumable hemp products must have all SOPs and scheduled processes reviewed and approved upon initial approval to operate and during inspections, to the extent that the regulatory authority deems necessary to ensure safety, sanitary conditions, and prevent possible contamination of consumable hemp products or ingredients used during processing;
1) Scientific evidence including stability or challenge studies may be required to demonstrate the safety, consistency, and stability of any traditional food product that has had hemp incorporated as an ingredient. These may include:

a. Challenge studies for the validation of food safety processing procedures, product storage conditions, and shelf life include pathogen growth inhibition studies, pathogen inactivation studies, and combination growth and inactivation studies.

b. Shelf-life studies involve the testing of consumable hemp products to determine the length of time a product may be stored under defined conditions during which the product remains safe, retains desired sensory, chemical, physical, and biological characteristics as well as complies with any label declaration.

2) A formal Hazard Analysis and Critical Control Point (HACCP) plan may be required by the regulatory authority. HACCP plans shall be in compliance with 21 CFR § 120.8 Hazard Analysis and Critical Control Point (HACCP) plan - Code of Federal Regulations (ecfr.io).

B. During storage, transportation, processing, and transfer, including the time at a transfer station, consumable hemp products and any ingredients must be kept in a manner that:
   1) Prevents contamination;
   2) Inhibits pathogen growth; and
   3) Ensures wholesomeness.

C. Each manufacturing or processing operation, such as receiving, holding, thermal processing, chilling, freezing, packaging, labeling, storing, and transporting, shall be evaluated to determine whether the step is a critical control point;
   1) A hazard analysis shall be conducted;
   2) A processing operation that is deemed to be a critical control point shall be carried out based on approved scheduled processes to prevent potential hazards to public safety and is monitored to verify control;
   3) Production records shall be maintained that:
      a. Document compliance with the requirements established by approved SOPs, scheduled processes, this Code, and any applicable local, state, tribal, and federal regulations;
      b. Identify which employee is responsible for monitoring and controlling the critical control point; and
      c. Identify an approved source of the ingredients that are stored and processed in the facility and provide the following:
         i. The name, address, and telephone number of the source;
         ii. The name, address, and telephone number of the transporter of the ingredient from the source to the facility;

iii. The type of ingredient received, including identifying information such as brand name, statement of identity, or, if applicable, the licensed grower or processor that produced any hemp or hemp extract used in the consumable hemp products;
iv. A lot number, batch number, or other identifier, if available;
v. The date the ingredient was received; and
vi. All identifying lot numbers of the consumable hemp products into which the specific ingredients will be incorporated.

D. Scheduled processes shall take into account the critical factors that may impact the safety or stability of a consumable hemp product or an ingredient and shall:
   1) Ensure the safety of the consumable hemp product;
   2) Describe corrective actions for each critical control point that include;
      a. Action to be taken if the critical limits for each critical control point are not met;
      b. Who is responsible for implementing the corrective actions;
      c. What records will be developed and maintained of the actions taken; and
      d. Length of time for retention, i.e., two (2) years, or as required by the regulatory authority.
   3) Be taught to employees, and made available to all employees in a language they understand;

E. When monitoring and verifying temperatures at a critical control point, one or more continuous monitoring thermometers must be provided that:
   1) Document the air temperature within a temperature-controlled room or vehicle area at a time interval not to exceed one hour;
   2) Produce a record that can be made available to the regulatory authority or any other local, state, tribal, or federal regulatory agency;
   3) Are accurate to within ± 3° Fahrenheit;
   4) Are validated at least monthly; and
   5) Are calibrated in accordance with the manufacturer's recommendations.

6. Receiving

A. All activities involved with receiving ingredients or other supplies must be performed in a designated area identified in the process plan.

B. All receiving areas must have an appropriate barrier that separates processing areas and can reasonably prevent entry of:

1) Insects;
2) Vermin;
3) Pathogenic microorganisms;
4) Toxic or deleterious chemicals;
5) Foreign matter; or
6) Dust.

C. Dock and overhead doors are to be open only when ingredients, consumable hemp products, refuse, or other items are being:
   1) Received;
   2) Removed from premises; or
   3) Moved between receiving areas.

D. Receiving logs shall include:
   1) Date and time of delivery;
   2) Name and quantity of products received;
   3) Identifying number (batch/lot number) of each item received;
   4) Name of the product manufacturer or operator and, if different, the name of the delivery company;
   5) Name of employee who received the shipment; and
   6) Be maintained for two (2) years or as required by the regulatory authority.

E. All deliveries must be inspected for damage and potential contamination;
   1) TCS-food ingredients must have their temperature checked, documented at time of arrival to the facility, and information retained; and
   2) Reports of out-of-control temperature, damaged, or contaminated deliveries shall be recorded in receiving logs with the name of the employee performing the delivery inspection and shall be:
      a. Reviewed, signed by the reviewer, and dated within one (1) week of the occurrence;
      b. Maintained for two (2) years or as required by the regulatory authority; and
      c. Made available to the regulatory authority or any other local, state, tribal, or federal regulatory agency upon request.

F. All ingredients must be clearly labeled with the:
   1) Name of ingredient;
   2) Identifying batch or lot number;
   3) Date the ingredient was received at the facility; and
   4) Expiration or use-by date.

G. If an ingredient has been removed from its original packaging, its new packaging must be clearly labeled with the:
    1) Name of ingredient;
    2) Identifying batch or lot number from original package;
    3) Date the ingredient was removed from its original package;
    4) Date the ingredient was received at the facility; and
    5) Expiration or use-by date.

H. All ingredients must be traceable to their sources and must have an authentic Certificate of Analysis from a traceable source.

I. Spoiled, unwholesome, vermin-infested, or insect-infested ingredients are not allowed in the facility and shall be:
    1) Removed immediately from the premises and properly disposed; or
    2) Placed in a segregated area temporarily until proper disposal if:
        a. Not practicable to remove immediately; or
        b. Required to be collected by a local, state, tribal, or federal regulatory agency for examination or testing.

7. Storage

A. All ingredients and consumable hemp products shall be kept in secure controlled environments that meet the requirements set forth in this Code and are considered either a dry storage area, refrigerated storage area, or freezer storage.

B. Storage SOPs shall preserve freshness, prevent contamination, and maintain stability of any ingredients or consumable hemp products.
    1) The operation must implement written procedures to control storage areas and provide specific storage procedures for raw (cured) hemp, and consumable hemp products.

C. This Code applies to all storage areas; however, hemp may need to be stored in separate areas that meet any applicable security requirements determined to be necessary by the regulatory authority.
    1) All storage areas should be constructed of easily cleaned materials (non-porous, non-toxic) and with limited unreachable, difficult-to-clean areas.
    2) Air filters or scrubbers should be installed and used as appropriate.

D. Shelf-stable ingredients shall be:
    1) Stored on food-safe shelving that is a minimum of:
        a. 6 inches off the floor; and
        b. 18 inches away from walls; and
    2) Stored away from sources of heat and light.

E. Palletized ingredients may be stored on the floor for a specified period of time pending:
    1) Shipment;
    2) Movement to allow cleaning; or
    3) Relocation to permanent storage racks.

F. Dry storage areas may be used to store packaged or containerized bulk food that is not TCS food or ingredients and shall:
    1) Be maintained between 50°– 70° Fahrenheit;
    2) Have adequate ventilation to control humidity and prevent the growth of pathogenic microorganisms;
    3) Have a thermometer in plain sight and easily accessible for checking;
    4) Have smooth, impervious, and cleanable floors;
    5) Have walls and a roof and ceiling that:
        a. Are vermin and insect proof; and
        b. Afford protection against the weather; and

G. Refrigerated storage areas shall:
    1) Be maintained between 32º– 41° Fahrenheit;
    2) Have readily observable thermometers that are:
        a. Easily read;
        b. Accurate to ±3° Fahrenheit; and
    3) Have a temperature sensor that is positioned to register the warmest air in the refrigerated space to verify adequate cooling or several thermometers placed throughout the area for accuracy and consistency in temperature reading.

H. Refrigerator units shall:
    1) Have an appropriate amount of open, slotted shelves to allow for proper air circulation around shelves and refrigerator walls to maintain proper food temperatures; and
    2) Have doors that have a good seal and close tightly to maintain the temperature and efficiency of the unit.

I. Freezer storage areas shall:
   1) Be maintained at or below 0° Fahrenheit;
   2) Have readily observable thermometers that are:
      a. Easily read;
      b. Accurate to ±3° Fahrenheit; and
   3) Have temperature sensors that are positioned to represent the actual storage temperature, or several thermometers placed throughout the area for accuracy and consistency over a larger area;

J. Freezer units shall:
   1) Have an appropriate amount of open, slotted shelves to allow for air circulation around shelves and freezer walls to maintain adequate food temperatures; and
   2) Have doors that have a good seal and close tightly to prevent heat gain.

K. In the case of a power outage:
   1) The facility must install and maintain a standby power source and automatic switch-over controls for all smoke and gas alarms, detection meters, ventilation systems, lighting, and other emergency systems.

L. Foods and food ingredients that require time/temperature control for safety (TCS):
   1) The internal temperature of TCS food and ingredients must be kept at:
      a. 41° Fahrenheit or less; or
      b. 135° Fahrenheit or greater; and
   2) The internal temperature of foods and food ingredients with a non-proteolytic *Clostridium botulinum* potential hazard (such as reduced oxygen packaging with one barrier), which includes consumable hemp concentrates, is kept at 38° Fahrenheit or less during refrigerated storage;
   3) When a TCS food or food ingredient is kept at temperatures other than these, an approved scheduled process specifying a temperature and time at that temperature must be used;

M. All storage areas shall be maintained in a clean and sanitary condition;
   1) Breakage and spills in storage areas are cleaned up immediately; and
   2) Toxic and obnoxious odors and fumes are prevented from accumulating in storage areas.

N. All ingredients and consumable hemp products shall be clearly labeled and stored in a manner that:

1) Facilitates first-in and first-out procedures; and
2) Ensures the ingredients are fit for human consumption and fit for purpose.

O. Dry, refrigerated, or freezer storage areas:
   1) Shall, if not continuously monitored, have their temperature and humidity documented at least two (2) times daily during hours of operation, without exception, ideally upon opening and before closing;
   2) Shall have clearly posted records of their temperature, humidity, and the employee responsible for recording the temperature and humidity; and
   3) All records of the temperature and humidity, as well as any corrective actions taken, are maintained for two (2) years, or as required by the regulatory authority.

8. Equipment

A. Any ingredients or consumable hemp products intended for human consumption shall be prevented from coming into contact with a surface or substance other than a surface or substance intended for food contact or incorporation into food.

B. Heating and cooling media that are in close contact with ingredients or consumable hemp products, such as those in plate heat exchangers, shall be food grade, generally recognized as safe per federal regulations, or, through equipment design, provided a minimal chance of contacting any aspect of the finished consumable hemp product.

C. Cleaning and Sanitizing Equipment
   1) Warewashing machinery must be operated in accordance with manufacturers recommendations and must be compliant with applicable laws.
      a. A log indicating date, time, and name of employee performing the activity must be maintained each time the cleaning method is used; and
         i. Logs must be kept for two (2) years, or as required by the regulatory authority;
         ii. Logs must be made available to the regulatory authority or any other local, state, tribal, or federal regulatory agency upon request.

D. Equipment used for processing ingredients and consumable hemp products must be:

1) Designed and constructed for its intended use;
2) When associated with a critical control point, provided with instrumentation or ensure monitoring to allow:
    a. The control of critical factors;
    b. The monitoring of critical factor control and implementation of a scheduled process; and
    c. Verification of process control; and
3) Maintained in a sanitary and working condition;
4) Monitored to verify that process requirements are met; and
5) Tested and calibrated, following manufacturer's instructions, to ensure accuracy.

E. Materials used as contact surfaces of equipment and utensils must be:
    1) Nontoxic and do not impart toxic or deleterious matter to ingredients or consumable hemp products;
    2) Inert to the ingredients used to make consumable hemp products and do not migrate to or contaminate consumable hemp products;
    3) Nonporous and nonabsorbent;
    4) Corrosion-resistant;
    5) Durable;
    6) If stainless steel, made of stainless steel of American Iron and Steel Institute Type 304, or equivalent; and
    7) Maintained in good condition.

F. Contact surfaces of equipment and utensils must be designed, constructed, and maintained to be:
    1) Smooth;
    2) Easily cleanable;
    3) Free of difficult to clean internal surfaces;
    4) Self-emptying or self-draining if an interior surface;
    5) Visible for inspection or readily disassembled for inspection;
    6) If equipment and utensils are manually cleaned, they must be:
        a. Readily accessible for cleaning without having to dissemble; or
        b. If not readily accessible, readily disassembled for cleaning with the use of simple tools kept available near the equipment; and
    7) If equipment and utensils are cleaned and sanitized by pressurized cleaning-in-place (CIP), they must be readily accessible to the cleaning and sanitizing solutions without disassembly.

G. Equipment not used to make consumable hemp products that receives splash or refuse must be smooth and easily cleanable.

H. The operator shall use equipment that is certified or classified for sanitation as complying with recognized food equipment standards, such as those published by the:
   1) National Science Foundation (NSF);
   2) American National Standards Institute (ANSI);
   3) Bakery Industry Sanitation Standards Committee;
   4) Underwriters Laboratory (UL);
   5) American Society for Testing and Materials (ASTM).

I. Food temperature measuring devices:
   1) Shall not have sensors or stems constructed of glass, except that thermometers with glass sensors or stems that are encased in a shatterproof coating such as a candy thermometer may be used;
   2) Shall be accurate to ±2° Fahrenheit in the intended range of use; and
   3) Shall be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy.

J. Temperature measuring devices used to monitor and/or verify the temperature of food, ingredients, and temperature-controlled storage units shall be calibrated for accuracy based on the manufacturer's recommendations, and periodically verified. Calibration logs must be maintained.
   1) Calibration or accuracy check logs must contain:
      a. The employee's name who performed the calibration or accuracy check;
      b. The temperature measuring device's unique identification number;
      c. The area of the facility the unit is in, which shall correspond with the facility layout in the approved process plan;
      d. The method of calibration or accuracy check used; and
      e. Any approved standard that was used in the calibration or accuracy check process;
   2) Logs must be:
      a. Maintained for two (2) years or as required by the regulatory authority; and
      b. Made available to the regulatory authority or another local, state, tribal, or federal regulatory agency upon request.

9. Cleaning and Sanitation Procedures

A. Surfaces that will come into contact with consumable hemp products or ingredients are cleaned and sanitized:
   1) Using a process that is scientifically proven to remove soils and kill pathogens, for example:
      a. Remove all soil on surfaces with warm, soapy water;
      b. Wash with clean water;
      c. Dry as to not dilute sanitizing solution;
      d. Wipe down surface with approved sanitizing solution at the appropriate concentration in accordance with the EPA-registered label use instructions for the sanitizing solution. (see FDA Model Food Code sections 4-501.114 and 7-204.11); and
      e. Allow to air dry;
   2) As often as needed to prevent contamination;
   3) At a minimum:
      a. Following processing;
      b. When there is an interruption in processing of greater than two (2) hours;
      c. When there is a change from working with raw foods to working with ready-to-eat foods;
      d. Between uses with raw fruits and vegetables and with TCS food;
      e. At a frequency to prevent allergen cross-contact;
      f. If processing TCS consumable hemp or ingredients, at least every four (4) hours.

B. When a time greater than four (4) hours separates the start of processing from previous cleaning and sanitizing, surfaces that come into contact with consumable hemp products or ingredients are cleaned and sanitized again before processing resumes; [Refer to FDA Model Food Code sections 4-602.11, 4-602.12, and 4.602.13]

C. The cleaning and sanitizing schedule and procedure used must be shown through scientific study to kill pathogens on the treated surfaces and comply with this Code.

D. When a clean-in-place (CIP) system is used:
   1) Cleaning and sanitizing agents are:
      a. Fully circulated through a fixed system to contact all interior product contact surfaces;

b. Effective in cleaning and sanitizing consumable hemp products contact surfaces; and
c. Used in accordance with the chemical manufacturer's instructions; and

2) The design, construction, maintenance, and operation of the piped CIP system:
   a. Prevents the contamination of consumable hemp products and ingredients by cleaning and sanitizing agents;
   b. Must ensure that the system can completely drain cleaning and sanitizing solutions; and
   c. Is validated; and
3) The operation of the piped CIP system using chemicals that are potentially hazardous to public health is a critical control point that shall be controlled, monitored, and documented as set forth in the “Critical Control Points” section of this Code.

E. Surfaces in the facility or equipment surfaces that do not contact consumable hemp products or ingredients and do not receive splash or refuse are cleaned as often as necessary to maintain sanitary conditions by:
   1) Removing soils; and
   2) If wet, including the use of detergents or other cleaning agents.

F. Steam or compressed air that is used for cleaning shall be free from deleterious or harmful matter that might contaminate consumable hemp products or ingredients.

G. When cleaning and sanitizing, all consumable hemp products, ingredients, and packaging should be protected from contamination by any aspect of the cleaning or sanitizing process or removed from the area being cleaned.

H. When equipment and utensils are washed, rinsed, and sanitized using a three-compartment sink:
   1) Perform warewashing as described in FDA Model Food Code section 4-603.14, 4-603.15, and 4-603.16.
   2) Each sink compartment shall be large enough to accommodate immersion of the largest equipment and utensils. If equipment and utensils are too big for a warewashing machine. Refer to FDA Model Food Code section 4-301.12.
      a. An approved SOP for cleaning and sanitizing the piece of equipment must be outlined and kept in the designated area;
      b. Employees shall be trained to clean these items properly.

3) A temperature measuring device shall be provided and readily accessible for frequently measuring the washing and sanitizing temperature.
    a. Hot sanitization is accomplished in water ≥170° Fahrenheit.
4) The washed, rinsed, and sanitized items air dry before stacking or nesting;
5) Items shall not be cloth dried except for utensils that have already been air-dried, which may be polished with cloths that are maintained clean and dry.

I. Dry cleaning:
    1) If used, dry cleaning methods such as brushing, scraping, and vacuuming shall contact only surfaces that are soiled with dry food residues that are not TCS for food safety.
    2) Cleaning equipment used in dry cleaning food-contact surfaces may not be used for any other purpose.

J. Consumable hemp products or ingredient contact surfaces, utensils, equipment, and general facility surfaces are cleaned or cleaned and sanitized as set forth in written sanitation SOPs that:
    1) Are available to employees in a form they understand; and
    2) Ensure proper sanitation throughout the facility.

K. Documentation:
    1) A log indicating date, time, and name of employee performing the cleaning must be maintained each time the cleaning method is used; and
    2) Logs must be kept for two (2) years or as required by the regulatory authority; and
    3) Logs must be made available to the regulatory authority or any other local, state, or federal regulatory agency upon request.

L. Cleaned equipment and utensils are stored to prevent contamination.

M. Unused equipment and nonessential items may not be stored in areas of the facility where consumable hemp products could become contaminated.

N. The facility is:
    1) Maintained free of vermin and insects; and
    2) When used to exterminate vermin and insects, pesticides:
        a. Are used based on:
            i. Manufacturer’s instructions;
            ii. Any applicable state/federal laws; and
            iii. This Code.

O. Unless specifically approved for use in food processing areas, pesticides are used only in areas that are not used for storage or processing of consumable hemp products.

P. Poisonous or toxic materials must be:
   1) Kept in the original bulk container before use;
   2) Prominently and distinctively marked or labeled for easy identification;
   3) Used in accordance with manufacturer's guidelines;
   4) Approved for use in food facilities; and
   5) Not used or stored in a way that will contaminate ingredients, consumable hemp products, or packaging and labeling materials.

10. Employee Hygiene

A. The operator shall ensure that any individual in the facility:
   1) Practices good personal hygiene so that the individual does not contaminate ingredients, consumable hemp products, packaging and labeling materials, or the facility;
   2) Is excluded from working with ingredients, consumable hemp products, packaging and labeling materials, and any surfaces intended for contact with ingredients, consumable hemp products, or packaging and labeling materials (see FDA Model Food Code sections 2-201.11, 2-201.12, and 2-201.13):
      a. When the individual exhibits or reports a symptom of:
         i. Vomiting;
         ii. Diarrhea;
         iii. Jaundice;
         iv. Sore throat with fever; or
         v. A lesion containing pus such as a boil or infected open wound.
      b. When the individual has a diagnosed illness due to:
         i. Norovirus;
         ii. Hepatitis A virus;
         iii. *Shigella* spp.;
         iv. Shiga toxin-producing *Escherichia coli*;
         v. Typhoid fever (caused by *Salmonella* Typhi); or
         vi. *Salmonella* (non-typhoidal).
      c. When the individual has a history of exposure to:
         i. Norovirus within the past 48 hours;

ii. Shiga toxin-producing *Escherichia coli* or *Shigella* spp. within the past three (3) days;
iii. Typhoid fever within the past 14 days; or
iv. Hepatitis A within the past 30 days.

B. Employees in the facility:
1) Shall report the information as specified in previous Section 10, subsection A, in this Code.
2) Shall clean their hands and exposed portions of their arms by adhering to a procedure written in their SOPs to reduce pathogens and remove soils:
a. Immediately upon entrance to any area containing ingredients or consumable hemp products;
b. Immediately before engaging in preparation for the production of consumable hemp products, including, without limitation:
i. Touching any surfaces intended for contact with ingredients, consumable hemp products, or packaging and labeling materials;
ii. Handling consumable hemp products;
iii. Handling ingredients;
iv. Handling packaging or labeling materials;
v. Handling clean equipment and utensils; or
vi. Unwrapping single-service and single-use articles.
c. After touching bare human body parts other than clean hands and exposed portions of arms, including, without limitation, surrogate prosthetic devices for hands and arms;
d. After using the toilet;
e. After coughing, sneezing, using a handkerchief or disposable tissue;
f. After using tobacco or electronic vaporizers;
g. After eating or drinking;
h. After handling soiled equipment or utensils;
i. During preparation for production of consumable hemp products, as often as necessary to remove soil and contamination and to prevent cross-contamination when changing tasks;
j. When switching between working with ingredients or unfinished consumable hemp products;
k. Before donning gloves for working with consumable hemp products or ingredients;
l. After engaging in any other activities that may contaminate the hands.
3) Shall wear:
a. Clean outerwear;
b. Hair covering and beard covering, if applicable;

c. No jewelry except for a plain ring such as a band.

4) If handling consumable hemp products, ingredients, or packaging and labeling materials shall:
   a. Maintain trim and clean fingernails;
   b. Not wear artificial fingernails or fingernail polish unless wearing intact gloves in good repair.
5) Store personal items in a designated non-working area;
6) Shall not smoke or engage in an activity that might contaminate consumable hemp products or ingredients.

C. Employees shall be provided:
   1) Personal protective equipment and hygiene supplies;
   2) Lockers or similar storage facilities for the secure storage of personal items in a designated non-working area;
   3) Adequate toilets and handwashing facilities as set forth in this Code;
   4) A designated area for employees to eat and drink beverages that is not used in conjunction with processing or storage of:
      a. Ingredients;
      b. Consumable hemp products; or
      c. Packaging or labeling materials;
   5) Sanitizer foot baths and hand dips, as applicable.

D. The non-working area may not be used as storage for:
   1) Toxic chemicals;
   2) Consumable hemp products;
   3) Ingredients;
   4) Packaging materials;
   5) Processing equipment; or
   6) Anything directly involved with the manufacturing of consumable hemp products.

E. Employees using gloves while working with consumable hemp products, ingredients, or touching any surfaces which consumable hemp or hemp-derived products or ingredients come into contact with shall:
   1) Wash hands thoroughly before putting on the gloves;
   2) After an activity that is likely to have soiled the gloves:
      a. Wash hands; and
      b. Replace the gloves; and
   3) Use gloves that are intended for food contact.

F. All employees shall wear gloves when handling any hemp, hemp extract, or another hemp-derived ingredient.

11. Manufacturing

A. Extractions
1) Extraction Operations
    a. Quality and Safety Controls for Cannabis Concentrate Extraction Hemp extraction includes processes that refine aboveground hemp plant components into a more purified and potent form and can be generally divided into three methods: hydrocarbon solvents (such as butane), non-hydrocarbon solvents (water, alcohol/ethanol, CO_2) and dry sieves (screens and filters).
    b. The facility must have written safety and quality control procedures designed to maximize safety and minimize potential product contamination.
    c. The facility shall ensure products are continually produced to established standards and specifications.
    d. All workers must have documented training in the standard operating procedures and tasks specific to quality control and safety procedures.
2) Equipment Installation and Training
    a. The facility must show evidence that a qualified technician or manufacturer's representative installed the extraction equipment.
    b. All production workers must receive training in operations, safety and maintenance from a qualified professional such as a chemist, certified engineer, industrial hygienist or other authorized technical or safety representative.
    c. The facility must install and maintain a standby power source and automatic switch-over controls for all smoke and gas alarms, detection meters, ventilation systems, lighting and other emergency systems in case of a power outage.
3) Emergency Procedures
    a. The facility must establish written emergency evacuation procedures in case of a fire, explosion, chemical spill or other emergency.
    b. Workers must be trained in emergency procedures with annual refresher training at a minimum.
    c. Evacuation drills should be conducted quarterly, results must be documented, and corrective actions implemented and documented.
    d. Emergency signage must be posted.
4) Food-Grade Chemicals

a. The facility must ensure all components such as propylene glycol or glycerin used in the production of a food-based consumable hemp product are certified food grade with written documentation.

5) Water-Based Extraction
    a. Water Quality
        i. Procedures must specify that only potable drinking water or ice made from potable drinking water is used in the production of an extract or consumable hemp product.
        ii. Documented water analysis or other proof of potability is required.
6) Carbon Dioxide (CO_2)-Based Extraction
    a. CO_2 Monitoring
        i. If CO_2 is used as solvent, a certified industrial hygienist or engineer must install a CO_2 monitoring and alarm system in the work area where extraction is conducted, or where CO_2 is stored.
        ii. Monitors must include real-time reports of CO_2 levels and must activate as required by state regulations and OSHA (alarm activates at 5,000 ppm for 8-hour time-weighted average; see OSHA Method ID-209 and the OSHA Technical Manual for guidance).
        iii. CO_2 should be recovered to the maximum extent possible.
        iv. Install proper ventilation (air change 6X per hour unless specified by certified installer) including at floor level.
        v. Ensure actions taken are in accordance with the system's specifications and with applicable local, state, tribal and federal regulations.
7) Use of Dry Ice
    a. The operator must ensure that any room where dry ice is stored or used to extract is well ventilated to prevent against the accumulation of dangerous levels of CO_2.
    b. The operator must install a CO_2 monitor with alarm in all closed areas where CO_2 extraction is performed. Monitors must include real-time reports of CO_2 levels.
    c. All equipment and PPE used shall be suitable for use and material handling at extremely cold temperatures.
8) Ethanol or Alcohol-Based Extraction
    a. Food-Grade Ethanol
        i. If using ethanol or alcohol to extract, the criteria applicable to solvent-based extraction applies.

i. Ethanol must be food grade or at least 190-proof pure; isopropanol alcohol is not recommended.

9) Solvent-Based Extraction
    a. Solvent Safety
        i. If a flammable or volatile hydrocarbon solvent is used to extract, the operation must use a certified industrial hygienist or engineer to:
            a) Install solvent extraction equipment in a room separate from other production areas.
            b) Establish maximum amount of flammable solvents or materials authorized for storage within the licensed premises.
            c) Install Division-1 Class-1 electrical equipment (or state-authorized equivalent) in production area and solvent storage area in accordance with applicable regulations to control ignition and spark sources.
            d) Install proper ventilation (air change 6X per hour unless certified installer provides specifications) including at floor level.
            e) Install a gas monitoring system as required by local regulations.
            f) Install fire suppression system as required by local fire code.
            g) Ensure all workers receive safety training on equipment, materials and risks such as explosion, fire, gas release, evacuation, etc. Document all training participation; repeat for new hires and existing workers periodically.
            h) Ensure use of ground straps/grounded workstations and non-static clothing.
            i) Ensure proper control of solvent gas release during open cycle of extractor with the use of an exhaust hood and hand-held leak detector.
            j) Establish procedures for safe handling of compressed gas cylinders.
            k) Ensure all support equipment meets spark/ignition requirements and is UL certified or equivalent.
            l) Establish/maintain occupancy levels.
        ii. Engineer/hygienist assessment and installation information must be on file
    b. Solvent Recovery

i. All equipment must be professional grade and the system must perform closed-loop extraction that is capable of recovering the solvent.
ii. The extraction system should be constructed of materials that meet American Society of Mechanical Engineers (ASME), ASTM or equivalent standards.
iii. Pumps used to assist with recovery of a flammable solvent must not produce any ignition source (e.g., pneumatic, compressed-air-driven piston pump).
iv. For extraction units plumbed to permanent water supply, operation must ensure water temperature remains between 60°F and 100°F and is flushed weekly.
v. Self-contained units must be visually inspected weekly, and flushing-fluid changed according to manufacturer instructions.
vi. Solvent should be collected and stored in medical-grade containers when practical to maintain purity.
vii. Solvent containers must be replaced or safely purged, cleaned and sanitized periodically.

c. Food-Grade Solvents
    i. The operator must ensure that all solvents used in the extraction process are the highest purity practical; at a minimum, food-grade solvent must be used.
    ii. A current copy of safety data sheets and a receipt of purchase for all solvents used or to be used in an extraction process must be kept on file.
    iii. For all solvents used, a Certificate of Analysis (COA) from the original manufacturer with purity and impurity limits and results must be maintained.
        a) Certificates must be retained for two (2) years or as required by the regulatory authority.
d. Waste Solvent Disposal
    i. The operator must safely handle, store and dispose of all flammable solvents, flammable materials, chemicals and waste in accordance with all applicable local, state, tribal and federal regulations.
    ii. Solvent should be removed from waste material to the maximum extent possible before disposal.
    iii. Disposal process records must be retained for two (2) years or as required by the regulatory authority.

B. Consumable hemp products shall be manufactured as set forth in SOPs that are:
   1) Approved by the regulatory authority upon initial approval to operate and during inspections;
   2) Readily available to employees in a form they understand;
   3) Ensure the consistent and safe manufacture of consumable hemp products; and
   4) Accurately reflect the actual procedures in use in the facility.

C. When a frozen ingredient or consumable hemp product is removed from freezer storage in order to be segregated, organized, or moved:
   1) It shall remain frozen; and
   2) It may not be refrozen after having been permitted to thaw from a prior freezing.

D. The operator shall ensure that:
   1) Pathogenic microorganisms are excluded or eliminated from consumable hemp products before offering for human consumption;
   2) All consumable hemp products go through processing which:
      a. Eliminates or reduces the number of pathogens in the consumable hemp product so that it is safe for human consumption; and
      b. Achieves the necessary reduction in spoilage organisms for a stated or desired shelf-life under normal conditions of storage and distribution; and
   3) The cooking, cooling, or reheating of consumable hemp products or combinations of ingredients are important steps in the preparation of food. During cooling, the time food spends in the danger zone must be minimized. When reheating food, it must quickly reach the proper temperature for the correct amount of time.
      a. See additional specifics of this important safety precaution in FDA Model Food Code sections 3-401.11, 3-401.12, 3-401.13, 3-403.10, and 403.11.

E. When an operator utilizes a commercially-available food product in a consumable hemp product, they are to be used in a way that renders them unrecognizable as the commercial food product unless approval is granted by the company that produces the commercially-available food product.

F. A challenge/stability/shelf-life study (see FDA Model Food Code section 5. subsection A.1) may be required by the regulatory authority to:

1) Ensure manufacturing and packaging processes prevent contamination of consumable hemp products; and
2) Establish how hemp-derived ingredients affect, or are affected by, different food matrices; and
3) Identify the microbial growth rate in different consumable hemp products when stored and exposed to different environmental conditions.

G. All new or unique consumable hemp product forms may be required to be evaluated and approved by the regulatory authority prior to being made available to qualified patients and consumers.

12. Trade Secrets

A. The operator shall inform and furnish information to the regulatory authority of an ingredient or a recipe that the operator considers a trade secret in order to assess if an immediate and substantial danger to public health exists involving the ingredient or recipe.

B. If the regulatory authority determines that the information about the ingredients or recipe is necessary to conduct a disease outbreak investigation, they may need to and shall disclose the trade secret to the appropriate investigators.

C. The regulatory authority shall maintain the confidentiality of trade secret information in accordance with applicable local, state, tribal, and federal regulations.

13. Packaging

A. All consumable hemp products shall be individually packaged at the original point of processing unless otherwise outlined in SOPs.

B. Any container or packaging containing consumable hemp products shall protect the contents from contamination.

C. Consumable hemp product packaging shall be:
1) Designed and constructed to maintain the safety and integrity of consumable hemp products:
2) Made from materials that:
    a. Are food-safe;

b. Are appropriate for the intended use;
c. Do not migrate to or might be absorbed by the consumable hemp products; and
d. Comply with the requirements of the FDA in 21 CFR Parts 174, 175, 176, 177, and 178 for indirect food additives; and

3) Evaluated before use for characteristics that may impact the consumable hemp product, such as:
   a. Permeability to:
      i. Water and water vapor;
      ii. Oxygen; and
      iii. Other gases; and
   b. Tolerance to:
      i. Heat;
      ii. Cold;
      iii. Chemicals used in processing;
      iv. Strength;
      v. Elasticity;
4) Stored so that it is protected from contamination; and
5) Not reused.

D. Packaging that fails to comply with the requirements of this regulation are replaced in a manner that prevents contamination and ensures safety.

14. Labeling

A. Prior to leaving a facility, all consumable hemp products must be labeled in accordance with this Code, the Nutrition Labeling and Education Act and 21 CFR 101.

B. All information on the label shall be printed legibly and be:
1) Prominent
2) Conspicuous;
3) In appropriate font;
4) In English;
5) In colors that make the writing clearly visible; and.
6) Using indelible material.

Consumable hemp products labels and the labeling information required in this regulation shall be:
1) Durable;

2) Conspicuous;
3) Legible; and
4) Able to remain a consumable hemp product in conformance with this Code for the shelf life of the product.

C. Prior to leaving a facility where processing occurs, labeling on consumable hemp products is required to display:
   1) Statement of identity, in bold type on the principal display panel, and as the most prominent printed item on the panel;
   2) Content of cannabinoid (e.g., X mg CBD) on front of container;
   3) The net quantity of contents, which provides the amount of food in the container or package by:
      a. Weight in U.S. Customary System (ounces, pounds) and equivalent metric units (grams, milliliters);
      b. Measure (e.g., fluid ounce); or
      c. Numeric count if numeric count gives adequate information as to the quantity of food; and
   4) The common or usual name of the ingredients in descending order of prominence by weight with sub-ingredients listed;
      a. Products that contain any of the hemp-derived ingredients must declare them by name on the ingredient list;
      b. Products that contain any of the hemp seed-derived ingredients (hulled hemp seed, hemp seed protein powder, and hemp seed oil) must declare them by name on the ingredient list.
      c. Amount and type of cannabinoid (e.g., X mg CBD) must be listed; and
   5) A statement of the major food allergens the consumable hemp products may contain or have protein derived from to include:
      a. Milk;
      b. Egg;
      c. Fish;
      d. Crustacean shellfish;
      e. Tree nuts;
      f. Wheat;
      g. Peanuts;
      h. Soybeans;
   6) Any chemical preservative additive must be listed with:
      a. The common or usual name of the ingredient;
      b. A description of Its function, such as "preservative" or "mold inhibitor"; and

7) Facility name, street address, city, state, and zip code of the manufacturer, distributor, or packer of the consumable hemp product; and
8) Nutrition labeling of food per 21 CFR 101; and
9) Numerical count of servings per container;
    a. As determined by FDA for food products.
10) Lot number (could be a QR code or scannable barcode) identifying the complete history of the manufacturing, packaging, labeling, and/or holding of a lot; and
11) Storage instructions to ensure food safety.
12) See additional information in FDA Guidance for Industry: Food Labeling Guide at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide

D. Labeling shall be accomplished by placing the information required in this regulation on the food packaging by:
    1) Imprinting;
    2) Embossing;
    3) Lithography;
    4) Ink jetting; or
    5) Another method approved by the regulatory authority.

15. Packaging and Labeling Prohibitions

A. Consumable hemp product packaging and labeling shall be compliant with this Code, as well as local, state, tribal, and federal regulations.

B. Packaging and labeling of consumable hemp products may not bear any:
    1) Resemblance to the trademarked, characteristic, or product-specialized packaging of any commercially-available food product unless approved by the company that produces the commercially-available food product; or
    2) Statement, artwork, or design that could reasonably mislead any person to believe that the package contains anything other than a consumable hemp product.

C. A consumable hemp product may not be packaged in a manner which is modeled after or resembles a brand of products primarily consumed by or marketed to children.

16. Transportation of Consumable Hemp Products

A. Operators must submit a plan to the regulatory authority that outlines all aspects of the delivery of consumable hemp products, including, but not limited to how consumable hemp products will remain under safe conditions during transportation.

B. Product storage area of transportation vehicles must be maintained:
   1) In a clean and sanitary manner;
   2) In good repair;
   3) To protect consumable hemp products from contamination; and
   4) Complies with the requirements established in 21 CFR 1.908(c).

C. Detailed logs of each delivery are to be maintained which include:
   1) Inventory tracking code number and lot number of the consumable hemp products delivered;
   2) Date of delivery;
   3) The time consumable hemp products left the facility;
   4) Temperature of the consumable hemp products at time of departure from the facility;
   5) The time of arrival to their destination;
   6) Temperature of non-shelf stable consumable hemp products upon arrival to their destination,
   7) Invoice or bill of landing which indicate:
      a. The transportation agent responsible; and
      b. The person who was responsible for receiving the consumable hemp products.

D. If any products are declined upon arrival due to damage or unsafe temperature it shall be documented.

E. All logs and receiving documents must be:
   1) Reviewed by management.
   2) Stored for two (2) years or as required by the regulatory authority; and
   3) Made available to the regulatory authority or any other local, state, tribal, or federal regulatory agency upon request.

17. Quality Control Plan

A. Each facility shall have a quality control plan in place that:
   1) Identifies who has the responsibility and authority to approve or reject all ingredients, consumable hemp products, packaging, labeling, and in-process materials;
   2) Identifies who has the authority to review processing records to assure that no deviations from approved processes have occurred.
   3) Requires documentation of all related activities.

B. If errors have occurred, they must be fully investigated and appropriate corrective actions that have been taken must be documented.

C. Each facility shall set forth the responsibilities and procedures applicable to the quality control plan and maintain logs of any investigations which:
   1) Identify the employees responsible;
   2) Are maintained for two (2) years or as required by the regulatory authority;
   3) Are made available to the regulatory authority or any other local, state, tribal or federal regulatory agency upon request.

18. Laboratory Testing

A. Operators shall ensure homogeneity and safety, and shall establish the validity of the production process for all individual types of consumable hemp products by carrying out a validation study on any new or unique consumable hemp products or if a new packaging process is used.

B. Any hemp used as an ingredient in a consumable hemp product shall be tested according to the regulations set forth by the regulatory authority. Microbial and chemical (i.e., pesticides) contaminants are of particular concern. (See Appendix A in this document for FOCUS-suggested testing requirements and tolerance levels.)

C. The regulatory authority may randomly test samples and examine consumable hemp products and ingredients as often as necessary for enforcement of this Code.

19. Refuse and Refuse Disposal

A. The disposal of all refuse from a facility, including trash, hemp refuse, hazardous refuse, and liquid refuse shall be performed in a manner consistent with local, state, tribal, and federal laws.

B. Consumable hemp products or ingredients that are found to have a level of THC greater than 0.3 percent may require additional considerations and destruction as marijuana, as per USDA or local, state, and tribal regulations.

C. Refuse containers must be:
   1) Adequate in number to maintain sanitary conditions;
   2) Accessible to employees at locations where refuse is generated;
   3) Labeled to not be suitable for any hemp-containing refuse products;
   4) Covered;
   5) Easily cleanable;
   6) Placed on a hard and impermeable surface.

D. If refuse containers are located inside of the facility, they shall be:
   1) Leak proof;
   2) Emptied and cleaned:
      a. In a manner that maintains a sanitary condition;
      b. Removed at a frequency that will minimize the development of objectionable odors and other conditions that attract or harbor insects and rodents.

E. If the refuse containers are located outdoors, they shall be:
   1) Leak proof; or
   2) Provide a drain that conveys refuse water from the container directly into a sewerage system that:
      a. Meets all applicable state and local codes;
      b. Properly disposes of refuse water;
   3) Large enough to hold refuse until removed from premises;
   4) Covered;
   5) Vermin and insect proof;
   6) Maintain the facility and surrounding grounds in a sanitary condition;
   7) Comply with the requirements in any applicable local, state, and federal laws.

F. Finished consumable hemp products that fail laboratory testing due to exceeding the acceptable hemp THC level must be placed in a segregated area and be disposed of in accordance with the Controlled Substance Act (CSA) and Drug Enforcement Administration (DEA) regulations because such material constitutes marijuana, a Schedule I controlled substance under the CSA. Consequently, the material must be collected for destruction by a person authorized under the CSA to handle marijuana, such as a DEA-registered reverse distributor, or a duly authorized federal, state, or local law enforcement officer.

G. All operators must keep records of any refuse they dispose of for two (2) years or as required by the regulatory authority that include:
   1) The date and time of disposal;
   2) The manner of disposal;
   3) The volume and weight of the refuse scheduled for destruction;
   4) The signature of the employee overseeing the disposal of the refuse.

20. Exemptions

A. Alternative methods of receiving, storage, sanitation, delivery, processing, monitoring and verification other than that specified in this Code may be used if:
   1) The regulatory authority has issued written approval of the alternative method based on a review that determines equivalency;
   2) The regulatory authority's written approval of the variance is available during inspections.

B. The operator may use equipment that does not meet a requirement set forth in this Code when written approval is granted by the regulatory authority based on a review that indicates the equipment and its use are:
   1) Not harmful to public health;
   2) Certified as safe for use by a qualified engineer, chemist, industrial hygienists, or equivalently certified professional.

Appendix A: FOCUS Testing Requirements

This Appendix is being provided as a resource to officials who are tasked with setting up hemp testing programs in their state. The content is an excerpt taken directly from the FOCUS Manufacturing Standard. Copies of the FOCUS Standards can be accessed through the AFDO website, FOCUS Website, or by emailing a request to gap@focusstandards.org.

Product Testing

A. Product Testing Plan

1. The operator must ensure all products sold or transferred are free from contaminants and adulterants as specified in the product testing plan and/or product specification.

2. The operator must develop a testing plan that addresses all risks to products.

    a. Testing must be done on all batches and final products.
    b. All test reports must reference the corresponding batch.
    c. Test results must match batch/lot and date produced.
    d. Test results must be provided with all final products.
    e. Supplier-provided test results must be from a certified lab and must be checked for accuracy.
    f. Test results must be retained for all raw hemp and hemp-derived products for three (3) years

3. The operator must review all test lab reports to ensure:
    a. Testing laboratory is certified to ISO 17025, FOCUS Standard, or Equivalent
    b. Certificate of Analysis lists batch/lot number that matches product tested
    c. The report is complete:
        1. Date;
        2. Methodology performed and method reference;
        3. Laboratory technician(s) signature or code;
        4. Complete data provided;
        5. Equipment protocol data provided (equipment and methods)
4. All test standards are subject to federal, state and local laws and regulations.

B. Sampling Procedures

1. The operator must apply a documented procedure for collection of sample product material for laboratory analysis.
2. Procedures must adhere to the designated testing facility criteria and established industry standards.
3. The sampling log must define the batch or lot size, production date, lot-received date, container type, how samples are obtained and who performed the sampling.
4. The operator must demonstrate that samples were sufficiently homogenous and are representative of the product sold.
5. Samples must be retrieved, stored and transported in original, clean packaging that is clearly marked and packaged in a way that preserves the composition of the sample.
6. Samples must be sealed with tamper-evident tape and not be broken except by an authorized person.
7. Records of sampling, laboratory data and chain-of-custody documents must be kept on file for review for three years from test date.
8. If testing procedures require a third-party laboratory worker to obtain test samples at the production site, the operator shall document procedures, train workers and laboratory staff, and provide the equipment necessary to facilitate an onsite sample collection.

C. Testing Lab Standards

1. The operator must use a testing laboratory that meets ISO 17025 equivalent, the FOCUS Laboratory Standard or relevant state standard; if such a laboratory is not available, operation must maintain documentation to validate the laboratory methods that were used.
2. The operation must retain valid certification documents for all testing laboratories used.

D. Allowable Thresholds

1. The operation must establish documented thresholds for the presence of biological, chemical and physical contaminants.
2. Thresholds must adhere to established local, state, tribal or federal regulatory standards and FOCUS standards, but can be more stringent.
3. Threshold levels should be stated in commonly understood units such as parts per million (PPM or ppm) or colony-forming unit (CFU or cfu).

E . Microbiological Testing

1. All products must be tested for aerobic plate count.
2. Product test results must validate that less than one colony forming unit (CFU) per gram of tested material is present for *Escherichia coli* or *Salmonella* species or the product shall be rejected.
3. Products must be tested for the presence of yeast and molds.
4. Test reports must include method reference.

F. Solvent and Chemical

1. Consumable hemp products must be tested for the following solvents to the maximum extent practical:

    a. Acetone < 1 ppm
    b. Benzene < 0 ppm
    c. Butane/ Heptane/ < 50 ppm
    d. Hexane < 10 ppm
    e. Polyacrylonitrile (PAN) < 1 ppm
    f. Polycyclic Aromatic Hydrocarbons (PAHs) < 1 ppm
    g. Toluene < 1 ppm
    h. Total Xylenes < 1ppm
    i. Solvent-extracted products made with Class 3 or other solvents must not exceed 0.5% residual solvent by weight or 50 parts per million (ppm) per one gram of solvent-based product.
    j. The product must test at or below 50 ppm total.

2. Test results must meet local, state, tribal, and regulations and limits – if these are not available or applicable, the limits specified above apply.

    a. Test reports must provide specific data for all listed and detected solvents.

    b. The test report should list the solvents that were not or could not be tested.

    c. If the test equipment's Limit of Detection (lowest possible detection limit) is above the specified limit for a solvent, the equipment's LOD amount will be considered sufficient to exceed safe contamination limits.

3. Tolerance levels may be revised based on accepted technical publications.
4. Additional substances may be added to the required list as necessary to protect the quality and safety of products.

5. If local laboratories cannot provide the level of testing specified, labs should test for solvents to the maximum extent of their technical capabilities.

G . Metals

1. Testing for heavy metals must include but is not limited to lead, arsenic, cadmium and mercury.
2. Test results must meet federal, state and local regulations and limits – if these are not available or applicable, the following apply:

    a. Lead – max limit < 6 ppm
    b. Arsenic – max limit < 10 ppm
    c. Cadmium – max limit < 4.1 ppm
    d. Mercury – max limit < 2.0 ppm

3. If the extracted hemp material used to make a consumable hemp product was tested for metals and test results indicate the batch/lot was within established limits, then the consumable hemp product should not require additional testing for metals.

H. Pesticide Residue

1. The operator must test all product batches for pesticides; results for residue must be within limits specified in federal, state and local regulations – where not specified, 0.1 ppm or a positive result at the Limit of Detection (equipment's lowest possible detection amount) will be considered to exceed safe residue limits.
2. Pesticide residue testing must analyze samples for the presence of chlorinated hydrocarbons, organophosphates, carbamates and pyrethroids, neonicotinoids, acaracides, fungicides and bactericides to the maximum extent practical.

    a. The test plan must meet all federal, state, local and tribal regulations.
    b. If local laboratories cannot provide the level of testing specified, labs should test for pesticides to the maximum extent of their technical capabilities.

I. Potency and Cannabinoid Profile

The operation must test products for cannabinoid profiles and provide results for levels of THC, THC-A, CBD, CBD-A, CBN and terpenoid profile as applicable to the product specification.

J. Contaminants and Filth

1. The operator must inspect all products for contaminants and filth.

    a. Contaminants include any biological or chemical agent, foreign matter, or other substances not intentionally added to products that may compromise food safety or suitability.

2. The operator must document allowable thresholds for physical contaminants as part of the product test plan.

    a. Inspection requirements must be included in the product test plan for third party testing.

3. Inspection records must indicate a continual process of physical inspection has taken place for all batches.

K. Stability Testing

1. The operator must complete stability/shelf-life testing and assessment on perishable products that have an established expiration date or products with the potential for substantial breakdown of quality and/or safety over time.
2. Test results and analysis must be retained for two (2) years.

L. Test Results Analysis

1. All products with pending tests must be segregated in containers, marked “quarantined” and held in a secure location until test results are received. Containers must include batch/lot code for tracking.
2. The operator shall designate a qualified staff member to review each test result against the product specification. If the product meets all specifications, the batch of product shall be released to the next step in the process.
3. Products that do not meet specifications must be rejected and quarantined.
4. All quarantined batches/lots held for testing, releases to production or rework, and final disposition must be documented in inventory records.
5. The facility shall document and retain all test results and Certificates of Analysis for three (3) years.

M. Batch Monitoring

1. If required by the operator’s test plan, they must collect and store a control sample of product from each production batch.

2. An organized storage area and reference system should be in place for all samples.
3. All product samples must be kept in storage for a period of one year past expiration date or related quality control date in case of product recall.
4. Any sample involved in a pending claim or legal dispute shall not be destroyed.

N. Test Records

1. Test logs must list the batch/lot/facility/product test date.
2. The operator must maintain all test logs and test results (laboratory reports) for a minimum of two (2) years from the date test was performed, including test results received from qualified suppliers.