Testimony In Opposition to L.D. 40

An Act to Protect Liberty and Advance Justice in the Implementation, Administration and Enforcement of the Cannabis Legalization Act and To Implement Certain Recommendations of the Subcommittee on Non-substantive Changes to the Maine Medical Use of Cannabis Act

Before the Joint Standing Committee on Veterans and Legal Affairs

March 4, 2024

Senator Hickman, Representative Supica, and members of the Joint Standing Committee on Veterans and Legal Affairs:

My name is Malina Dumas. I am an attorney with the law firm Dentons and am here on behalf of the trade group CannabisME, which consists of operators in the adult use cannabis industry, to speak in opposition to L.D. 40. The members of CannabisME share some of the same frustrations with enforcement that precipitated this bill, and there are some changes to the cannabis laws in the sponsor's amendment that any member of industry would support. This includes provisions that support the growth of the adult use cannabis industry by allowing for more flexibility in operations. For example, it would allow cultivation facilities more options for sourcing genetics and create a process for pre-approval of packaging and label by the Office of Cannabis Policy that would give businesses certainty that their packaging and labeling would not later be deemed non-compliant. The group also generally supports some reduction in fines and progressive enforcement policies.

The problem with L.D. 40 is not the smaller more targeted changes, but changes to fundamental health and safety regulations that have been adopted across the country as regulatory best practices. These changes are likely have significant unintended consequences that will harm adult use cannabis businesses, including small craft cannabis businesses, in the long term. CannabisME would likely have been able to support a narrowly tailored bill that included some of these provisions, but the sponsor's amendment goes too far.

It is important to recognize that while legalization of adult use cannabis has gained acceptance over the years, it remains a Schedule I controlled substance under federal law. A measure to significantly decrease regulatory requirements for cannabis businesses, strip the regulators of their ability to effectively enforce the rules or engage in future rulemaking, and create access to cannabis for minors would make Maine an outlier among other states that have legalized cannabis. This will have significant long term impacts as well as short term impacts.

While L.D. 40 does not expressly state that it will eliminate mandatory tracking or testing, the group tracking described in the bill will not provide protections to the industry or consumers that are afforded by a robust seed to sale tracking and testing program. The bill would create a group tracking program that would be unique to Maine and, thus, there may not be a service provider that can or is willing to develop software that would only apply to a single state. This creates an enormous risk that L.D. 40 effectively eliminates seed to sale tracking in Maine's adult use program.

With regard to mandatory testing, the chairs of the committee have stated in prior meetings that there are bills that the committee may still use to make other substantive changes that would change testing and/or tracking requirements. Those proposed amendments have not been published yet. We do have concerns about how piecemeal changes to the program through another vehicle could intersect with provisions in L.D. 40—such as restrictions on the number of audit tests that can be completed in a 60 day period by OCP—to undo testing entirely. Regardless, group tracking of cannabis products will undermine the integrity of the testing program putting consumers at risk and creating increased liability for cannabis businesses. Even if L.D. 40 does not mandate the implementation of group tracking for all cannabis products, and rather allows the Office of Cannabis Policy the discretion to pursue this change, that is a significant policy decision that the legislature (as opposed to the regulatory body) should make. The committee has debated group tracking at length in previous legislative sessions, and should not approve a bill that automatically authorizes this shift along with other sweeping changes to the existing laws.

The impacts of deregulating the market and/or eliminating tracking and testing requirements that align with best practices cannot be overstated. They include the risk that cannabis businesses lose access to important professional services, illicit operators have access to the market, and that Maine businesses will be foreclosed from participating in interstate commerce when there is federal legalization—guaranteeing that Maine becomes an importer state.

Professional service providers such as financial institutions and insurance providers and their own regulators rely on robust seed to sale tracking to provide assurance that illicit product is not being diverted into or out of the legal markets and that businesses are not using state legal programs to launder money. Modifying this fundamental regulatory tool to a significantly less effective version, is likely to put access to critical professional services at risk. Over the past several years the number of institutions in Maine willing to bank with adult use cannabis businesses and the scope of financial service they have been willing to have provided, which now include lending to adult use cannabis businesses and their employees, has expanded significantly. As discussed in the attached testimony on L.D. 1757, a bill that also sought to modify seed to sale tracking, from the Maine Credit Union, such changes could force financial institutions to stop working with cannabis businesses in the state. With nowhere to deposit money, cannabis businesses will become targets for violent crime and will be forced to pay employees, vendors and service providers with cash.

Robust seed to sale tracking protects against the diversion of illegal product into the adult use market. This market, which has sales of over two hundred million dollars last year and is continuing to see exponential growth, is an attractive market. Unlike other markets, such as apples and alcohol, there is substantial illicit market that is pervasive in the state and around the country. Without adequate seed to sale tracking illicit operators can sell their products into the adult use market forcing state legal businesses to directly compete with them and risking market destabilization.

Finally, if Maine's regulatory regime deviates wildly from programs in other states, which if L.D. 40 passes, it will, it is likely that Maine businesses will be foreclosed from participating in those programs in the future as evidenced by hemp and interstate commerce bills that are being introduced in other states. After the federal government legalized hemp, states started enacting new regulations to set certain standards for hemp products because the federal government has not yet done so. These regulatory regimes prohibit the sale of hemp products manufactured in other states if they do not comply with the importing state's own standards. One such example can be found in regulations adopted by the state of Kentucky:

> Section 1, (2) "Approved source" means:
>
> (a) A Kentucky hemp grower or handler licensed by the Kentucky Department of Agriculture, or an out-of-state hemp grower or handler who is duly authorized to produce hemp under the laws of the applicable jurisdiction;
>
> (b) A hemp product manufacturer or processor permitted by the Kentucky Department for Public Health or
>
> (c) A manufacturer or processor permitted by another state regulatory authority for hemp-derived cannabinoid products *if that state has been approved by the department as having equivalent state standards for processing, laboratory testing, and labeling requirements.*

See 902 KAR 45:190.

Bills with an interstate commerce component that have been introduced in anticipation of federal legalization of cannabis likewise would require any imported products to meet the same standards as products manufactured in state. This includes proposed legislation that was introduced in the Maine State Legislature just last year. The language in L.D. 1765, *An Act Authorizing the Governor to Enter into Interstate Agreements Regarding the Cannabis Industry* included specific standards that would apply to out-of-state commercial cannabis businesses exporting product to Maine. The overarching requirement was that the contracting state (i.e. the state sending products to Maine) would need to apply standards for their own cannabis operators that meet or exceed the requirements under Maine state law for adult use and/or medical cannabis businesses. If L.D. 40 passes, then the most likely scenario when cannabis is legalized is that every other state in the country will exceed the standards that are applied in Maine, and Maine will not meet or exceed the standards of any other state. If that is the case, and the trends for how interstate commerce bills are being drafted persist, then Maine would become an importer state and Maine craft cannabis would not reach the national marketplace.

Every other state that has legalized medical or adult use cannabis imposed stringent tracking and testing requirements. Rolling back these requirements now will set Maine businesses up to fail.

For all of these reasons, CannabisME opposes L.D. 40 as drafted and urges you to vote ought not to pass or, in the alternative, to create a study committee to make recommendations for necessary changes to the adult use law. Thank you in advance for taking these comments into consideration.

Maine Credit Union League

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Neither for Nor Against LD 1757

An Act to Amend the Laws Governing the Reporting and Tracking of Adult Use Cannabis

Joint Committee on Veterans and Legal Affairs

April 24, 2023

Senator Hickman, Representative Supica, and Distinguished Members of the Joint Committee on Veterans and Legal Affairs,

My name is Robert Caverly and I serve as the Vice President of Advocacy & Outreach at the Maine Credit Union League. The League proudly represents Maine's 50 credit unions and more than 725,000 members statewide. Please accept our testimony neither for nor against LD 1757; An Act to Amend the Laws Governing the Reporting and Tracking of Adult Use Cannabis.

As this committee is aware, providing financial services to the cannabis industry is a challenge that requires compliance with federal requirements. Despite the challenge, Maine has credit unions that remain committed to providing this important community service, as they have done since 2014.

Maine's current regulations for the adult-use cannabis industry more closely align with national standards. This consistency means that it is far easier to provide financial services to adult-use cannabis providers and is part of why we have consistently urged this committee to make the medical program reporting requirements more similar to adult-use, rather than widening the gap.

Deviating from the current law will likely decrease the access to financial services that these businesses have due to financial regulatory requirements. It is our concern that if LD 1757 were to pass, adult-use providers that reduce the tracking requirements as proposed will lose access to financial services due to being out of compliance with the expectations of federal financial regulators.

If the goal of this committee is to ensure a well-run cannabis industry that has access to financial services, we would encourage the alignment of Maine law with national standards and to look to states that have a robust and well banked cannabis-industry. Indeed, that is the perspective we have represented in our testimony on LD 355, 788, and 1529, as well as in our letter this committee and legislative leadership in January 2022.

Thank you for the opportunity to offer testimony on this important topic. If the League can be of any assistance during the deliberations of this bill or others similar, please do not hesitate to contact us.

131st MAINE LEGISLATURE

FIRST SPECIAL SESSION-2023

Legislative Document	**No. 1765**
H.P. 1129	House of Representatives, April 25, 2023

An Act Authorizing the Governor to Enter into Interstate Agreements Regarding the Cannabis Industry

Reference to the Committee on Veterans and Legal Affairs suggested and ordered printed.

ROBERT B. HUNT
Clerk

Presented by Representative PERRY of Bangor.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 28-B MRSA c. 1, sub-c. 12 is enacted to read:

SUBCHAPTER 12

INTERSTATE AGREEMENTS

§1201. Definitions

As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

1. Agreement. "Agreement" means an agreement entered into under this subchapter between the Governor and another state or states regarding commercial cannabis activity.

2. Commercial cannabis activity. "Commercial cannabis activity" means the transportation, cultivation, manufacture, testing, purchase, sale or distribution of cannabis or cannabis products.

3. Contracting state. "Contracting state" means a state with which the Governor has entered into an agreement pursuant to this subchapter.

4. Maine commercial cannabis business. "Maine commercial cannabis business" means an individual or entity authorized to engage in commercial cannabis activity in this State pursuant to this chapter or Title 22, chapter 558-C.

5. Out-of-state commercial cannabis business. "Out-of-state commercial cannabis business" means an individual or entity authorized under the laws of another state to engage in commercial cannabis activity within that state.

6. State. "State" means a state of the United States or any district, commonwealth, territory or possession subject to the legislative authority of the United States.

§1202. Agreement by Governor

The Governor may enter into one or more agreements with another state or states authorizing commercial cannabis activity in this State by an out-of-state commercial cannabis business or authorizing a Maine commercial cannabis business to engage in commercial cannabis activity in the contracting state, as long as the provisions of this subchapter are met.

§1203. Federal action required

An agreement entered into pursuant to this subchapter takes effect upon or after the occurrence of the following:

1. Federal law permits interstate transfer. Federal law authorizes the interstate commercial cannabis activities authorized by the agreement;

2. Federal expenditures prohibited. Federal law prohibits the expenditure of federal funds to prevent the interstate commercial cannabis activities authorized by the agreement;

3. Opinion of United States Department of Justice. The United States Department of Justice issues an opinion or memorandum allowing or tolerating the interstate commercial cannabis activities authorized by the agreement; or

4. Opinion of Attorney General of United States. The Attorney General of the United States issues a written opinion that, based on review of federal judicial decisions and administrative action, implementation of the agreement will not result in significant legal risk to this State.

§1204. Agreement requirements

An agreement entered into pursuant to this subchapter must contain provisions that:

1. Department authorization. Require an out-of-state commercial cannabis business to comply with the requirements of this Title or Title 22, chapter 558-C, as appropriate, in order to engage in commercial cannabis activity in this State;

2. Standards. Require the contracting state to apply standards to out-of-state commercial cannabis businesses operating in the contracting state that meet or exceed the standards found in this chapter or Title 22, chapter 558-C, as appropriate, regarding:

A. Tracking and tagging cannabis plants, adult use cannabis and adult use cannabis products from immature cannabis plant to the point of retail sale, disposal or destruction;

B. Testing cannabis and cannabis products prior to selling or distributing to ensure the cannabis and cannabis products do not exceed the maximum level of allowable contamination for any contaminate that is injurious to health and for which testing is required and to ensure correct labeling;

C. Identifying adulterated or misbranded cannabis products and destroying those products; and

D. Packaging, labeling, marketing and advertising of cannabis and cannabis products;

3. Public health and safety emergencies. Require the appropriate regulatory authority of the contracting state to address public health and welfare emergencies concerning cannabis or cannabis products that are sold or intended for sale within this State, including the prompt recall or embargo of adulterated or misbranded cannabis or cannabis products;

4. Investigate alleged noncompliance. Require the appropriate regulatory authority of the contracting state to investigate and reasonably cooperate with this State's investigation of instances of alleged noncompliance with the agreement and laws and rules applicable to out-of-state commercial cannabis businesses operating in this State in accordance with mutually agreed-upon procedures;

5. Promote inclusion. Require the contracting state to promote the inclusion and support of individuals and communities in the cannabis industry who are linked to populations and neighborhoods that were negatively or disproportionately affected by cannabis criminalization as determined by the Governor; and

6. Transportation prohibited. Prohibit the transportation of cannabis or cannabis products by an out-of-state commercial cannabis business or a Maine commercial cannabis business through a state that does not authorize that transportation.

§1205. License required; rules

An out-of-state commercial cannabis business may not engage in commercial cannabis activity in this State unless authorized to do so in accordance with this Title or Title 22,

chapter 558-C, as appropriate. The department shall adopt rules to implement, administer and enforce this subchapter. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

§1206. Affix signature

When the Governor, on behalf of the State, executes an agreement pursuant to this subchapter, the Governor shall affix the Governor's signature to the agreement under a recital that the agreement is executed pursuant to the provisions of this subchapter and subject to the limitations and qualifications contained in this subchapter.

§1207. Report

By January 15, 2024, and annually thereafter, the department shall submit a report to the joint standing committee of the Legislature having jurisdiction over adult use cannabis and medical use cannabis matters listing all agreements entered into pursuant to this subchapter, including, but not limited to, information regarding the terms and conditions of each agreement, the activities undertaken by the department and other state agencies to implement the agreement and the effects of the agreement on the adult use and medical use cannabis industries in this State.

SUMMARY

This bill permits the Governor to enter into interstate agreements authorizing the transportation, cultivation, manufacture, testing, purchase, sale or distribution of cannabis or cannabis products into and out of this State by entities licensed in Maine pursuant to the Maine Revised Statutes, Title 28-B, chapter 1 or Title 22, chapter 558-C. Such agreements will be effective if one of the following occurs: (1) federal law allows for the interstate transfer of cannabis or cannabis products; (2) federal law specifically prohibits the expenditure of federal funds to prevent the interstate transfer of cannabis or cannabis products; (3) the United States Department of Justice issues an opinion or memorandum allowing or tolerating the interstate transfer of cannabis products; or (4) the Attorney General of the United States issues a written opinion that implementation of these agreements will not result in significant legal risk to this State.

The agreements must require a cannabis business from the contracting state to be authorized to operate in this State pursuant to either Title 28-B, chapter 1 or Title 22, chapter 558-C and that the contracting state apply standards on these businesses equal to or exceeding Maine standards on: tracking; tagging; testing; identifying and destroying adulterated or misbranded cannabis products; labeling; marketing; and advertising. The contracting state must also agree to address public health and safety emergencies concerning cannabis and cannabis products and agree to assist in investigations of noncompliance with the agreement or Maine's laws or rules. The agreements must also prohibit the transportation of cannabis or cannabis products in states that do not authorize such transportation.

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety
(Amended at Subject Matter Committee)

902 KAR 45:190. Hemp-derived cannabinoid products; packaging and labeling requirements.

RELATES TO: KRS Chapter 13B, 217.015, 217.025, 217.035, 217.037, 217.039, 260.850, 438.305(4), 2023 Ky Acts ch. 78

STATUTORY AUTHORITY: KRS 217.125, 217.127, 217.135, 217.155

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125(1) authorizes the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act, KRS 217.005 through 217.215. KRS 217.125(2) requires the secretary to provide by administrative regulation a schedule of fees for permits to operate and for inspection activities carried out by the cabinet pursuant to KRS 217.025 through 217.390. KRS 217.135 authorizes the secretary to establish food standards by administrative regulation including a reasonable definition, standard of identity, and designation of optional ingredients that shall be named on the label. KRS 217.155 allows the cabinet or its duly authorized agent free access at reasonable times for the purpose of inspection any factory, warehouse, or establishment where foods, drugs, devices, or cosmetics are manufactured or held for sale. This administrative regulation establishes the registration, processing, and manufacturing procedures to utilize hemp-derived cannabinoid products in foods and cosmetics, the labeling and packaging requirements for products containing hemp-derived cannabinoids, the requirements for retail sale of hemp-derived cannabinoid products, and methods for use of hemp-derived cannabinoid as an additive to food products.

Section 1. Definitions.

(1) "Adult-use cannabinoid" means a product with intoxicating properties that changes the function of the nervous system and results in alterations of perception, cognition, or behavior.

(2) "Approved source" means:

(a) A Kentucky hemp grower or handler licensed by the Kentucky Department of Agriculture, or an out-of-state hemp grower or handler who is duly authorized to produce hemp under the laws of the applicable jurisdiction;

(b) A hemp product manufacturer or processor permitted by the Kentucky Department for Public Health or

(c) A manufacturer or processor permitted by another state regulatory authority for hemp-derived cannabinoid products if that state has been approved by the department as having equivalent state standards for processing, laboratory testing, and labeling requirements.

(3) "Cabinet" is defined by KRS 217.015(3).

(4) "Cannabidiol" or "CBD" is defined by KRS 217.039(1)(a).

(5) "Cannabinoid" means a compound found in the hemp plant Cannabis sativa L from a United States Department of Agriculture sanctioned domestic hemp production program and does not include cannabinoids derived from any other substance.

(6) "Child-resistant" means packaging that is:

(a) Designed or constructed to be significantly difficult for children under five (5) years of age to open and not difficult for adults to use properly; and

(b) Resealable to maintain this effectiveness for children through multiple openings for any product intended for more than a single use or containing multiple servings.

(7) "Cosmetic" is defined by KRS 217.015(7).
(8) "Food service establishment" is defined by KRS 217.015(21).
(9) "Hemp" is defined by KRS 260.850(5).
(10) "Hemp-derived cannabinoid" means an ingestible, inhalable, or cosmetic product that is processed or derived from hemp.
(11) "Home-based processor" is defined by KRS 217.015(56).
(12) "Hydrogenation" means the chemical reaction between molecular hydrogen (H_2) and another compound or element.
(13) "Imminent health hazard" is defined by KRS 217.015(24).
(14) "Infused" means adding a cannabinoid ingredient to an ingestible cannabinoid product.
(15) "Non-intoxicating cannabinoid" means a product with non-psychoactive properties that does not change the function of the nervous system and does not result in alteration of perception, cognition, or behavior.
(16) "Person" is defined by KRS 217.015(32).
(17) "Proof of age" is defined by KRS 438.305(4).
(18) "Revocation" means the permit to operate is cancelled by the department.
(19) "Serious adverse event" means a medical occurrence associated with the use of a cannabinoid product that results in one or more of the following:
(a) Death;
(b) A life-threatening event;
(c) Inpatient hospitalization, or prolongation of an existing hospitalization;
(d) A persistent or significant incapacity, or substantial disruption in the ability to conduct normal life functions; or
(e) A congenital anomaly or birth defect.
(20) "Tentatively identified compounds" or "TIC" means compounds detected in a sample that are not among the target analytes.

Section 2. Permit and Product Registration.
(1) In-state permit.
(a) A person located in Kentucky seeking to process, manufacture, store, or distribute hemp-derived cannabinoid products shall be permitted by the cabinet.
(b) The permit shall be:
1. Nontransferable in regard to person or address;
2. Posted in a conspicuous place in the facility; and
3. Renewed annually.
4. Include the fee paid in accordance with:
a. 902 KAR 45:180, for a food processing establishment;
b. 902 KAR 45:180, for a cosmetic manufacturer; and
c. 902 KAR 45:110, Section 1(3) and (6), for a food service establishment; and
5. Include the product registration fee required by subsection (4) of this section.
(2)
(a) Effective January 1, 2024, all out-of-state processors and manufacturers of hemp-derived cannabinoid products available for distribution in Kentucky shall submit an annual registration to the department.
(b) The registration for an out-of-state processor or manufacturer shall:
1. Be renewed annually by December 31 each year; and
2. Include:
a. A copy of the current, valid permit to process or manufacture hemp-derived cannabinoids issued from the state regulatory authority;
b. A copy of the state regulation pertaining to the production of hemp-derived cannabinoid products; and

c. The product registration fee required by subsection (4) of this section.

(3) Cannabinoids requiring registration:

(a) Adult-use cannabinoids shall include:

1. Delta-10-tetrahydrocannabinol (Delta-10-THC);
2. Delta-9-tetrahydrocannabinol (THC) with three-tenths of one percent (0.3%) or less Total THC;
3. Delta-8-tetrahydrocannabinol (Delta-8-THC);
4. Delta-9-tetrahydrocannabinolic acid A (THCA-A) with three-tenths of one percent (0.3%) or less Total THC;
5. Delta-9-tetrahydrocannabivarin (THCV);
6. Delta-9-tetrahydrocannabivarinic acid (THCVA);
7. Delta-6-tetrahydrocannabinol (Delta 6);
8. Hexahydrocannabinol (HHC)(-);
9. Tetrahydrocannabiphorol (THCp); and
10. Tetrahydrocannabinol (THCM);

(b) Non-intoxicating cannabinoids shall include:

1. Cannabidiol (CBD);
2. Cannabidiolic acid (CBDA);
3. Cannabidivarin (CBDV);
4. Cannabidivarinic acid (CBDVA);
5. Cannabichromene (CBC);
6. Cannabichromenic acid (CBCA);
7. Cannabigerolic acid (CBGA);
8. Cannabigerol (CBG);
9. Cannabinol (CBN); and
10. Cannabitriol (CBT); and

(c) All other cannabinoids are prohibited for sale in Kentucky unless pre-approved by the cabinet.

(4) An annual registration fee of $200 per adult-use cannabinoid product shall be paid to the cabinet by check or money order made payable to the Kentucky State Treasurer.

(5) All in-state processors and manufacturers permitted by the cabinet, and all out-of-state processors and manufacturers registering with the cabinet shall submit:

(a) The name and address of the applicant;

(b) The name and address of the brand or company whose name shall appear on the label, if other than the applicant's;

(c) The name of the product;

(d) The name and address of the origin of the adult-use cannabinoid product with which the final product was manufactured;

(e) A complete copy of the front and back of the label that will appear on the product; and

(f) A certificate of analysis from an accredited third-party laboratory for the lot for each product.

(6) A new registration shall be required for changes:

(a) In the chemical composition or formula of the cannabinoid product;

(b) To the serving size or directions for use; or

(c) In ownership.

Section 3. Processing, Manufacture, Storage, or Distribution of Hemp-derived Cannabinoid Products.

(1) All processors and manufacturers shall meet:

(a) The applicable requirements of 902 KAR 45:160 Section 2(1)(u); and

(b) The requirements of 902 KAR 45:160, Sections 4, 5, 6, 7, 8, 9, 10, 11, and 14.

(2) Hemp-derived cannabinoid products shall not be manufactured, marketed, sold, or distributed by a home-based processor.
(3) A business that processes, manufactures, warehouses, distributes, sells, or serves adult-use hemp-derived cannabinoid products shall not employ any person who is under twenty-one (21) years of age, unless the person employed is at least eighteen (18) years of age and under the supervision of a person twenty-one (21) years of age or older.
(4) Non-intoxicating cannabinoid products shall:
(a) Have at least a fifteen (15) non-intoxicating cannabinoid to one (1) adult-use cannabinoid ratio; and
(b) Contain two and five-tenths (2.5) milligrams or less of adult-use cannabinoid per serving.
(5) The serving size of an ingestible cannabinoid product shall be:
(a) As a whole unit where one (1) unit equals one (1) serving;
(b) Equal the maximum amount recommended, as appropriate, on the label for consumption per occasion in whole units; and
(c) Based on the amount typically consumed.
(6) A hemp-derived cannabinoid processing or manufacturing facility shall not treat or otherwise adulterate a cannabinoid product with:
(a) Any non-cannabinoid additive that increases toxicity or addictive potential, excluding caffeine;
(b) Alcohol;
(c) Nicotine; or
(d) Other chemicals that may increase carcinogenicity or cardiac effects.
(7) All products shall be homogenized to ensure uniform distribution of cannabinoids throughout the product.
(8) Only permitted hemp-derived cannabinoid processing facilities shall perform cannabinoid extraction, conversion, catalyzation, distillation, hydrogenation, or other refinement processes.
(9) A hemp-derived cannabinoid processor or manufacturer shall only use the following solvents: water, glycerin, vegetable oils, animal fats, butane, propane, carbon dioxide, ethanol, isopropanol, acetone, heptane, ethyl acetate, and pentane. The use of any other solvent is expressly prohibited unless pre-approved by the cabinet.
(10) A hemp-derived cannabinoid processor using hydrocarbon-based solvents shall use only such solvents of ninety-nine (99) percent or better purity. Nonhydrocarbon-based solvents shall be food grade.
(11)
(a) A current copy of safety data sheets and a receipt of purchase for all solvents used or to be used in an extraction process shall be kept on file;
(b) The processor shall retain in its facility a certificate of analysis (COA) from the original manufacturer with purity and impurity limits and results for all solvents used; and
(c) Certificates shall be retained for two (2) years.
(12)
(a) Solvents shall be collected and stored in food-grade containers when practical to maintain purity; and
(b) Solvent containers shall be replaced or safely purged, cleaned, and sanitized periodically.
(13) Extraction processes shall take place in an environment properly ventilated to control all sources of ignition where a flammable atmosphere is, or could be, present.
(14) Cannabinoid processing facilities shall not use pressurized canned flammable fuel, such as butane intended for use in outdoor activities, handheld torch devises, and refillable cigarette lighters.

(15) Cannabinoid processing facilities using carbon dioxide shall have equipment and facilities approved by local fire code officials, if applicable.
(16) Processes using flammable gas or flammable liquid shall have leak or gas detection measures, or both.
(17) A permittee shall not use dimethylsulfoxide (DMSO) in the manufacture of hemp-derived cannabinoid products, and possession upon the permitted premises is prohibited.
(18)
(a) A hemp-derived cannabinoid manufacturer may use terpenes or other hemp essential oil but shall not use non-cannabinoid derived inactive ingredients not listed in the federal Food and Drug Administration inactive ingredient database at https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm in the manufacture of inhalable hemp-derived cannabinoid product and concentrate intended for use through a vaporizer delivery device or pressurized metered dose inhaler; and
(b) Any non-cannabinoid derived inactive ingredients used shall be less than or equal to the concentration listed in the database.
(19) The following substances shall be prohibited in hemp-derived cannabinoid extraction intended for inhalation:
(a) Acetates;
(b) Medium-chain triglycerides (MCT);
(c) Polyethylene glycol (PEG);
(d) Propylene glycol (PG or PPG);
(e) Diketones:
1. 2,3-butanedione (Diacetyl);
2. 2,3-pentanedione (acetylpropionyl); and
3. 3-hydroxybutanone (acetoin);
(f) Myclobutanil;
(g) Artificial food coloring; and
(h) Benzoic acid.

Section 4. Product Sampling and Testing Requirements.
(1) Sampling and testing for all hemp-derived cannabinoid products shall be:
(a) Done for each batch or process lot; and
(b) Conducted with representative samples to ensure all batches or process lots are adequately assessed for contaminants, and that the hemp-derived cannabinoid profile is consistent throughout.
(2) Testing shall only be performed on the final product equivalent to what will be consumed.
(3) Samples shall be collected using appropriate aseptic techniques.
(4) A hemp-derived cannabinoid processing or manufacturing facility shall assign each batch or process lot a unique batch or lot number that shall be:
(a) Documented and maintained in the processing and manufacturing facility for at least two (2) years and available to the department upon request;
(b) Provided to the individual responsible for taking samples; and
(c) Included on the product label.
(5) Sample size, handling, storage, and disposal.
(a) Hemp-derived cannabinoid products samples shall consist of enough material from the batch or process lot to ensure that the required attributes in the products are homogenous and consistent with the testing facility's accredited sampling policies and procedures.
(b) A hemp-derived cannabinoid processing or manufacturing permittee shall prepare sampling policies and procedures that contain the information necessary for collecting and transporting samples from hemp-derived cannabinoid products in a manner that

does not endanger the integrity of the sample for any analysis required by this administrative regulation.

(6) Reserve samples.

(a) Processors and manufacturers shall collect and hold reserve samples of each batch or process lot of packaged and labeled product.

(b) The reserve samples shall:

1. Be held using the same container-closure system that the packaged and labeled product is distributed, or if distributing to be packaged and labeled, using a container-closure system that provides the same characteristics to protect against contamination or deterioration;

2. Be identified with the batch or process number;

3. Be retained for the shelf-life date, as applicable, or for two (2) years from the date of distribution of the last batch or process lot of the product associated with the reserve sample; and

4. Consist of at least twice the quantity necessary for all tests or examinations to determine if the product meets specifications.

(7) Laboratory requirements.

(a) Testing facilities used by the hemp-derived cannabinoid processing or manufacturing facility shall be an independent third-party, fully accredited to the standard established by International Organization for Standardization (ISO) 17025 by an International Laboratory Accreditation Cooperation recognized accreditation body.

(b) The testing facility shall:

1. Maintain ISO 17025 accreditation; and

2. Comply with all required analytes standards for the relevant test methods of:

a. Cannabinoids;

b. Microbial impurities;

c. Mycotoxins;

d. Residual pesticides;

e. Heavy metals; and

f. Residual solvents, if applicable.

(c) Hemp-derived cannabinoid processing or manufacturing facilities shall maintain on file proof of a valid certificate of accreditation for the laboratory completing product testing that:

1. Is issued by an accreditation organization; and

2. Attests to the laboratory's competence to perform testing, including all the required analytes for the relevant test methods required.

(8) Testing requirements.

(a) A processing or manufacturing facility shall test every batch or process lot of hemp-derived cannabinoid product for sale or distribution prior to sell or transfer.

(b) Test shall be performed using a cannabinoid quantification technique with a high enough specificity and sensitivity to differentiate between cannabinoids and isomers of cannabinoids.

(c) Hemp-derived cannabinoid products shall be tested for:

1. Cannabinoids;

2. Microbial impurities;

3. Mycotoxins;

4. Residual pesticides;

5. Heavy metals; and

6. Residual solvents, if applicable.

(d) Infused hemp-derived cannabinoid products may not require additional testing for microbial impurities, mycotoxins, residual pesticides, heavy metals, or residual

solvents, as applicable, if the cannabinoid concentrate used to make an infused product was:

1. Tested for microbial impurities, mycotoxins, residual pesticides, heavy metals, or residual solvents in compliance with this administrative regulation; and
2. Test results indicate the batch or process lot was within established limits.

(e) An infused hemp-derived cannabinoid product shall be tested if the addition of ingredients or processing practice create a reasonable or foreseeable microbial impurity, mycotoxin, residual pesticide, heavy metals, or residual solvents hazard.

(f) All vaporizer delivery device or pressurized metered dose inhaler cartridge batches or process lots shall be tested for Acetates.

(g) In accordance with KRS 217.039, all applicable certificates of analysis shall accompany the final product.

(9) Standards for hemp-derived cannabinoid testing.

(a) A testing facility shall establish a limit of quantitation of one (1) milligram per gram (mg/g) or lower for all adult-use hemp-derived cannabinoids analyzed and reported.

(b) A testing facility shall report the result of the hemp-derived cannabinoid testing on the certificate of analysis, that includes at minimum:

1. Total tetrahydrocannabinol concentration, calculated in accordance with paragraph (c) of this subsection and reported in percentages;
2. Tetrahydrocannabinol-A concentration;
3. Milligrams per serving for total tetrahydrocannabinol and the primary cannabinoid marketed, excluding cosmetics, as applicable;
4. Milligrams per package for total tetrahydrocannabinol and the primary cannabinoid marketed, excluding cosmetics, as applicable; and
5. The results of all other hemp-derived cannabinoids analyzed on the COA both as a percentage and milligrams per gram (mg/g).

(c) The following calculation shall be used for calculating total tetrahydrocannabinol concentration expressed in weight: Total cannabinoid concentration (mg/g) = (cannabinoid acid form concentration (mg/g) x 0.877) + cannabinoid concentration (mg/g).

(d) For hemp-derived cannabinoid infused products, excluding cosmetics, potency shall be reported as milligrams of total tetrahydrocannabinol and the primary cannabinoid marketed, excluding cosmetics per gram.

(e) Cannabinoid products shall not contain a delta-9 tetrahydrocannabinol concentration of more than three-tenths of one percent (0.3) on a dry weigh basis.

(f) The serving size from a vaporizer delivery device or pressurized metered dose inhaler shall not exceed one (1) inhalation lasting two (2) seconds per serving.

(10) Standards for microbial impurities.

(a) Hemp-derived cannabinoid products shall be tested by a testing facility for the presence of microbial impurities.

(b) The sample of inhalable hemp-derived cannabinoid products shall be deemed to have passed the microbial impurities testing if the following conditions are met:

1. Total Escherichia coli is not detected above 100 colony forming units/gram;
2. Shiga toxin–producing Escherichia coli is not detected in one (1) gram;
3. Salmonella spp. is not detected in one (1) gram;
4. Pathogenic Aspergillus species A. fumigatus, A. flavus, A. niger, and A. terreus are not detected in one (1) gram;
5. Listeria Spp. is not detected in one (1) gram; and
6. A total combined yeast and mold not to exceed 100,000 colony forming units per gram.

(c) The sample of ingestible or cosmetic cannabinoid products shall be deemed to have passed the microbial impurities testing if the following conditions are met:

1. Total Escherichia coli is not detected above 100 colony forming units/gram;
2. Shiga toxin–producing Escherichia coli is not detected in one (1) gram;
3. Salmonella spp. is not detected in one (1) gram;
4. Listeria Spp. is not detected in one (1) gram; and
5. A total combined yeast and mold not to exceed 100,000 colony forming units per gram.

(d) If the sample fails microbial impurities testing, the batch or process lot from which the sample was collected shall not be released for retail sale.

(e) If a sample from a batch or process lot of a hemp-derived cannabinoid product fails microbiological contaminant testing, the batch may be further processed, if the processing method effectively sterilizes the batch.

(f) A batch or process lot that is sterilized in accordance with paragraph (e) of this subsection shall be sampled and tested in accordance with this administrative regulation, if not otherwise required for that product, for microbiological contaminants, and residual solvents.

(g) A batch or process lot that fails microbiological contaminant testing after undergoing a sterilization process in accordance with paragraph (e) of this subsection shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

(11) Standards for mycotoxin testing.

(a) Hemp-derived cannabinoid products shall be tested by a testing facility for the following mycotoxins: aflatoxin B1, B2, G1, and G2 ochratoxin A.

(b) A batch or process lot shall be deemed to have passed mycotoxin testing if the following conditions are met:

1. Total of aflatoxin B1, B2, G1, and G2 does not exceed twenty (20) microgram per kilogram (µg/kg) of substance; and
2. Ochratoxin A does not exceed twenty (20) µg/kg of substance.

(c) A batch or process lot that fails mycotoxin testing in accordance with this subsection shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

(12) Standards for testing residual pesticides.

(a) Hemp-derived cannabinoid products shall be tested by a testing facility for the following residual pesticides and shall not exceed the maximum allowable concentration for each:

Residual pesticide	Chemical Abstract Service (CAS) assigned number	Maximum allowable concentration stated in parts per million (ppm)
Abamectin	71751-41-2	0.5 ppm
Acephate	30560-19-1	0.4 ppm
Acequinocyl	57960-19-7	2.0 ppm
Acetamiprid	135410-20-7	0.2 ppm
Aldicarb	116-06-3	0.4 ppm
Azoxystrobin	131860-33-8	0.2 ppm
Bifenazate	149877-41-8	0.2 ppm
Bifenthrin	82657-04-3	0.2 ppm

Boscalid	188425-85-6	0.4 ppm
Carbaryl	63-25-2	0.2 ppm
Carbofuran	1563-66-2	0.2 ppm
Chlorantraniliprole	500008-45-7	0.2 ppm
Chlorfenapyr	122453-73-0	1.0 ppm
Chlormequat chloride	7003-89-6	0.2 ppm
Chlorpyrifos	2921-88-2	0.2 ppm
Clofentezine	74115-24-5	0.2 ppm
Cyfluthrin	68359-37-5	1.0 ppm
Cypermethrin	52315-07-8	1.0 ppm
Daminozide	1596-84-5	1.0 ppm
DDVP (Dichlorvos)	62-73-7	0.1 ppm
Diazinon	333-41-5	0.2 ppm
Dimethoate	60-51-5	0.2 ppm
Ethoprophos	13194-48-4	0.2 ppm
Etofenprox	80844-07-1	0.4 ppm
Etoxazole	153233-91-1	0.2 ppm
Fenoxycarb	72490-01-8	0.2 ppm
Fenpyroximate	134098-61-6	0.4 ppm
Fipronil	120068-37-3	0.4 ppm
Flonicamid	158062-67-0	1.0 ppm
Fludioxonil	131341-86-1	0.4 ppm
Hexythiazox	78587-05-0	1.0 ppm
Imazalil	35554-44-0	0.2 ppm
Imidacloprid	138261-41-3	0.4 ppm
Kresoxim-methy	143390-89-0	0.4 ppm
Malathion	121-75-5	0.2 ppm
Metalaxyl	57837-19-1	0.2 ppm
Methiocarb	2032-65-7	0.2 ppm
Methomyl	16752-77-5	0.4 ppm
Methyl parathion	298-00-0	0.2 ppm
Myclobutanil,	88671-89-0	0.2 ppm (prohibited at any concentration for inhalation)
Naled	300-76-5	0.5 ppm
Oxamyl	23135-22-0	1.0 ppm
Paclobutrazol	76738-62-0	0.4 ppm
Permethrins (measured as the cumulative residue of cis- and trans-isomers)	52645-531 (54774-45-7 and 51877-74-8)	0.2 ppm
Phosmet	732-11-6	0.2 ppm
Piperonyl_butoxide	51-03-6	2.0 ppm
Prallethrin	23031-36-9	0.2 ppm

Propiconazole	60207-90-1	0.4 ppm
Propoxur	114-26-1	0.2 ppm
Pyrethrins (measured as the cumulative residue of pyrethrin 1, cinerin 1 and jasmolin 1)	8003-34-7(121-21-1,25402-06-6 and 4466-14-2)	1.0 ppm
Pyridaben	96489-71-3	0.2 ppm
Spinosad	168316-95-8	0.2 ppm
Spiromesifen	283594-90-1	0.2 ppm
Spirotetramat	203313-25-1	0.2 ppm
Spiroxamine	118134-30-8	0.4 ppm
Tebuconazole	107534-96-3	0.4 ppm
Thiacloprid	111988-49-9	0.2 ppm
Thiamethoxam	153719-23-4	0.2 ppm
Trifloxystrobin	141517-21-7	0.2 ppm

(b) A batch or process lot that fails residual pesticide testing in accordance with paragraph (a) of this subsection shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

(13) Standards for testing for heavy metals.

(a) Hemp-derived cannabinoid products shall be tested by a testing facility for the following metals and shall not exceed the maximum allowable concentration for each:

1. Arsenic, maximum allowable concentration: one and five-tenths (1.5) ppm;
2. Cadmium, maximum allowable concentration: zero and four-tenths (0.4) ppm;
3. Lead, maximum allowable concentration: one (1) ppm; and
4. Mercury, maximum allowable concentration: one and two-tenths (1.2) ppm.

(b) Hemp-derived cannabinoid concentrate intended for inhalable products shall be tested by a testing facility for the following metals and shall not exceed the maximum allowable concentration for each:

1. Arsenic, maximum allowable concentration: zero and two-tenths (0.2) ppm;
2. Cadmium, maximum allowable concentration: zero and two-tenths (0.2) ppm;
3. Lead, maximum allowable concentration: zero and five-tenths (0.5) ppm; and
4. Mercury, maximum allowable concentration: zero and one-tenths (0.1) ppm.

(c) A batch or process lot that fails heavy metals testing in accordance with paragraph (a) of this subsection shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

(14) Standards for testing residual solvents.

(a) Hemp-derived cannabinoid products shall be tested by a testing facility for residual solvents, as appropriate, and shall not exceed the maximum allowable concentration for each solvent used according to the table below:

Solvent	CAS assigned number	Maximum allowable concentration stated in parts per million (ppm)
Acetone	67-64-1	1,000 ppm

Benzene*	71-43-2	2 ppm
Butanes, (measured as the cumulative residue of n-butane and iso-butane),	106-97-8 and 75-28-5	1,000 ppm
Ethanol	64-17-5	5,000 ppm
Ethyl Acetate	141-78-6	1,000 ppm
Heptanes	142-82-5	1,000 ppm
Hexanes* (measured as the cumulative residue of n-hexane, 2-methylpentane, 3-methylpentane, 2,2-dimethylbutane, and 2,3-dimethylbutane)	110-54-3, 107-83-5 and 79-29-8	60 ppm
Methanol*	67-56-1	600 ppm
Pentanes (measured as the cumulative residue of n-pentane, iso-pentane, and neo-pentane)	109-66-0, 78-78-4 and 463-82-1	1,000 ppm
2-Propanol (IPA)	67-63-0	1,000 ppm
Propane	74-98-6	1,000 ppm
Toluene*	108-88-3	180 ppm
Total Xylenes* (measured as the cumulative residue of 1,2-dimethylbenzene, 1,3-dimethylbenzene, and 1,4-dimethylbenzene, and the non-xylene, ethylbenzene),	1330-20-7 (95-47-6, 108-38-3 and 106-42-3 and 100-41-4)	430 ppm
Any other solvent not permitted for use pursuant to this regulation		1 ppm

*Note: These solvents are not approved for use. Due to their possible presence in the solvents approved for use, limits have been listed here accordingly.

(b) A processing or manufacturing facility shall be exempt from testing for solvents if the facility:

1. Did not use any solvent listed in paragraph (a) of this subsection;
2. Used a mechanical extraction process to separate cannabinoids; or
3. Used only water, animal fat, or vegetable oil as a solvent to separate the cannabinoids.

(c) If a sample from a batch or process lot fails solvent testing, the batch or process lot may be remediated using procedures that would reduce the concentration of solvents to less than the action level.

(d) A batch or process lot that is remediated in accordance with this subsection shall be:

1. Sampled and tested in accordance with this administrative regulation; and
2. Tested for solvents if not otherwise required for that product under this administrative regulation.

(e) A batch or process lot that fails solvent testing that is not remediated or that if remediated fails testing shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

(15) Plant material, such as flower, shake, and plant trim, used to process and manufacture hemp-derived cannabinoid products shall have:

(a) A water activity (Aw) rate of less than 0.65; and

(b) A total combined yeast and mold not to exceed 100,000 colony forming units per gram.

(16) Failed testing and remediation.

(a) A sample that fails any initial testing may be reanalyzed by the testing facility.

(b) If the reanalyzed sample passes, the processing or manufacturing facility shall resample the batch or process lot using another accredited testing facility to confirm the result in order for the batch or process lot to pass testing.

(c) A batch or process lot shall fail testing if the testing facility detects the presence of a contaminant in a sample above any limit of detection (LOD) established in this administrative regulation:

1. During an initial test where no reanalysis is requested; or
2. Upon reanalysis as described in this subsection.

(d) If a sample fails a test or a reanalysis, the batch or process lot:

1. May be remediated or sterilized in accordance with this administrative regulation; or
2. If it cannot be remediated or sterilized in accordance with this administrative regulation, it shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

(e) A hemp-derived cannabinoid product batch or process lot shall only be remediated twice. If the batch or process lot fails after a second remediation attempt and the second retesting, the entire batch or process lot shall be destroyed in a manner approved by the cabinet.

(f) A hemp-derived cannabinoid product from a batch or process lot that failed testing shall not be combined with another batch or process lot. Mixed products shall be considered adulterated, regardless of the LOD or defect level of the final product.

(17) A processing or manufacturing facility shall:

(a) Have detailed procedures for:

1. Sterilization processes to remove microbiological contaminants; and
2. Reducing the concentration of solvents; and

(b) Document all sampling, testing, sterilization, remediation, and destruction that result from a failed test in accordance with this administrative regulation.

(18) Hazard analysis and risk-based preventive controls.

(a) Processing facilities shall conduct a hazard analysis in accordance with 902 KAR 45:160 Section 2(1)(u) to identify and evaluate, based on experience, illness data, scientific report, and other information known, or reasonably foreseeable hazards associated with each type of cannabinoid product produced by extraction, conversion, catalyzation, or distillation, hydrogenation, or other refinement processes, and shall include:

1. Processing reagents or catalysis;
2. Processing by-products or compounds; and
3. Tentatively identified compounds.

(b) The hazard analysis shall include an evaluation of the hazards identified to assess the severity of illness or injury from the hazard and the probability that the hazard will occur in the absence of preventive controls.

(c) A processing facility shall identify and implement preventive controls to provide assurances that any hazards requiring a preventive control shall be significantly minimized or prevented, and the hemp-derived cannabinoid product not adulterated.

(d) The cabinet may initiate an investigation of a processing facility as a result of a by-product or compound with no toxicity study or a TICs report from a testing facility and may require a processing or manufacturing facility to submit samples for additional testing, including testing for analytes that are not required by this administrative regulation, at the processing or manufacturing facility's expense.

(19) Certificate of analysis.

(a) The testing facility shall:

1. Generate a certificate of analysis (COA) for each representative sample that the testing facility analyzes; and

2. Ensure the COA contains the results of all required analyses performed for the representative sample.

(b) The COA shall contain, at minimum:

1. The testing facility's name, premises address, and license number, processor's or manufacturer's name, and premises address;

2. Batch or lot number of the batch or process lot from which the sample was obtained. For products that are already packaged at the time of sampling, the labeled batch or lot number on the packaged hemp-derived cannabinoid products shall match the batch or lot number on the COA;

3. Sample identifying information, including matrix type and unique sample identifiers;

4. Sample history, including the date collected, the date received by the testing facility, and the date of all sample analyses and corresponding testing results;

5. The analytical methods, analytical instrumentation used, and corresponding LOD and limits of quantitation (LOQ); and

6. Analytes detected during the analyses of the sample that are unknown, unidentified, or injurious to human health if consumed, if any.

(c) The testing facility shall report test results for each representative sample on the COA as an overall "pass" or "fail" for the entire batch:

1. When reporting qualitative results for each analyte, the testing facility shall indicate "pass" or "fail";

2. When reporting quantitative results for each analyte, the testing facility shall use the appropriate units of measurement as required in accordance with this administrative regulation;

3. When reporting results for each test method, the testing facility shall indicate "pass" or "fail";

4. When reporting results for any analytes that were detected below the analytical method LOQ, indicate "<LOQ", notwithstanding cannabinoid results;

5. When reporting results for any analytes that were not detected or detected below the LOD, indicate "ND"; and

6. Indicate "NT" for any test that the testing facility did not perform.

(d) The testing facility shall retain the reserve sample, consisting of any portion of a sample that was not used in the testing process. The reserve sample shall be kept at minimum, for forty-five (45) business days after the analyses, after which time it may be destroyed and denatured to the point the material is rendered unrecognizable and unusable.

(e) The testing facility shall securely store the reserve sample in a manner that prohibits sample degradation, contamination, and tampering.

(20)

(a) In accordance with 2023 Ky. Acts ch. 78, a cannabinoid manufacturer or processor that ships adult-use products out of state for use or sale outside the Commonwealth of Kentucky:

1. Shall abide by the testing and labeling requirements of this administrative regulation if the receiving state or jurisdiction does not have testing and labeling requirements; or

2. May defer to the receiving state's testing requirements if that state has equivalent testing requirements.

3. Products intended for out-of-state sale shall be stored separately from in-state products and shall have signage indicating the products are for out-of-state sale.

(b) Batch number of the batch from which the sample was obtained shall be on the COA for all products shipped out of state.

Section 5. Record Keeping.

(1) A master formulation record shall be prepared and maintained for each unique hemp-derived cannabinoid product.

(2) The master formulation record shall include at least the following information:

(a) Name of the hemp-derived cannabinoid product;

(b) Ingredient identities and amounts;

(c) Specifications on the delivery device (if applicable);

(d) Complete instructions for preparing the hemp-derived cannabinoid product, including equipment, supplies, and description of the manufacturing steps;

(e) Process controls and procedures; and

(f) Any other information needed to describe the production and ensure its repeatability.

(3) A batch or process lot manufacturing record shall be created for each production batch of hemp-derived cannabinoid product.

(4) The batch manufacturing record shall include at the least the following information:

(a) Name of the hemp-derived cannabinoid product;

(b) Master formulation record reference for the hemp-derived cannabinoid product;

(c) Date and time of preparation of the hemp-derived cannabinoid product;

(d) Production batch number;

(e) Signature or initials of individuals involved in each manufacturing step;

(f) Name, vendor, or manufacturer, production batch number, and expiration date of each ingredient;

(g) Weight or measurement of each ingredient;

(h) Documentation of process controls;

(i) Any deviations from the master formulation record, and any problems or errors experienced during the manufacture, and corrective actions; and

(j) Total quantity of the hemp-derived cannabinoid product manufactured.

Section 6. Product Packaging and Labeling.

(1) Each hemp-derived cannabinoid product manufactured, marketed, sold, or distributed in the commonwealth shall be packaged and labeled in accordance with KRS 217.037, 2023 Ky. Acts ch. 78, and this administrative regulation.

(2) Each container of adult-use cannabinoid product shall:

(a) Have a tamper-evident seal; and

(b) Be in child-resistant packaging.

(3) Each container of non-intoxicating cannabinoid product or cosmetic shall have a tamper-evident seal.

(4) Cannabinoid product packaging shall not include:

(a) Any cartoon images;

(b) Likeness to images, characters, or phrases that are popularly used to advertise to children;

(c) Likeness to or imitation of any commercially available candy, snack, baked good, or beverage packaging or labeling;

(d) The terms "candy" or "candies", or any variation in the spelling of these words; or

(e) The logo of the department or cabinet, or any seal, flag, crest, coat of arms, or other insignia that could reasonably mislead any person to believe the product has been endorsed, manufactured, or used by any state, county, or municipality or any agency

thereof, excluding the use of seals associated with state or federal programs used in accordance with state or federal law and regulations.

(5) The total amount of hemp-derived cannabinoid per serving and the total amount per container shall accurately reflect testing results and shall not contain less than eighty (80) percent or more than 120% of the concentration of total cannabinoid content as listed on the product label:

(a) For hemp-derived cannabinoid ingestible and inhalable products, potency shall be labeled as milligrams per serving for total tetrahydrocannabinol and the primary cannabinoid marketed, as applicable; and milligrams per package for total tetrahydrocannabinol and the primary cannabinoids marketed; and

(b) Other hemp-derived cannabinoids labeled milligrams per gram (mg/g) per serving, excluding cosmetics, and milligrams per package, if listed on the label.

(6) Adult-use hemp-derived cannabinoid products shall include the following warning label statements:

(a) "This product is intended for use by adults 21 years and older. Keep out of reach of children."

(b) "There may be health risks associated with the consumption of this product."

(c) "There may be additional health risks associated with the consumption of this product for those who are pregnant, nursing, or plan to become pregnant."

(d) "The intoxicating effects of this product may be delayed by two or more hours."

(e) " May cause drowsiness or impairment. Do not drive a motor vehicle or operate machinery while using this product."

(f) "Use of this product may result in a positive drug screen".

(7) A quick response or QR code may be used as a link to the warning statements required by subsection (7) of this section. The QR code shall be labeled as "Warning Statements" directly above or below the code and shall be large enough to be smart-phone readable.

Section 7. Retail Sale of Hemp-derived Cannabinoid Products.

(1) All hemp-derived cannabinoid products sold in a retail establishment shall:

(a) Be from an approved source;

(b) Be packaged and labeled in accordance with this administrative regulation; and

(c) Have a valid certificate of analysis available upon request.

(2) Retail establishments and food service establishments offering adult-use hemp-derived cannabinoid products shall register with the cabinet at https://redcap.chfs.ky.gov/surveys/?s=C8AHC9AYMP74REEM within ninety (90) days of the effective date of this emergency administrative regulation.

(3) Only cannabinoid products registered in accordance with Section 2 of this administrative regulation may be offered at retail establishments and food service establishments.

(4) Cannabinoid retailers shall maintain records of cannabinoid product purchase, including the name and address of the cannabinoid processor or manufacturer, and the wholesaler or distributor.

(5) Only non-intoxicating and cosmetic cannabinoid products may be sold to persons under the age of twenty-one (21).

(6) All adult-use hemp-derived cannabinoid products shall:

(a) Be secured in the retail setting to prevent theft or other access to persons under the age of twenty-one (21); and

(b) Not be sold, gifted, or otherwise transferred to any person under the age of twenty-one (21).

(7)

(a) Any person who sells adult-use hemp-derived cannabinoid products at retail shall require proof of age of the buyer to verify the buyer is age twenty-one (21) years or older; and

(b) May deliver or ship adult-use hemp-derived cannabinoid products to consumers over twenty-one (21) years of age in packages clearly marked "Adult-use only"

Section 8. Ingestible Hemp-derived Cannabinoid Products at Food Service Establishments.

(1) Only registered, pre-packaged adult-use ingestible cannabinoid products may be offered as ready-to-consume or for direct consumption at food service establishments.

(2) Adult-use cannabinoids shall not be added to an ingestible food product at a food service establishment.

(3) Non-intoxicating cannabinoids may be added to an ingestible product prior to retail sale at a food service establishment.

(4) The non-intoxicating cannabinoid shall be obtained from an approved source.

(5) The food service establishment shall obtain a valid certificate of analysis from the approved source and provide a copy upon inspection.

(6) A food service establishment offering non-intoxicating cannabinoid products in a finished food product shall provide to consumers upon request:

(a) The common name of the product; and

(b) The manufacturer or distributor of the product.

(7) A food service establishment shall notify the cabinet within one (1) business day of becoming aware or within one (1) business day of when the food service establishment should have been aware of any serious adverse event to a hemp-derived cannabinoid product sold by the establishment.

Section 9. Inspection and Enforcement.

(1) The cabinet or its duly authorized agent shall conduct an onsite inspection of all hemp-derived cannabinoid processing and manufacturing establishments, storage warehouses, and distribution centers.

(2)

(a) Retail establishments offering adult-use cannabinoid products shall be inspected by the cabinet or its duly authorized agent; and

(b) Retail establishments offering only non-intoxicating cannabinoid products may be inspected by the cabinet or its duly authorized agent upon complaint, receipt of a report of a serious adverse event, or at the discretion of the cabinet.

(3) The location of the permitted or registered establishment, all general business records, including employee records, and vehicles utilized to transport products are subject to reasonable inspection.

(4) Permitted or registered establishments shall cooperate with the cabinet or its duly authorized agent during any inspections, complaint investigation, requests for information or data, in order to verify compliance with this administrative regulation.

(5) The permit holder shall take immediate steps to correct conditions that have caused an imminent health hazard.

(6)

(a) The permit holder shall notify the cabinet within twenty-four (24) hours of the knowledge of an imminent health hazard that cannot be controlled by immediate corrective action or if product, product packaging, cosmetic, or cosmetic packaging has become contaminated because of an imminent health hazard.

(b) Notification to the cabinet shall be made by:

1. Email to food.safety@ky.gov; or
2. Phone to (502)564-7181.

(7) If the cabinet has evidence that a processing or manufacturing facility has failed to act to correct an imminent health hazard, the following enforcement provisions shall be

initiated:

(a) Suspend the permit without an administrative hearing; or

(b) Suspend that portion of the processing or manufacturing operation affected by the imminent health hazard without an administrative hearing.

(8) If a permit suspension is due to an imminent health hazard, the permit holder may request an administrative hearing.

(9) A permit holder shall notify the cabinet within one (1) business day of becoming aware of any serious adverse event to a hemp-derived cannabinoid product sold or transferred by the permit holder.

(10) In all other instances of violation of this administrative regulation, the cabinet shall serve the permit holder with a written notice specifying the violation and afford the holder an opportunity to correct.

(11) If a permit holder has failed to comply with the written notice within the timeframe granted, the cabinet shall issue a notice of intent to suspend the permit.

(12) The notice in subsection (10) of this section shall include notification that the permit shall be suspended at the end of ten (10) days following service of the notice, unless a written request for an administrative hearing is filed with the cabinet by the permit holder within the ten (10) day period.

(13) Any person whose permit has been suspended may request a reinspection for the purpose of reinstatement of the permit. Within seven (7) days following receipt of a written request, including a statement signed by the applicant that in his or her opinion the condition causing suspension of the permit has been corrected, the cabinet shall make an inspection, and if the inspection reveals that the condition causing suspension of the permit has been corrected, the permit shall be reinstated.

(14) For a permitted facility that has had a suspended permit two (2) or more times within a five (5) year period, the cabinet shall initiate permit revocation proceedings. Prior to this action, the cabinet shall notify the permit holder in writing, stating the reasons for which the permit revocation is being sought and advising that the permit shall be permanently revoked at the end of ten (10) days following service of the notice, unless a request for an administrative hearing is filed with the cabinet pursuant to KRS Chapter 13B by the permit holder within the ten (10) day period.

WESLEY W. DUKE, General Counsel
ERIC C. FRIEDLANDER, Secretary

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