CABINET FOR HEALTH AND FAMILY SERVICES

Department for Public Health

Division of Public Health Protection and Safety

(Emergency Amended After Comments)

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

RELATES TO: KRS Chapter 13B, 217.015, 217.025, 217.035, 217.037, 217.039, [~~217.155,~~] 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[~~process~~] 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[~~cannabinoid~~], 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**[~~**tetrahydrocannabinols, tetrahydrocannabinolic acids that are artificially or naturally derived, delta-8 tetrahydrocannabinol, delta-9 tetrahydrocannabinol, the optical isomers of delta-8 tetrahydrocannabinol or delta-9 tetrahydrocannabinol, and any artificially derived cannabinoid that is reasonably determined to have an intoxicating effect.**~~

~~**(2) "Artificially derived cannabinoid" means a chemical substance that is created by a chemical reaction that changes the molecular structure of any chemical substance derived from a plant of the genus Cannabis**~~].

(2)[~~**(3)**~~] "Approved source" means:

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

(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)[~~**(4)**~~][~~(2)~~] "Cabinet" is defined by KRS 217.015(3).

(4)[~~**(5)**~~] "Cannabidiol" or "CBD" is defined by KRS 217.039(1)(a).

(5)[~~**(6)**~~][~~(3)~~] "Cannabinoid" means a [~~non-intoxicating~~] 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)[~~**(7)**~~] "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)[~~**(8)**~~][~~(4)~~] "Cosmetic" is defined by KRS 217.015(7).

(8)[~~**(9)**~~][~~(5) "Department" means the Kentucky Department for Public Health.~~

~~(6)~~] "Food service establishment" is defined by KRS 217.015(21).

(9)[~~**(10)**~~][~~(7)~~] "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)[~~(8)~~] "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 concentrate 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)[~~**(13)**~~][~~(9)~~] "Person" is defined by KRS 217.015(32).

(17)[~~**(14)**~~] "Proof of age" is defined by KRS 438.305(4).

(18)[~~**(15)**~~] "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)[~~**(16)**~~] "Tentatively identified compounds" or "TIC" means compounds detected in a sample [~~**using gas chromatography mass spectrometry**~~] that are not among the target analytes [~~**for the residual solvent analysis**~~].

[~~**(17) "Topical" means a hemp-derived cannabinoid product intended to be applied to the skin or hair.**~~]

Section 2. **Permit and Product Registration**[~~**Processing, Manufacture, Storage, or Distribution of Hemp-derived Cannabinoid Products**~~][~~Permits~~].

(1) **In-state permit.**

(a) A person located in Kentucky seeking to process, manufacture, store, or distribute hemp-derived **cannabinoid products**[~~**cannabinoids**~~] shall be permitted by the cabinet[~~a hemp-derived ingestible or cosmetic cannabinoid product shall submit an Application for Permit to Operate a Food Plant or Cosmetic Manufacturing Plant, DFS-260, incorporated by reference in 902 KAR 45:160, to the department~~].

(b)[~~**(2)**~~] The permit shall be:

1.[~~**(a)**~~] Nontransferable in regard to person or address; [~~and~~]

2.[~~**(b)**~~] Posted in a conspicuous place in the facility; [**~~and~~**]

3.[~~**(c)**~~] Renewed annually;[~~.~~]

4. Include[~~**(3)**~~] the fee paid in accordance with:

a.[~~**(a)**~~] 902 KAR 45:180, for a food processing establishment;

b.[~~**(b)**~~] 902 KAR 45:180, for a cosmetic manufacturer; and

c.[~~**(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 less than three tenths of one percent (0.3%) Total THC;

3. Delta-8-tetrahydrocannabinol (Delta-8-THC);

4. Delta-9-tetrahydrocannabinolic acid A (THCA-A) with less than three tenths of one percent (0.3%) 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)[~~(4)~~] 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)[~~(5)~~] 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 [~~(6) An adult-use hemp-derived cannabinoid processing or manufacturing facility, or distributor, shall not employ anyone under twenty-one (21) years of age~~].

(4) Non-intoxicating cannabinoid products shall:

(a) Have at least a twenty-five (25) 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)[~~(7)~~] A hemp-derived cannabinoid processing or manufacturing facility shall not treat or otherwise adulterate a cannabinoid product[**, ~~concentrate, cannabinoid extract, or edible product~~**] with:

(a) Any non-cannabinoid additive that increases toxicity or addictive potential, **excluding caffeine**;

(b) **Alcohol**[**~~Caffeine~~**];

(c) Nicotine; or

(d) Other chemicals that may increase carcinogenicity or cardiac effects.

(7)[~~(8)~~] All [**~~edible~~**] products shall be homogenized to ensure uniform **distribution**[**~~disbursement~~**] of cannabinoids throughout the product.

(8)[~~(9)~~] Only permitted hemp-derived cannabinoid processing facilities shall perform cannabinoid extraction, conversion, catalyzation, [**~~or~~**] distillation, **hydrogenation, or other refinement** processes.

(9)[~~(10)~~] A hemp-derived cannabinoid processor or manufacturer shall only use the following solvents: water, [**~~vegetable~~**] 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 **preapproved** [**~~approved~~**] by the cabinet.

(10)[~~(11)~~] 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)[~~(12)~~](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)[~~**(13)**~~](a) Solvents shall be collected and stored in **food**[~~**medical**~~]-grade containers when practical to maintain purity; and

(b) Solvent containers shall be replaced or safely purged, cleaned, and sanitized periodically.

(13)[~~**(14)**~~] 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)[~~**(15)**~~] 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)[~~**(16)**~~] Cannabinoid processing facilities using carbon dioxide shall have equipment and facilities approved by local fire code officials, if applicable.

(16)[~~**(17)**~~] Processes using flammable gas or flammable liquid shall have leak or gas detection measures, or both.

(17)[~~**(18)**~~] A permittee shall not use dimethylsulfoxide (DMSO) in the manufacture of hemp-derived cannabinoid products, and possession upon the permitted premises is prohibited.

(18)[~~**(19)**~~](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)[~~**(20)**~~] The following substances shall be prohibited in hemp-derived cannabinoid extraction intended for inhalation:

(a) **Acetates**[~~**Vitamin E acetate (VEA)**~~];

(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);[~~**and**~~]

(f) Myclobutanil;

(g) Artificial food coloring; and

(h) Benzoic acid.

Section **4**[**3**]. 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) [~~For~~] Hemp-derived cannabinoid **product**[~~concentrates, extracts, and edible products,~~] samples shall consist of enough **material**[~~samples~~] 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 [~~concentrates, extracts, and edible~~] 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 [~~**and processing chemicals**~~], 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)[~~(7)~~] Testing requirements.

(a) A processing or manufacturing facility shall test every batch or process lot of hemp-derived cannabinoid **product**[~~**concentrate, extract, or edible products**~~] 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 [~~**concentrate, extract, or edible**~~] products shall be tested for:

1. Cannabinoids;

2. Microbial impurities;

3. Mycotoxins;

4. Residual pesticides;

5. Heavy metals; and

6. Residual solvents [~~**and processing chemicals**~~], if applicable.

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

residual solvents[~~**processing chemicals**~~], 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**[~~**processing chemicals**~~] in compliance with this administrative regulation; and

2. Test results indicate the batch or process lot was within established limits.

(e)[~~**(d)**~~] 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**[~~**processing chemicals**~~] hazard.

(f)[~~**(e)**~~] All vaporizer delivery device or pressurized metered dose inhaler cartridge batches or process lots shall be tested for **Acetates**[~~**Vitamin E Acetate**~~].

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

(9)[~~**(8)**~~] 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. [~~Total CBD concentration, calculated in accordance with paragraph (d) of this subsection and reported in percentages;~~

~~4. CBD-A concentration;~~

~~5.~~] Milligrams per serving for total tetrahydrocannabinol and **the primary cannabinoid marketed, excluding cosmetics**[~~total CBD~~], as applicable;

4.[~~6.~~] Milligrams per package for total tetrahydrocannabinol and **the primary cannabinoid marketed, excluding cosmetics**[~~total CBD~~], as applicable; and

5.[~~7.~~] The results of all other hemp-derived cannabinoids analyzed on the COA both as a percentage and [~~in either~~] milligrams per gram (mg/g) [~~if by weight or milligrams per milliliter (mg/mL) if by volume~~].

(c) The following calculation shall be used for calculating total tetrahydrocannabinol[~~:~~

~~1. For~~] concentration expressed in weight: Total cannabinoid concentration (mg/g) = (cannabinoid acid form concentration (mg/g) x 0.877) + cannabinoid concentration (mg/g)[~~; or~~

~~2. For concentration expressed in volume: Total cannabinoid concentration (mg/mL) = (cannabinoid acid form concentration (mg/mL) x 0.877) + cannabinoid concentration (mg/mL)~~].

(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**[~~total CBD~~] per gram.

(e) [~~Adult-use hemp-derived~~] 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)[~~**(9)**~~] Standards for microbial impurities.

(a) Hemp-derived cannabinoid [~~**concentrate, extract, or edible**~~] 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; [~~**and**~~]

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**[~~**non-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; [~~**and**~~]

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**[~~**concentrate or extract**~~] 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[~~**, and processing chemicals**~~].

(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)[~~**(10)**~~] Standards for mycotoxin testing.

(a) Hemp-derived cannabinoid [~~**concentrate, extract, or edible**~~] 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)[~~**(11)**~~] Standards for testing residual pesticides.

(a) Hemp-derived cannabinoid [~~**concentrate, extract, or edible**~~] 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)[~~(12)~~] Standards for testing for heavy metals.

(a) Hemp-derived cannabinoid [~~**concentrate, extract, or edible**~~] 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)**[~~**zero and four-tenths (0.4)**~~] 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)[~~**(13)**~~] Standards for testing residual solvents [~~**and processing chemicals**~~].

(a) Hemp-derived cannabinoid [~~**concentrate, extract, or edible**~~] products shall be tested by a testing facility for residual solvents [~~**and processing chemicals**~~], as appropriate, and shall not exceed the maximum allowable concentration for each solvent used according to the table below:

Solvent [~~or processing chemical~~]	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**[~~**1,000**~~] 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**[~~**None Detected**~~]
*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)[~~(14)~~] 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)[~~(15)~~] 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 [**~~concentrate, extract, or edible~~**] 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)[**~~(16)~~**] 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)[~~(17) Tentative identification of compounds (TICs).~~

~~(a) The testing facility shall provide the processing or manufacturing facility with a complete report of any TICs identified.~~

~~(b) The processing or manufacturing facility shall conduct a hazard analysis in accordance with the requirements of 902 KAR 45:160 Section 2(1)(u) to identify~~

~~and evaluate based on experience, illness data, scientific reports, and other information known or reasonably foreseeable hazards associated with any reported TICs.~~

~~(c) 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 a preventive control.~~

~~(d) A processing or manufacturing 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 will not be adulterated.~~

~~(e)~~] The cabinet may initiate an investigation of a processing [~~or manufacturing~~] 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)[~~(18)~~] 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[~~, and permit number~~];

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. [~~**An attestation from the testing facility supervisory or management employee that all LOQ samples required by this administrative regulation were performed and met the acceptance criteria; and**~~

~~7.~~] 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) [~~**(f) The testing facility shall provide the reserve sample to the cabinet upon request.**~~

~~**(19)**~~](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 **or labeling** requirements; or

2. May defer to the receiving state's **or jurisdiction's** testing and **labeling** requirements if that state has equivalent testing **and labeling** 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**[**4**]. 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**[**5**]. 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**[~~**ingestible or cosmetic hemp-derived**~~] 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) [~~**Ingestible hemp-derived**~~] 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)[~~**(4)**~~] 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**[~~**as reported by the testing facility**~~]:

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

(b)[~~**total CBD, as applicable;**~~

~~**(b) For hemp-derived cannabinoid concentrates total tetrahydrocannabinol and total CBD, as applicable shall be labeled in percentages; and**~~

~~**(c) The results of all**~~] Other hemp-derived cannabinoids **labeled**[~~**as a percentage, in either**~~] milligrams per gram (mg/g) **per serving, excluding cosmetics, and milligrams per package, if listed on the label.**

(6) All cannabinoid products shall include the common cannabinoid description in the product name, such as "Delta-8 THC gummies" or "Full-spectrum CBD extract" using the same or larger font than the product name.

(7) Adult-use[~~**if by weight, or milligrams per milliliter (mg/mL) if by volume, as applicable**~~.

~~**(5) The name of the hemp-derived cannabinoid product that includes a product modifier such as "Delta-8 THC product," or "CBD product" using the same or larger font than the product name.**~~

~~**(6) Adult-use**~~] hemp-derived cannabinoid [~~**ingestible**~~] 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**[~~**women**~~] who are pregnant, **nursing**[~~breastfeeding~~], 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 **heavy** machinery while using this product."

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

(8) 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**[**6**]. 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** [~~**cannabidiol**~~] products may be sold to persons under the age of twenty-one (21).

(6)[~~**(4)**~~] 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)[~~**(5)**~~](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"[~~**, adult signature (21 years of age or over) required" and request adult-signature-only service from the carrier**~~.

~~**(6) The cabinet or its duly authorized agent shall inspect retail establishments for compliance with this administrative regulation.**~~

~~**(7) A retail establishment not in compliance with this administrative regulation shall be provided notice of the violation.**~~

~~**(8) All products not in compliance with this administrative regulation may be seized and destroyed by the cabinet or its duly authorized agent.**~~

Section **8**[~~**7**~~]. 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[~~Except as established in subsection (3) of this section, an ingestible or cosmetic product label shall include, in a print no less than six (6) point font, the following information:~~

(a) A statement of identity or common product name that shall be stated upon the principal display panel of the label;

(b) The net quantity of contents expressed in both standard English and metric units of measurement located in the lower thirty (30) percent of the principal display panel of the label parallel to the base of the container;

(c) The ingredients of the hemp-derived cannabinoid product, in descending order of predominance by weight;

(d) The name of the manufacturer or distributor;

(e) A statement that the hemp-derived cannabinoid product is within the federal legal limit of zero and three-tenths (0.3) percent delta-9 tetrahydrocannabinol;

(f) The total amount of cannabinoid per serving for ingestible products, or the total amount per container for cosmetic products;

(g) Suggested use instructions or directions, including serving sizes; and

(h) An expiration date, if any.

(3) An ingestible or cosmetic product that has a total area of twelve (12) square inches or less available to bear labeling shall be labeled in accordance with subsection (2) of this section, except the print may be smaller than six (6) point font but shall not measure less than 1/32 of an inch in height.

(4) Each container of ingestible or cosmetic hemp-derived cannabinoid product shall have a tamper evident seal.

(5) Product packaging, labeling or advertising material for any hemp-derived cannabinoid product shall not bear any implicit or explicit health claims stating that the product can diagnose, treat, cure, or prevent any disease.

~~Section 4. Hemp-derived Ingestible Cannabinoid Products.~~] [**~~(1) Only cannabidiol or CBD~~**] [~~hemp-derived cannabinoids~~] may be added to an ingestible product [~~during the manufacturing process or~~] prior to retail sale at a food service establishment.

(4)[~~(2)~~] The **non-intoxicating**[**~~hemp-derived~~**] cannabinoid [**~~ingredient~~**] shall be obtained from an approved source.

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

(6)[~~(4)~~] [~~Food or ingestible product shall not contain a total delta-9 tetrahydrocannabinol concentration of more than zero and three-tenths (0.3) percent on a dry weight basis or contain tetrahydrocannabinol as the primary hemp-derived cannabinoid.~~

~~(5)~~] A food service establishment offering **non-intoxicating cannabinoid**[**~~cannabidiol or CBD~~**] [~~hemp-derived 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)[~~(5)~~] 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**[**~~adverse reactions~~**] to a hemp-derived cannabinoid product sold by the establishment[~~; and~~

~~(c) A statement that the hemp-derived cannabinoid product is within the federal legal limit of zero and three-tenths (0.3) percent delta-9 tetrahydrocannabinol~~].

Section **9**[**~~8~~**]. 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[~~, **and retail establishments**~~].

(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)[~~(3)~~] 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)[~~(4)~~] The permit holder shall take immediate steps to correct conditions that have caused an imminent health hazard.

(6)[~~**(5)**~~](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)[~~(6)~~] 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)[~~(7)~~] If a permit suspension is due to an imminent health hazard, the permit holder may request an administrative hearing.

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

(10)[~~(9)~~] 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)[~~(10)~~] 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)[~~(11)~~] 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)[~~(12)~~] 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)[~~(13)~~] 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.

902 KAR 45:190E

REVIEWED:

10-13-23

Wesley W. Duke Date
General Counsel, Cabinet for Health and Family Services

APPROVED:

10/13/23

Eric C. Friedlander Date
Secretary, Cabinet for Health and Family Services

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation: 902 KAR 45:190E
Agency Contact: Julie Brooks
Phone Number: (502)564-3970
Email: julied.brooks@ky.gov

Contact Person: Krista Quarles
Phone Number: (502) 564-6746
Email: CHFSregs@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This emergency 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, and methods for use of hemp-derived cannabinoids as an additive to food products.

(b) The necessity of this administrative regulation: Many hemp-derived cannabinoid products sold in Kentucky are currently unregulated. This emergency administrative regulation is necessary to ensure that all hemp-derived cannabinoid products produced and sold in the state are safe for human consumption.

(c) How this administrative regulation conforms to the content of the authorizing statutes: 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 or its duly authorized agents 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.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This emergency administrative regulation ensures all hemp-derived cannabinoid products manufactured, processed, distributed, or sold are safe for human consumption, are labeled in a manner that allows the end user to understand the effects of the products, and prohibits the sale of products to a person under the age of twenty-one (21).

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendment to this emergency administrative regulation clearly defines hemp-derived cannabinoid products that are for adult-use only and separates these from nonintoxicating hemp-derived cannabinoid products, adds requirements for processing facilities, revises the requirements for manufacturing facilities, adds product testing requirements to incorporate the federal Food and Drug Administration standards for product safety, adds the requirement for a retail store to register with the department,

and adds enforcement actions should a processing or manufacturing facility violate the provisions of this administrative regulation. The amended after comments version revises the defined terms to distinguish adult-use products from non-intoxicating products, adds a registration for out-of-state processors and manufacturers, revises the retail establishment and food service establishment requirements, revises the testing requirements, and revises the labeling requirements.

(b) The necessity of the amendment to this administrative regulation: The amendment to this emergency administrative regulation is necessary because many hemp-derived cannabinoid products sold in Kentucky are currently unregulated by both the state and the federal Food and Drug Administration. Some products containing hemp-derived cannabinoids have concentrations that produce a psychoactive effect and are unsafe if consumed in large quantities. The labels of some products make it difficult to determine the amount of hemp-derived cannabinoid per serving, and other products are packaged to mimic candies or other items that may appeal to children and young adults. The amendment to this emergency administrative regulation is necessary to ensure that all hemp-derived cannabinoid products produced and sold in the state are safe for human consumption, are properly label, and are not targeted for sale to persons under the age of twenty-one (21).

(c) How the amendment conforms to the content of the authorizing statutes: House Bill 544 from the 2023 legislative session requires the cabinet to immediately begin the process of regulating delta-8 tetrahydrocannabinol and any other hemp-derived substances, revises the labeling and testing requirements for all hemp-derived cannabinoid products, and prohibits the possession of covered products by a person under the age of twenty-one (21). The bill contained an emergency clause.

(d) How the amendment will assist in the effective administration of the statutes: The amendment to this emergency administrative regulation will ensure products manufactured, processed, marketed, and sold in the commonwealth are safe for human consumption.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: There are currently forty-seven (47) manufacturers of cannabidiol (CBD) products registered with the department. Retail stores that sell CBD or other hemp-derived cannabinoid products, including those that contain delta-8, are not registered with the department at this time.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Current manufacturers permitted by the department will need to ensure their products meet the manufacturing and testing requirements established by this emergency administrative regulation. Retail stores will need to register with the department, allow for inspection by the cabinet or its duly authorized agent, and ensure all products sold meet the requirements of this emergency administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): This emergency administrative

regulation will not impact the cost of the currently registered processing and manufacturing facilities.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Producers and manufacturers will be able to ensure the products offered are of the highest quality and do not unintentionally target the sale to persons under the age of twenty-one (21). Retail stores will be able to sell products that meet the highest manufacturing standards.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: The current budget for the food manufacturing permitting and inspection program is $1,080,900. The increase in required permitting and inspection processes to implement this emergency administrative regulation will cost the department an additional $500,800 in the first year.

(b) On a continuing basis: The department will continue to need an additional $500,800, at a minimum, in subsequent years. An increase in permitted facilities will result in increased costs.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Funding to implement and enforce this emergency administrative regulation will be from a mix of fees paid to the department and state general fund dollars.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: The emergency amendment to this administrative regulation does not increase the required fees and does not establish new fees.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This emergency administrative regulation does not establish any new fees and does not increase the existing fees. Currently manufacturers and processors pay the fee in accordance with 902 KAR 45:180.

(9) TIERING: Is tiering applied? (Explain why or why not) Tiering is applied. Testing for solvents is only required if the products listed in this emergency administrative regulation are used in the manufacturing or processing procedures.

FISCAL NOTE

Administrative Regulation: 902 KAR 45:190E
Agency Contact: Julie Brooks
Phone Number: (502)564-3970
Email: julied.brooks@ky.gov

Contact Person: Krista Quarles
Phone Number: (502) 564-6746
Email: CHFSregs@ky.gov

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The amendment to this emergency administrative regulation will impact the Food Safety Branch in the Department for Public Health.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 217.125, 217.127, and 217.135.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? Current estimates indicate this emergency administrative regulation will generate between $5,875 and $47,000 in the first year. This figure was determined using the current fee structure in 902 KAR 45:180 multiplied by the number of currently permitted facilities. The minimum fee is $125, and the maximum is $1,000.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This emergency administrative regulation will generate between $5,875 and $47,000 in subsequent years. This figure is subject to change based on changes in the number of permitted facilities.

(c) How much will it cost to administer this program for the first year? Cost to the department to implement this emergency administrative regulation will be approximately $500,800 in the first year. This figure was determined using the fiscal year 2020 salary and fringe rates for a minimum of four additional environmental health inspection program staff ($125,200X4).

(d) How much will it cost to administer this program for subsequent years? Ongoing cost to the department to implement this emergency administrative regulation will be approximately $500,800 in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year? The amendment to this emergency administrative regulation will not generate cost savings for the regulated entities.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years? The amendment to this emergency administrative regulation will not generate cost savings for the regulated entities.

(c) How much will it cost the regulated entities for the first year? The costs to the regulated entities will be the required permitting fees ($125 up to $1,000), and any costs associated with the testing and labeling requirements.

(d) How much will it cost the regulated entities for subsequent years? The regulated entities will continue to pay the annual permit fee ($125 up to $1,000) and costs associated with the testing and labeling requirements in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings(+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below. *"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)]* This emergency administrative regulation could have a major economic impact to the Cabinet for Health and Family Services. It is estimated that an additional $500,800 is needed to cover the costs for increased staff. While some of these costs will be offset by the required permitting fees, the total revenue received will not completely cover the anticipated costs.

STATEMENT OF CONSIDERATION

RELATING TO 902 KAR 45:190E

Cabinet for Health and Family Services
Department for Public Health
Division of Public Health Protection and Safety

Amended After Comments

(1) A public hearing on 902 KAR 45:190E was held on September 25, 2023, at 9 a.m. via the Zoom Cloud Meetings platform. In addition to those who attended the public hearing, written comments were received during the public comment period.

(2) The following individuals provided comments via the public comment process:

Name and Title	Agency/Organization/Entity/Other
Ross Ballard, II	
Joe Bilby, General Counsel	Kentucky Department of Agriculture
Matthew Bratcher, Executive Director	KY NORML (National Organization for the Reform of Marijuana Laws
Director	Kentucky Cannabis Foundation
Owner	One Love Hemp Dispensary
Sam Burney, Director of Partnerships	Kentucky Heritage Hemp Company
Liz Burrows	Region 6 KY Agency for Substance Abuse Policy (KY ASAP) Local Board
Elizabeth Butler	
Ben Caudill	
Casey Dickson	
Evan Dickson	
William M. Edwards, Jr., Founder	Brannen Schneider, LLC DBA Kentucky Slushie
Howard Faught	
Dana Emmitt-Hall	
Bobby Gaffney, Chief Science Officer	Kentucky Heritage Hemp Company
Charles George, Executive Director	Wine and Spirit Wholesalers of Kentucky
Launi Gum, Program Director	Champions for a Drug Free Grant County
Project Coordinator	
Jane Harrod	Early Bird CBD

Josh Hartsel, Cofounder	Fractal Hemp, LLC
Stephanie Hensley	
Jim Higdon, Co-founder	Cornbread Hemp
Jimmy Higdon, State Senator	14th Senate District
Rebecca Johnson	
Doug Koch	
Jennifer Lantz, Director of Quality and Compliance	Kentucky Heritage Hemp Company
Barry D. Lee, Superintendent	Casey County Schools
Chris Lindsey, Director of State Advocacy and Public Policy	American Trade Association for Cannabis and Hemp (ATACH)
Hannah Looney	
Robert Matheny, Owner	KY CBD Pharmacy
Board member	Kentucky Cannabis Freedom Coalition
Jonathan Miller, General Counsel	U.S. Hemp Roundtable
Katie Moyer, President	Kentucky Hemp Association
K. Brad Oakley, Member	Jackson Kelly, PLLC
	Kentucky Beer Wholesalers Association
William S. Palmer	
Alice Peterson, President	Kentucky Heritage Hemp Company
Bill Peterson, CEO	Kentucky Heritage Hemp Company
William Polyniak, Partner	Bluegrass Hemp Oil
	Kentucky Cannabis Company
Jody Roberts, US Army Master Sergeant (RET)	
Keith L. Rogers, Chief of Staff	Kentucky Department of Agriculture
Annie Rouse, Co-founder and Chief Operating Officer	OP Innovates
Mike Shaffor	
Phyllis Smith	PJ Smith Enterprises, LLC
	DBA Essentially Hemp
Shannon Stiglitz, Senior VP of Governmental Affairs	Kentucky Retail Federation
Julian Stone	
Dee Dee Taylor, Board Member	Kentucky Hemp Association
CEO/Founder	502 Hemp Wellness Center
Christopher M. Ware, Founder and CEO	KCA Labs
Eric Zipperle	Cornbread Hemp

(3) The following individual from the promulgating administrative body responded to the written comments:

Name and Title	Agency/Organization/Entity/Other

Julie Brooks	Department for Public Health
Regulation Coordinator	Cabinet for Health and Family Services
William Daniel Bell	Department for Public Health
Assistant Division Director	Cabinet for Health and Family Services
Troy Wilkerson	Department for Public Health
Food Safety Inspector	Cabinet for Health and Family Services

SUMMARY OF COMMENTS AND AGENCY'S RESPONSES

(1) Subject: Non-intoxicating products

(a) Comment: Jim Higdon and Eric Zipperle, Co-founders of Cornbread Hemp, commented: "We are a CBD company based in Kentucky that makes USDA organic full spectrum CBD products with a legal amount of naturally occurring delta-9 THC, below the federal limit of 0.3%. We do not make delta-8 THC products or any intoxicating product that would be considered for "adult use".

"We support the effort to regulate intoxicating products made with delta-8 and other synthetic cannabinoids, but our products should not be regulated the same way. Our products are non-intoxicating, even though they contain a modest amount of THC. Our customers take our full spectrum CBD products as supplements to help support their pain, anxiety, and sleep issues. Many customers tell us that they take our products because it helps them relax without intoxicating them.

"Therefore, we were surprised to learn that because our products contain a very small amount of THC — 2mg per serving — they are defined as "adult use cannabinoids" in the emergency regulations published on August 1. The new regulations do not distinguish our products from delta-8 or other synthetic compounds. That's not correct, and this error could jeopardize our entire business.

"At Cornbread Hemp, we make USDA certified organic CBD products that are 100% plant-based and third-party lab tested. We hope that we can be a model for what a good, responsible CBD brand can be in Kentucky.

"Our biggest concern, as it stands now, is the distinction between full-spectrum CBD products, as we make at Cornbread Hemp, that are certified organic with a natural ratio of CBD-dominant products with a modest amount of naturally-occurring delta-9 THC.

"Our strongest product is 50 milligrams of CBD to 2 milligrams of delta-9 THC. And we believe that this is a non-intoxicating product."

(a) Comment: Charles George, Executive Director, Wine and Spirits Wholesalers of Kentucky, commented: "I want to lead our support to ensuring that there is a delineation between these broad spectrum and full-spectrum CBD products that do not include, or that may include trace amounts of THC but have no history of marketing or no intention of being intoxicating products. We strongly believe there needs to be that distinction between non-intoxicating and intoxicating.

"We want to make sure that there is a clear distinction between intoxicating and non-intoxicating. For these products that are clearly intoxicating, ingestible products that are clearly intoxicating, I really don't see a high distinction between these and alcohol.

We have a good, pretty sound system when it comes to alcohol oversight, and we think many of these same principles can be applied to these intoxicating products.

"We strongly believe any regulatory structure must address and delineate all intoxicating hemp-derived products, synthetics or compounds that contain THC. Without this delineation, consumer confusion would abound, as it would be difficult to know the potential intoxicating effect of the product one is purchasing.

"We believe a reasonable level must be determined that does not capture broad-spectrum and full-spectrum CBD products containing non-intoxicating traces of THC. If these products are included as 'adult use', they will undergo unnecessary heightened scrutiny and cause consumer confusion.

"Assuming a reasonable definition of 'adult use' can be established, these intoxicating products should undergo more rigorous oversight than non-intoxicating products.

"While our members have not yet begun distributing hemp-derived intoxicating products, we believe there are many legitimate hemp industry members who are making quality products, both intoxicating and non-intoxicating, that warrant a sound regulatory structure to ensure these legitimate products can be sold safely."

(a) Comment: Jimmy Higdon, State Senator, 14th Senate District, commented: "When the General Assemble passed HB 544 the Legislstive intent was to eliminate Unregulated intoxicating products like delta-8 that pose a health crisis for Kentucky and the nation especially with our youth. We need strong regulations on delta-8 THC and keep it out of the hands of minors.

"I fear that under a literal reading of the regulation's definition of "adult-use cannabinoid," products with *any amount of THC* would be treated akin to delta-8, regardless of whether the product is actually intoxicating. This would sweep in thousands of popular *non-intoxicating* hemp-derived products such as CBD and full-spectrum hemp extracts. Such a reading would have a devastating impact on Kentucky's hemp farmers and its non-intoxicating hemp product industry. I strongly recommend adjustments in proposed regulation to ensure appropriate treatment of non-impairing products. The new regulation needs to protects non-intoxicating hemp products while strictly regulating adult-use cannabinoids, ."

(a) Comment: Bill Peterson, CEO, Alice Peterson, President, Bobby Gaffney, Chief Science Officer, Jennifer Lantz, Director of Compliance and Quality, and Sam Burney, Director of Partnerships, Kentucky Heritage Hemp (KHH) Company, commented: "If there is concern about the level of intoxicating cannabinoids in hemp/CBD food products, Kentucky could follow other states' lead and set a minimum ratio of CBD to THC, such as 15-to-1

- There are many state-approved hemp genetics which have a naturally occurring ratio of 15-to-1 CBD-to-THC.

"THCa, the acid form of Delta-9 which is not intoxicating until/unless heated/combusted/aerosolized, should not be lumped in with Delta-9 THC."

(a) Comment: Joe Bilby, General Counsel, and Keith Rogers, Chief of Staff for the Kentucky Department of Agriculture, commented: "We believe the regulation should establish a numerical threshold to separate those products which contain a sufficient

quantity of intoxicating cannabinoids to cause a consumer to experience an intoxicating effect from other products which may contain those same cannabinoids but in a quantity that is insufficient to cause the consumer to experience that effect.

"Studies suggest that for an adult consumer to experience an intoxicating effect, the product must contain at least three to five milligrams of intoxicating cannabinoids. For that reason we suggest establishing a numerical threshold of 2.5 milligrams of intoxicating cannabinoids per package: a product with less than that quantity would not constitute an adult-use cannabinoid product, while a product that a quantity of intoxicating cannabinoids equal to or greater than 2.5 milligrams per package would be deemed an adult-use cannabinoid product.

"It is vitally important to remember that quantities (milligrams), no concentrations (percentages) provide the appropriate basis for distinguishing intoxicating products from non-intoxicating ones."

(a) Comment: Jonathan Miller, General Counsel, U.S. Hemp Roundtable, commented: "The regulation's definition of what is intoxicating, and therefore subject to strict scrutiny, would sweep in thousands of popular non-intoxicating hemp-derived products such as CBD.

"We understood you were planning to draw the line between intoxicating and non-intoxicating products at 0.3% total THC, such that products exceeding this amount of THC, including delta-8, or any combination of THCs, would be classified as 'adult-use' products and subject to stricter regulations.

"A plain reading of the regulation's definition of 'adult-use cannabinoid' appears to include products with any amount of THC, regardless of whether the product is actually intoxicating. Such a reading would have a devastating impact on Kentucky's hemp farmers and its non-intoxicating hemp product industry. Non-intoxicating broad-spectrum and full-spectrum hemp and CBD products are the lifeblood of the national and state hemp industry.

"By lumping these non-intoxicating products into an adult-only framework aimed at regulating impairing products, the regulation will impose significant burdens on the state and domestic hemp industry.

"In any case, we strongly urge you to amend the regulation to clarify that non-intoxicating cannabinoids and hemp products continue to be governed by the existing regulatory regime for CBD."

(b) Response: The cabinet understands that people use cannabinoid products for a variety of reasons and that not all products should be considered as "adult-use" only. The cabinet agrees this administrative regulation should be amended to separate adult-use cannabinoid products from non-intoxicating products.

The cabinet is amending this administrative regulation in response to some of these comments.

(2) Subject: Support for keeping products legal

(a) Comment: Dana Emmitt-Hall commented: "I have a son with severe autism. He is the reason I became involved in the pilot program. He is the reason I have advocated for medical cannabis.

"He is 19, he is not 21. So we have individuals under the age of 21 who very much need this medicine. There's a lot of moms in my place who have advocated for their children. We grow it and I product it and I give it to him. So what are we going to do for folks like me."

(a) Comment: Elizabeth Butler commented: "Please do not accidentally block my access to CBD products, which help me and other members of my family. Kentucky leads in hemp products and the hemp industry is important to the state. I understand that the proposed regulation could be interpreted to ban products with ANY amount of THC, including the tiny amount in full-spectrum CBD products, which are more effective than single isolates. Please modify the regulation to eliminate this danger."

(a) Comment: Doug Koch commented: "I have used hemp products to help alleviate my anxiety and depression symptoms as well as my early onset arthritis symptoms and would be devastated to loose access to these products. Please do not allow this to happen."

(a) Comment: William S. Palmer commented: "Please keep the CBD & Delta products legal in Kentucky. These products have helped so many of us that use it for medicinal purposes. What the alternative would be is prescription drugs which is killing Americans."

(a) Comment: Julian Stone commented: "Please keep all Delta THC and CBD products legal and regulated for the sale to persons above 21 years of age."

(a) Jody Roberts, US Army Master Sergeant (RET), commented: "Please keep Delta and CBD products legal in Kentucky. I have been using these products since they became legal in Kentucky and they have changed my life.

"There is no reason to eliminate the availability of these products just because medical cannabis will eventually be available. Not everyone that benefits from Delta and CBD will be able to get medical cannabis.

"I will also be contacting my State Senator and Congressperson, as well as the Governor, to let them know of this action, that is being considered without representation from every Kentuckian, in my opinion.

"Thanks in advance for your assistance in sustaining the legality of these products."

(a) Comment: Evan Dickson commented: "I'm writing today to let you know some of the benefits towards CBD and Delta products. I'm 38 years old and recently had to have both hips replaced. This caused severe pain before during and after the surgeries I opted out of taking painkillers due to a prior addiction, so I turned to CBD and Delta products. These products are all natural and really help people with pain. The opioid crisis isn't getting any better and you know if this is made illegal that will make things even worse. I promise you these products are invaluable to people who really need

them. I'd be happy to talk more about my struggles regarding addiction and how delta and cbd products have been exactly what I needed. Thank you for your time."

(a) Comment: Stephanie Hensley commented: "I have epilepsy and I am emailing you today about Delta 8 and delta 9 if it was not for those delta I would still be having seizures but they help so much and they keep my body relaxed so I am begging you to please make delta 8 and delta 9 legal for Kentucky that way people that have issues like me or other issues that medicine don't help can go get and have that that relief I thank you so much for taking the time to read my Gmail I hope you consider to everything I just said and considered to pass to make it legal Delta 8 in Delta 9 is a very important thing in this world to people that have issues like me and other people that have other issues thank you so much and God bless."

(a) Ben Caudill commented: "I am writing in regards to the issue of the decision to try making Delta and CBD products illegal. I am a consumer of these products. I take the products for health reasons, not for enjoyment. I have a rupture disk in my neck and the Dr wants to do extensive surgery. Someone suggested I look into these products for medical reasons. I started taking them about 3 months ago, and they have really helped the issue of pain in my neck. To this day I still have not had to have the surgery, all I feel is due to due to the CBD products. Please do not make them Illegal."

(a) Comment: Casey Dickson commented: "I wanted to express my support of our local CBD and Delta retailers. I know countless people who use these products to manage pain, anxiety, depression, and have nothing but great things to say. I myself occasionally utilize these effects for overall wellness and mental health. We've come a long way towards understanding and utilizing hemp products for the benefit of man kind. I'd hate to see us taking steps in the wrong direction. Thank you for your time".
(a) Comment: Howard Faught commented: "Delta and CBD products help me tremendously with chronic pain and anxiety issues that I deal with on a daily basis. Please do not make these products illegal."

(a) Comment: Rebecca Johnson commented: "Only If you want to hurt local constituents... you will stop this use of Hemp. The use in edibles is strongly supported by people such as my self that are over 60 with autoimmune diseases and other long term ailments. It helps us have a better quality of life without drug dependant, Wether that is over the counter or pharmaceutical. If you really want to help the population quit aiding the drug companies and hindering local businesses that are making use of our natural resources. If you pursue this I can't see you any other way than- an enemy of the people."

(a) Ross Ballard, II, commented: Typical Republican action. Praise small businesses then drive a stake through their hearts. Kill the bill...."

(a) Mike Shaffor commented: "I am writing to support keeping hemp-derived products, such as Delta 8, legal and available to adults over the age of 21. From my experience, there are many benefits to these products. As a smoker for several decades, Delta 8 helped me wean myself off nicotine. I will have been tobacco-free for one year this

coming Thanksgiving. Hemp-derived products have also helped me with pain management.

"I believe these products should remain accessible to those who fall outside of the upcoming Medical Marijuana Conditions. That being said, I feel common sense regulations should be in place for these products."

(b) Response: The cabinet has not proposed an administrative regulation that would make the sale of CBD, other cannabinoid, or delta-8 products illegal. The intent of the administrative regulation is to ensure the products are safe for human consumption and to ensure intoxicating products are not sold to minors. Section 1(3)(b) of House Bill 544 requires the cabinet to file an emergency regulation that "prohibits the sale, gift, or other transfer of possession of covered products to a person who has not reached the age of 21 years".

The cabinet is not amending this administrative regulation in response to these comments.

(3) Subject: Sale of products outside the state of Kentucky

(a) Comment: Annie Rouse, Co-founder and Chief Operating Officer, OP Innovates, commented: "Until federal regulations exist, it is important to not create overly burdensome regulations that make Kentucky businesses less competitive on a national level.

"It is our recommendation to continue to allow Kentucky businesses to manufacture and warehouse any hemp-derived cannabinoid product in Kentucky for sales outside of the Commonwealth."

(a) Comment: Jonathan Miller, General Counsel, U.S. Hemp Roundtable, commented: "If a THC milligram limit per serving is adopted, additional language should be added that still allows a manufacturer to manufacture products that exceed the limited provided the products are to be sold exclusively out of state.

"The scope of the regulation for processing, manufacturing, storage, and distribution should not extend to products intended to be sold exclusively out of state. The regulation as written is inconsistent with federal and other state laws with respect to fundamental product characteristics, including but not limited to ingredients, testing requirements, and product packaging and labeling."

(b) Response: The cabinet is aware that the Federal Food and Drug Administration explicitly states cannabinoid products should not be considered for interstate commerce. However, this is in conflict with fair trade provisions. The cabinet will amend this administrative regulation for clarity.

The cabinet is amending this administrative regulation in response to these comments.

(4) Subject: Impact on business

(a) Comment: Shannon Stiglitz, Senior VP of Governmental Affairs, Kentucky Retail Federation, commented: "The Federation represents a diverse group of retailers impacted by the amendments to the regulation including pharmacies, convenience stores, restaurants and other retailers selling cannabinoid (CBD) products and adult-use hemp products.

"The primary concern of retailers is the requirement for retailers selling non-intoxicating hemp products or cannabinoid products to register with the Department of Public Health and be subject to health department inspections. House Bill 544 (RS 2023) was the impetus for the amendments to the regulation, and its intent was to impact the sale of Delta-8 products ensuring that only adults would have access to Delta-8 products and establish manufacturing and labeling requirements. If the General Assembly wanted to require registration or a type of licensure for CBD products, it would have established requirements in HB 325 (RS 2021). This statutory change requires cannabinoid manufacturers to be permitted as food manufacturers with the Department for Public Health. There is no such requirement included in KRS 217.039. Additionally, there is no mention of a recommendation for the Department for Public Health to require registration for retailers for selling any hemp-derived products, including Delta-8; and while the General Assembly requires the cabinet's regulations to include age restrictions on the sale of intoxicating hemp products, behind the counter sales, and proper labeling requirements, they made no suggestion of requiring retailers to register with the Department of Public Health for the selling of intoxicating or non-intoxicating hemp.

"From a regulatory perspective, the number of various sites and entities that would be required to be registered because of selling CBD would include facilities such as pharmacies who are currently permitted and inspected by the Kentucky Board of Pharmacy. Other locations sell these products that are not represented by the Federation including spas, doctors' offices, and many others. The sheer volume of locations the health department would need to inspect would dilute its ability to address the General Assembly's primary concern of Delta-8 products, which is restricting the sale intoxicating effects to those twenty-one years of age or older. It would not be unexpected for retailers to opt not to sell CBD products, in order to forego the registration and inspection requirements. Many Kentuckians use legal CBD products, and if retailers opt not to sell CBD products, many patients could lose access to CBD. Additionally, online retailers will not likely be subject to the same requirements of inspections or regulations, thus creating an unlevel playing field for brick-and-mortar retailers and online businesses. That regulatory imbalance would also create situations that would leave children with access to unregulated products in the marketplace. This was not the intention of the General Assembly.

"The definition of cannabidiol products as stated in KRS 217.005 "...means a non-psychoactive cannabinoid found in the hemp plant Cannabis sativa which has the chemical name 2-[(1R,6R)-3-methyl-6- prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol"

"In contrast, HB 544 defines a "covered product" as "...means any product containing delta-8 tetrahydrocannabinol or any other hemp-derived substance identified

by the Cabinet for Health and Family Services as having intoxicating effects on consumers;"

"The above definitions clearly delineate between CBD products without an intoxicating effect and intoxicating-hemp products the legislature intends to be age-restricted and stored behind the retail counter.

"We respectfully request that the requirement for retailer registration for the selling of non-adult use CBD be removed."

(a) Comment: Dana Emmitt-Hall commented: "I have been working on this issue for sometime. (2014/15).

"Became a widow in 2016 and received my late husbands life insurance settlement.

"I became a hemp farmer in 2017. Opened the first legal dispensary in 2018. Grew over 4,000 plants.

"2020 KDA/KSP came into my home during COVID lockdown and took my legally grown hemp. 11 people in my home without mask during the middle of COVID.

"I have not yet been compensated for my hemp crops.

"I spent our families entire life savings on those crops that were stolen.

"I have been checked out by the police 4 times and have been given the green light every time.

"I have been unable to advertise or promote our hemp dispensary and my only customers now are by word of mouth so our income is very limited.

"I followed the rules, paid my fees and learned everything from seed to sale about the hemp plant and the endocannabiniod system. I even have a certificate from the KY Nursing association where I completed a two day course of endocannabiniod medicine.

"I would like my comments to be made public and would like to attend the zoom meeting on Sept 18.

"I plan on completing the registry for our dispensary today."

(a) Comment: Jane Harrod, Early Bird CBD, commented: "I am a hemp farmer/CBD and need to learn about the new requirements and all the reasoning behind it. Obviously for health and safety reasons and that is very important and needed.

"My product is not intoxicating. I really do not want to be lumped into that same category."

(a) Comment: William Edwards, JR, Founder, Brannen Schneider, LLC, DBA Kentucky Slushie, commented: "I started a company recently here in Kentucky called Kentucky Slushie, actually Brannen Schneider doing business as Kentucky Slushie.

"I was ready to launch as these regulations came out. I have a full-spectrum slushie mix that I am offering. And, because I'm a Kentucky corporation and my co-packer exists in Tennessee, I was told that that's not acceptable to the cabinet, according to these regulations. Apparently we anted to keep or promote jobs in Kentucky. This Kentucky Slushie company is getting ready to go and incorporate in Tennessee because of this regulation.

"With regard to the cannabinoids staying under 0.3 percent during the entire process...Kentucky can do that. But every other state is going to allow enrichment

beyond that number to get to whatever product that they are going to put out under the federally-mandated 0.3 percent and they are going to send it to Kentucky. And those products are going to be legal. But a Kentucky corporation could not do the same.

"So we can consider a revision of these statutes or these recommendations or we are going to be pushing corporations out of the state."

(a) Comment: Dee Dee Taylor, Board member Kentucky Hemp Association and CEO/Founder 502 Hemp Wellness Center, commented: "I have been in this business with my husband since 2014. He was one of the first licensed processors in the state. He is no longer processing in this state. He moved his facility across state lines and is producing product there due to some of the overreach and regulations that already exist.

"I believe that some of these new rules will cause ever more people to move out of the state.

"My products are no longer manufactured in Kentucky. How will those out-of-state manufacturers comply with the new Kentucky regulations? How will my store be able to sell Kentucky products here even though they are manufactured out of state?"

(a) Comment: Katie Moyer, President, Kentucky Hemp Association, commented: "We originally were hoping that we could keep it very simple and focus on the age restriction of 21 and up and keeping products behind the counter and then making the testing process where it is not onerous for individuals, businesses to try to keep up with those things.

"We object to section 2(6) which prohibits the employment of anyone under age 21 in certain jobs in the industry. We propose that the same 18+ standards for alcohol be applied to adult-use cannabinoids. Persons 18 years of age or older may be employed by restaurants that serve alcohol but cannot handle the sales of such products themselves. This approach is consistent with 2023 RS HB 544, which prohibits person under the age of 21 from possessing such products. Thus, prohibiting possession or handling of the products by those under the age 21, rather than an outright ban on employment is the best approach."

(a) Comment: Robert Matheny, Owner, Kentucky CBD Pharmacy, and board member, Kentucky Cannabis Freedom Coalition, commented: "As a retailer in the state, I started out as a processor in 2018. And the hemp industry decided to regulate hemp on a state level and it banned the flower. Five years later we are wondering what decimated our industry. It's our regulations.

"I do not support any of these regulations further than the federal regulations we all have to operate by, because they are federally-regulated products. We're on the edge of decriminalizing cannabis in Kentucky and we're still trying to keep revenue and prohibit hemp products within the state when we should be thriving.

"I am just providing products that are here. And our regulators are trying to take them away."

(a) Hannah Looney commented: "I fear that if the bill is enacted as it is, only large corporations would be able to afford to stay in business, which would substantially affect consumer choice and health options. As someone who is currently recovering from

medical neglect and abuse from the past and current state of our health care systems, corrupt insurance companies, and outdated laws in his State. I'm putting money into the local economy here that supports the safest forms of medical care for me and my entire family, including my pets. Please do what is in the best interest of the people and animals of Kentucky and their individual freedoms to protect their health and autonomy. Please kindly respond and let me know what is being done to address these concerns."

(a) Comment: Joe Bilby, General Counsel, and Keith Rogers, Chief of Staff for the Kentucky Department of Agriculture, commented: "Section 2(1) of the regulation states that a person 'seeking to process, manufacture, store, or distribute hemp-derived cannabinoids in Kentucky shall be permitted by the cabinet'. We believe that the permitting requirement should apply to those who actually make cannabinoid products, not other who merely store or distribute them on a wholesale basis. We do not believe that the cabinet should require a permit for a warehouse operator or a wholesale distributor to obtain a permit. Additionally, regulating out-of-state entities that transport materials hemp products through Kentucky could lead to a legal challenge on the basis of the 2018 Farm Bill's interstate commerce language."

(a) Comment: Jonathan Miller, General Counsel, U.S. Hemp Roundtable, commented: "We oppose Section 2(6) which prohibits an adult-use hemp-derived cannabinoid processing or manufacturing facility or distributor from employing anyone under 21 yeas of age."

(b) Response: The intent of this administrative regulation is to ensure cannabinoid products are safe for consumption. The retail registry is intended to allow the cabinet to begin to know where products are being sold. The age limit was on the manufacture of products and not related to retail sales. The cabinet will mirror as best it can to the age limit guidelines from the Department of Alcoholic Beverage Control as found in KRS 244.090.

The cabinet is amending this administrative regulation in response to some of these comments.

(5) Subject: Retail sales

(a) Comment: Jim Higdon, Co-founder of Cornbread Hemp, commented: "There is no evidence of young people abusing these products. We are very concerned about age-gating, age-limiting our products in retail settings. Our primary retail partners in the state are natural food stores that do not sell other products that require identification at check, like no tobacco, no alcohol. Having age restrictions on these products can be complicated in a natural grocery setting, especially when almost all of our products in retail settings are contained behind locked cabinets, which are there to prevent expensive products from being shoplifted but also have the additional effect of preventing young people from accessing them because it requires a store staff member to get those products for the customer.

"We urge the cabinet to not limit full-spectrum products under 2.5 milligrams to any age restrictions. We understand the need for age restrictions on products intended to intoxicate, particularly these semi-synthetic, delta-8 products. We understand the need to restrict those to 21 and over for intoxicating purposes. For full-spectrum products, we urge the cabinet to no follow the lead of a very limited number of states. My understanding is fewer than 12 states have age restrictions on full-spectrum hemp products.

"Our biggest concern regarding retail sales is section 6, paragraph (5)(b) that says products sent by mail to consumers must be received with a signed order form a guarantee 21 and over. For eCommerce companies existing in Kentucky, this is an incredibly burdensome regulation and could very much complicate our ability to conduct business as an eCommerce company."

(a) Comment: Jim Higdon and Eric Zipperle, Co-founders of Cornbread Hemp, commented: "(5)(b) would have a detrimental impact on ecommerece sales. To our knowledge, no other state in America requires adult-signature-only service from parcel carrier, and would make direct-to-consumer sales nearly impossible.

"Furthermore, we are concerned with the apparent deliberations within CHFS to restrict purchases of full spectrum CBD products to consumers 21 years and over. To our knowledge, there are only ten states that restrict full spectrum CBD products to consumers over the age of 21. The one thing that these 10 states have in common is that they are states with active legal marijuana programs. In these states, the cannabis industry has successfully lobbied the government to curtail the free trade of full spectrum CBD products because they compete with cannabis products sold in dispensaries."

(a) Comment: Dee Dee Taylor, Board member Kentucky Hemp Association and CEO/Founder 502 Hemp Wellness Center, commented: "The problem with having the 21 and up signature at the time that comes out, that's absolutely impossible. A lot of people work and they are not going to be at home to sign for their packages. My website, I have an age verification checker on it. There are apps that you can have on your website that will fail an order if those people are under 21 years of age. I have done that even for CBD products. I limit it at 21. I think that is much more cost effective than trying to get people to sign for a package."

(a) Comment: Katie Moyer, President, Kentucky Hemp Association, commented: "Section 6(5)(b) requires retailers to ship packages to consumers over 21 while requesting a signature from someone over 21. It would be nearly impossible for mail carrier, private logistics companies, and delivery services to get a signature from an adult 21 or older for every single parcel. We recommend requiring or permitting the use of age verification checks from retailers or online stores, rathe than putting that additional work on our delivery drivers.

"Technology can kind of save us in this situation, where you're checking their age before they ever get the product shipped to them."

(a) Comment: Matthew Bratcher, Executive Director, Kentucky NORML (National Organization for the Reform of Marijuana Laws), Director, Kentucky Cannabis

Foundation, and Owner, One Love Hemp Dispensary, commented: There's a lot of good points being made today for the mailing, that's been vital."

(a) Comment: Charles George, Executive Director, Wine and Spirits Wholesalers of Kentucky, commented: "Section 6(5)(b) allows person selling at retail (presumably including manufacturers and retailers) to ship or deliver intoxicating products to consumer over 21 years old (we assume this will be corrected to 21 years old and older) and marked 'Adult-use only, adult signature required'. While a Kentucky seller would need to hold a permit with the Cabinet, there are no quantity limits, reporting or auditing requirements, or record maintenance as required with alcohol shipping.

"Using the alcohol shipping law as a guide, we recommend the requirements below for persons shipping and delivering intoxicating products. Please note, this must be coupled with a narrowing of the 'adult use' definition, as it would be unfair for non-intoxicating CBD products to be subject to these additional rules:

- Require a shipping permit for any in-state or out-of-state seller, in addition to any other required permits.
- Require use of licensed common carrier for manufacturers that ship to consumers.
- Prohibit retailers from shipping products via common carrier but allow local delivery by the retailer or third parties.
- Require adult signature upon delivery, with penalties for failure to do so.
- Require manufacturers to file a quarterly report with the Cabinet to include names and quantities of intoxicating products, recipient's name and address, purchase price, and shipping tracking number.
- Require common carriers to verify that the shipper has an active permit or license to ship intoxicating products into Kentucky.
- Require common carriers to file a quarterly report with the Cabinet to include recipient's name and address, shipment dates, weight of shipment, and shipping tracking number.
- Limit the quantity of intoxicating products to be shipped per consumer per month.
- Require an out-of-state manufacturer shipping into Kentucky to submit to the jurisdiction of the Commonwealth of Kentucky.
- Require manufacturers to maintain records and allow the Cabinet to perform an audit of the records and inspection of manufacturers premises.

"The shipping and delivery piece really caught my attention. In alcohol, we have gone through many struggles in kind of putting a handle on how we handle the shipping and delivery of alcohol. We went through it in Kentucky in 2020 with legislation that was passed related to the shipping and delivery of alcohol.

"Section 6(4)(a) requires intoxicating products sold at retail to be secured to prevent theft or other access to those under the age of 21. HB 544 requires products to be kept behind the counter. Does 'secure' mean that products can be displayed on the floor or shelves of a retailer (i.e. not behind the counter) if they are in a locked case?

"There are strong controls around these intoxicating products. We have a more robust regulatory system and oversight in place for shipping and delivering products.

"I don't think it is really clear that out-of-state companies that would ship products into Kentucky are they going to undergo any type of scrutiny? Do they have to get permitted?

"If you order wine on the internet and get it shipped to your house, that delivery person is supposed to check signature. And if they do not get your signature of a 21 and over individual, then they have to put that product back on the truck.

"Retailers in Kentucky cannot even ship alcohol. Manufacturers can ship alcohol. The reason for that distinction is, there are thousands and thousands of alcohol retailers across the country and it would be very difficult for the ABC to have any type of oversight."

(a) Comment: Jane Harrod, Early Bird CBD, commented: "For folks who have to work, they cannot be home to sing for a product stating when they're 75 years old that they are above 21. Let's utilize our technology and deal with that in a modern way."

(a) Comment: Barry D. Lee, Superintendent, Casey County Schools, commented: "This may not be the correct regulation to address the following concern but what can we do about possession for individuals under 18. There are regulations for underage alcohol possession, but there are none for these products. Can that be added in this regulation?"

(a) Comment: Bill Peterson, CEO, Alice Peterson, President, Bobby Gaffney, Chief Science Officer, Jennifer Lantz, Director of Compliance and Quality, and Sam Burney, Director of Partnerships, Kentucky Heritage Hemp (KHH) Company, commented: "Even though we at KHH and 7 Sons currently require proof of age over 21 to purchase CBD with any level of intoxicating cannabinoids ("full-spectrum CBD"), we don't necessarily believe the whole market should be subjected to this high standard.

"With a focus on health and wellness, we believe it is safe, and even highly desirable, to allow CBD with low levels of naturally occurring D-9 (full-spectrum CBD) to be available for purchase without age limitations.

"We oppose the requirement of an adult signature from parcel carriers upon delivery. This signature requirement would damage important e-commerce sales."

(a) Comment: Liz Burrows, Region 6 KY Agency for Substance Abuse Policy (KY ASAP) Local Board, and Barry D. Lee, Superintendent, Casey County Schools, commented: "The regulation should include language that expressly prohibits retailers from offering free samples to customers. FDA laws prohibits tobacco and vape retailers from providing free samples. The same should hold true for hemp-based THC.

"The regulations should stipulate that hemp-based THC in any form cannot be sold in vending machines.

"Provide a reasonable grace period (six months?) for retailers to sell off their non-Kentucky certified inventory of hemp-based THC products. FDA did this when they banned the use of 'low tar' and 'light' on cigarette packaging.

"Expressly prohibit promotional offers at retail point of sale such as 'Buy one get one free,' 20% off with special promo code etc. Such offers are illegal for cigarettes under current federal tobacco laws.

"Anyone selling or serving adult-use cannabinoid shall be 18 years of age or older and be trained in point of sale age verification."

(a) Comment: Joe Bilby, General Counsel, and Keith Rogers, Chief of Staff, for the Kentucky Department of Agriculture, commented: "We suggest the following revisions to language within the administrative regulation:

"Section 6(3): suggested revision: '...of twenty-one (21). No product which contains a quantity of intoxicating cannabinoids that is greater than or equal to 2.5 milligrams shall be sold to a person under the age of twenty-one (21);'

"Without this explicit prohibition, a product containing an unacceptably high quantity of intoxicating cannabinoids could be offered to sale to minor children under the pretense that it is a 'cannabidiol product'.

"Section 6(5)(b): suggested revision: '...over twenty-one (21) years of age at an address in a state or territory where such a product is lawful so long as such products are contained in packages...required and ~~request~~ adult-signature-only service is requested...'.

"The regulation should take account of the reality that some of these products remain prohibited in other states and territories. The regulation should require a person delivering or shipping such a product to comply with the laws of those jurisdictions."

(a) Comment: Jonathan Miller, General Counsel, U.S. Hemp Roundtable, commented: "Section 6(2) requires a retail establishment offering hemp-derived cannabinoid products of any kind to register with the Cabinet. Most states that require retailer registration require only sellers of ingestible or inhalable products to register. The Cabinet should do the same.

"Section 6(3) states that only CBD products may be sold to persons under 21 years of age, which is a significant limitation that would prohibit the sale of CBG, CBN, and other non-intoxicating cannabinoids to persons under 21. The age restriction should be limited to adult-use cannabinoids only, which also reflects the intent of HB 544.

"The special packaging and adult-signature requirements in Section 6(5)(b) would be highly disruptive to the industry and threaten e-commerce sales. If age verification is the goal, we urge the Cabinet to include language mandating that online sellers require consumers to state affirmatively that they are at least 21 years of age, and then by January 1, 2024, require verification of age by either (i) using a reliable online age verification service, or (ii) obtaining and examining a copy of a government issued identification prior to completing a purchase."

(a) Comment: Christopher M. Ware, Founder and CEO, KCA Labs, commented:

"Section 6(1)(c): What makes a certificate valid? Certificate of Analysis must be from an approved KDA licensed laboratory.

"Section 6(8): Very large cookies containing delta-9-THC below 0.3% THC are being offered commercially. These cookies are so large that they contain multiple adult doses of THC but meet the 0.3% THC requirement. Is there any restriction on these products other than the 0.3% THC limit?"

(b) Response: The cabinet is aware of the need to establish improved requirements for retail sales, including the need for serving size limits. The cabinet is also aware of the

need to distinguish between intoxicating, intended for adult-use, products and non-intoxicating products.

The cabinet is amending this administrative regulation in response to some of these comments.

(6) Subject: Training requirements for retailers

(a) Comment: Launi Gum, Program Director/Project Coordinator, Champions for a Drug Free Grant County, commented: "We understand from attending the Public Hearing that verbal comment was given by many who opposed various aspects of the regulations; however, there was one point made that we agree with as, again, it aligns with best practice for youth substance use prevention and that is the need for a training program for businesses. Again, this is a precedent set within the state of Kentucky with the TRUIST program for nicotine products and the STAR program for alcohol products."

(b) Response: The cabinet appreciates the recommendation to establish a training program for businesses. The sale of tobacco and alcohol is regulated under the jurisdiction of the Department of Alcoholic Beverage Control in the Public Protection Cabinet, which has differing standards for retail licensing.

The cabinet is not amending this administrative regulation in response to this comment.

(7) Subject: Product manufacturing and adulteration

(a) Comment: Annie Rouse, Co-founder and Chief Operating Officer, OP Innovates, comment: "Section 2.7, regarding the adulteration of cannabinoid products formulated with caffeine. There are hundreds of retail products in the U.S. and international markets right now that contain CBD and caffeine. In addition, a placebo-controlled trial analyzing CBD and caffeine found no safety concerns. If prohibited for sale in the state, Kentucky companies should continue to have the right to manufacture and sell these products outside of the state, so long as federally legal."

(a) Comment: Katie Moyer, President, Kentucky Hemp Association, commented: "A minor detail that is major to me because I'm a big proponent of terpenes and the use of essential oils in these products. Terpenes are very commonly added to vape products and were not listed as an approved ingredient in vapes. They often times give the flavor of cannabis to products, but they have so many more uses than just flavoring. We would like to see these included as an allowed ingredient in vapes.

"Section 2(19)(a) should include the use of terpenes, or cannabis essential oils in the production of adult-use cannabinoid vapes. Terpenes are naturally occurring, are commonly used as a carrier to dilute the resinous extracts contained in cannabis, and are one of the safest additives available.

"We recommend that Section 2(7) be amended to only prohibit the addition of cannabinoids to nicotine or nicotine products. There are a variety of small businesses that add cannabinoids to coffee, tea, and other beverages—this prohibition would

critically affect those retailers, coffee shops, and beverage manufacturers. Equally, this restriction is not found in 2023 RS HB 544.

"We would recommend we remove caffeinated products from the list of prohibited items. I think that nicotine, you're starting—getting into some very serious regulations. All of these regulations in the tobacco, nicotine markets, we don't want to get involved in that. But there's a lot of people that add cannabis to coffee, tea, chocolate, all of which contain caffeine. We wouldn't want to see any of those processor or manufacturers being excluded from selling in Kentucky."

(a) Josh Hartsel, Cofounder, Fractal Hemp, LLC, commented: "Significant progress has been made on the conversion of CBD to Delta-8 in recent years to minimize side product isomer formation. In a recent article published in the Journal of Natural Products (2020), researchers investigated several catalysts, solvents, temperatures, and reaction times to characterize the effects on the formation of Delta-8 THC as well as unwanted isomers of THC.

"Traditionally, this reaction has been carried out in hydrocarbon solvents like toluene, heptane, or hexane with p-toluene sulfonic acid at elevated temperatures. As the paper shows in Table 2 entries 3, 5-6**, the use of hexane results in incomplete conversion at room temperature over 36 hours and results in 13% iso-THC, which has not been pharmacologically characterized in any human studies.

"Further, companies in the Delta-8 space drive the reaction to maximize Delta-8 THC formation by heating to 100 C (Attached ILLNYE_CBD-D8_MasterSOP file)**. Heating contributes further to isomer formation and is undesirable. In contrast, entries 5-6** use toluene, which is a known carcinogen with a high boiling point that makes it practically impossible to remove from the final product. Entry 2** showcases the chlorinated hydrocarbon dichloromethane that shows near complete conversion of CBD to delta-8 THC at room temperature with no detectable delta-9 or isomer formation making it ideal for the conversion process. Additional advantages to the chlorinated dichloromethane and trichloromethane solvent family is that they are non-flammable, making them better suited for occupational health and safety, but they are low boiling point solvents that can easily be removed from the final product. The most important factor is the level of residual solvents in the final product and the chlorinated solvents can easily be removed well below safe human exposure limits set forth in the pharmaceutical industry in which these solvents are commonly used for drug manufacturing.

"Solvents to be added to the approved list:

"Chloroform and dichloromethane – advantages are lower side product formation, non-flammable and safer for work safety, lower boiling point for better removal from final product.

"Hexane – lower boiling point analog of heptane which is on the approved list for easier removal from final product.

"Methanol – low boiling alternative to ethanol with low solubility for plant waxes."
**Note: Graphic and resource submitted with written comment but not copied to statement of consideration.

(a) Comment: William Polyniak, Partner, Bluegrass Hemp Oil, Kentucky Cannabis Company, commented: "Our mission has always been to provide safe, natural, and

effective products to consumers. It is with this purpose in mind that I wish to express my grave concerns regarding the increasing production and distribution of synthetic cannabinoids such as delta-8, delta-9, HHC, THC-B, and the others to come if action is not taken.

"Over the past few years, synthetic cannabinoids—often marketed as safe alternatives to natural cannabis—have gained traction in the market. Unfortunately, these products do not represent the natural safety profile of cannabis or medical cannabis products as they claim. Moreover, they pose a considerable risk to public health, including causing life-threatening conditions and even death. It should be noted that a three-year-old child died eating delta-8 gummies. No person has died from injecting real cannabinoids, only these synthetic manufactured ones.

"Unlike full-spectrum CBD, which is extracted from cannabis sativa hemp plants and contains all the naturally occurring compounds such as CBD, THC, terpenes, and flavonoids that work in synergy to provide therapeutic benefits, synthetic cannabinoids are made using isolated CBD and other artificial additives. If these products were made from other esters, they would already be federally illegal. Due to the lack of natural compounds that provide a synergistic effect, these synthetic products are often less effective and, in many cases, dangerous with extreme side effects. The manufacturing processes of synthetic cannabinoids do not adhere to the same stringent safety standards, nor have they undergone any research to show that they are safe. Being manufactured, they do not share the same history as natural cannabis in human society.

"While natural cannabis and full-spectrum CBD have been studied for their medical benefits and have been proven to be generally safe when used responsibly, the same cannot be said for synthetic cannabinoids. These products are often packaged and marketed to target consumers seeking the recreational aspects of cannabis rather than its medical benefits, making them not only misleading but also potentially harmful.

"As a company that has been at the forefront of the hemp industry in Kentucky, it is disheartening to see the reputation of the Commonwealth and the industry at large being tarnished by such products. I respectfully urge the Kentucky Department of Cabinet for Health and Family Services to consider restricting the manufacture and distribution of synthetic cannabinoids made from isolated CBD within the state, not just those under 21, as that, should already be within the smoking laws and intoxication laws in Kentucky.

"By taking such an action, not only would the Department be safeguarding public health but also preserving the integrity of a burgeoning industry that holds significant promise for the Commonwealth of Kentucky."

(a) Comment: Bill Peterson, CEO, Alice Peterson, President, Bobby Gaffney, Chief Science Officer, Jennifer Lantz, Director of Compliance and Quality, and Sam Burney, Director of Partnerships, Kentucky Heritage Hemp (KHH) Company, commented: "Keep the rules which already exist requiring third-party lab testing.

"Testing labs must be certified and subject to audits to assure their accuracy and integrity.

"Stiff penalties must be applied to any certified testing lab that engages in "pay for play".

"With respect to testing Delta-8, our Chief Science Officer suggests adding language about testing intermediates/side products:

- When Delta-8 is converted from CBD, there are side products and intermediates that are synthesized.
- Two such products are Delta-8-iso-THC and Delta-4(8)-iso-THC. These side products are difficult to tease out through traditional HPLC (high pressure liquid chromatography) testing. Delta 4(8)-iso-THC actually elutes with Delta-9-THC in HPLC testing, causing inflated Delta-9-THC integration. Labs have developed GCMS methods to test for these intermediates, and we are aware of labs which have become quite proficient at it.
- Testing for such intermediate would allow a lab to determine if the Delta-8-THC is synthesized or naturally occurring."

(a) Comment: Joe Bilby, General Counsel, and Keith Rogers, Chief of Staff for the Kentucky Department of Agriculture, commented: "The rules set forth in this regulation should apply to every cannabinoid product, regardless of whether its components (1) were extracted or derived from cannabis that meets the legal definition of hemp in KRS 260.850; (2) were extracted or derived from cannabis that does not meet the legal definition of hemp in KRS 260.850; or (3) were created in a laboratory from source materials other than cannabis. The regulation should state explicitly that cannabinoid products cannot be made from substances that were extracted or derived from cannabis that did not meet the legal definition of hemp in KRS 260.850(5)(a). We suggest inserting a new subsection within Section 2 stating, 'No person shall process, manufacture, make, sell, or distribute a product that contains any substance that was extracted from or derived from cannabis with a delta-9 tetrahydrocannabinol concentration of more than three-tenths of one percent (0.3%) on a dry weight basis'."

(a) Comment: Jonathan Miller, General Counsel, U.S. Hemp Roundtable, commented: "Section 2(7) prohibits manufacturers or processors from adding (1) non-cannabinoid additive that increases toxicity or addictive potential; (2) caffeine; (3) nicotine; or (4) other chemicals that may increase carcinogenicity or cardiac effects. This is a major policy change as it significantly expands Kentucky's existing list of prohibited hemp products (see 302 KAR 50:070). Subcategories (1) and (4) are broad and may unnecessarily encompass a wide range of substances, while the prohibition of caffeine will have a significant impact on the hemp industry in the state and the manufacturers that produce caffeine-containing hemp products."

(b) Response: The cabinet is aware of the combination of cannabinoids and products containing caffeine, such as coffee and tea. The cabinet is amending this administrative regulation to exclude caffeine from the list of prohibited additives. The cabinet is also aware of the need to distinguish between intoxicating, intended for adult-use, and non-intoxicating products, and to distinguish between naturally occurring cannabinoids and synthetic products.

The cabinet is amending this administrative regulation in response to some of these comments.

(8) Subject: Food service establishments

(a) Comment: Annie Rouse, Co-founder and Chief Operating Officer, OP Innovates, commented: "Section 7, regarding food services establishments...opportunity to lead in bringing cannabinoids into the food and beverage service industry in a safe and regulated manner.

"...providing safe access to cannabinoids at food services establishments can benefit Kentucky's population. But we would suggest the following regulations be adopted:

"One, consumers must be ages 18 and older to purchase cannabinoid products not categorized as adult use cannabinoids. Two, consumers must be ages 21 and older to purchase adult use cannabinoids at concentrations of more than 2.5 milligrams per serving. Three, artificial cannabinoids are prohibited form being added to food and beverages at food service establishments. Four, food service establishments must apply for a license to serve and must have a HACCP plan in place. Five, any products that are used at food service establishments must be tested for potency and contaminants, aligning with the regulations for finished products set forth in the regulation. Six, servers and managers should undergo a training and/or certification program similar to the Kentucky Department of Alcohol Beverage Control STAR program, which may be established by the state to prevent the sales of these products to minors, to encourage responsible consumption practices, and to mitigate the risk of cross-contamination or adulteration of non-cannabinoid products.

"These adjustment to the food service establishment program would bolster a safe approach to serving cannabinoids in public settings, continues to support consumers who desire safe access to these products, and allows Kentucky to lead in an up-and-coming market for safe access to cannabinoids as a food and beverage additive."

(a) Comment: Katie Moyer, President, Kentucky Hemp Association, commented: "We do want to have ingestible cannabinoid products allowed in food service establishments. We think that is very important that people look at hemp as a vegetable. It is a food source. The flowers of the plant are super high in protein and would make a better protein source than the seeds. My company has done research on for years, we have been looking at research on using the seed for a food source. The flower, the resins, all the parts of this plant, not considering the wood, are fantastic in food products."

(a) Comment: Charles George, Executive Director, Wine and Spirits Wholesalers of Kentucky, commented: "We have recently observed delta-8 infused beverages being sold in restaurants and bars. It appears Section 7 would prohibit intoxicating products form being sold in restaurants (food service establishments). Would a bar that does not sell food be able to sell intoxicating products?"

(a) Comment: Jonathan Miller, General Counsel, U.S. Hemp Roundtable, commented: "Section 7(1) state 'Only CBD may be added to an ingestible product prior to retail sale at a food service establishment'. Prior language allowed all hemp-derived cannabinoids to be added to products. The limitation to CBD will be unworkable for many Kentucky hemp businesses and will have a negative impact on the economy. We urge the

Cabinet to remove this requirement and allow the addition of all hemp-derived cannabinoids to ingestible products sold at food service establishments, provided these products comply with the milligram limits we have proposed. Food service establishments should be required to register with the Department and be subject to audits to ensure compliance with Hazard Analysis and Critical Control Points and related food safety requirements."

(a) Comment: Christopher M. Ware, Founder and CEO, KCA Labs, commented:
"Section 7(1): Need to add 'except for beverage containing no more than 5mg THC per serving.
"Section 7(3): What makes a certificate valid?"

(b) Response: The cabinet did not intend for cannabidiol or CBD to be the only non-intoxicating cannabinoid allowed in food service establishments.

The cabinet is amending this administrative regulation in response to some of these comments.

(9) Subject: Safety of Delta-8 products

(a) Comment: Annie Rouse, Co-founder and Chief Operating Officer, OP Innovates, commented: "We felt it important to express our concern for artificial cannabinoids. Many in the industry will have you believe that the Delta-8 used in finished products is all natural, simply because Delta-8 can be found in the plant. While it is true that this compound is naturally-occurring, it is at trace levels lower than the concentrations of naturally-derived Delta-9 THC. These trace levels are not economical to extract. So, Delta-8 and other artificial cannabinoids are manufactured via chemical alteration using reagents and are therefore not natural. By definition these compounds are considered semi-synthetic and should be regulated as such substances. Historically humans have never consumed these semi-synthetic cannabinoids in concentrations being consumed today. In addition, there's zero safety studies on these compounds and their long-term effects.
"The reagents used to cannibalize the reactions are not tested in finished products, which may cause consumers to ingest these residual reagents at potentially harmful levels. While we do not believe in the prohibition or criminalization of these compounds, we feel as a measure of consumer safety these components need to be held to a higher quality standard, like those held by pharmaceutical drugs, including mandatory GC/MS testing for analyzing potency of these compounds with mandatory purity levels, in addition to testing for residual reagents, and milligram limits per serving in a finished product, among other requirements."

(a) Comment: Dee Dee Taylor, Board member Kentucky Hemp Association and CEO/Founder 502 Hemp Wellness Center, commented: "I do believe that delta-8 and delta-9 are considered wellness products. I have a lot of veterans. I have a lot of cancer patients. I am a retail establishment. I have an online service, and I ship these products legally throughout the entire United States."

(a) Comment: Charles George, Executive Director, Wine and Spirits Wholesalers of Kentucky, commented: "What has really piqued our interest in the alcohol beverage space, are beverage products that are being infused with delta-8 THC and marketed as intoxicating products. These are being promoted as direct alternatives to alcohol consumption.

"I don't really see a distinction between a delta-8 infused beverage with an alcoholic beverage, because they are intending to have the same effect on the user."

(b) Response: The cabinet is aware of the need to distinguish between intoxicating, intended for adult-use, products from non-intoxicating products, and to distinguish between naturally occurring cannabinoids and those that are fully synthetic.

The cabinet is amending this administrative regulation in response to some of these comments.

(10) Subject: Definitions

(a) Comment: Jim Higdon and Eric Zipperle, Co-founders of Cornbread Hemp, commented: "Section 1, paragraph (2), the definition of 'artificially derived cannabinoid' should not be defined as to be interpretable to include the process of decarboxylation, which is a necessary component of cannabinoid production.

"Section 1, paragraphs (4) and (17), what is the distinction between 'cosmetic' and 'topical' CBD products?"

(a) Comment: Jim Higdon, Co-founder of Cornbread Hemp, commented: "Section 1, paragraph (2) defines artificially-derived cannabinoids in such a way as it could include decarboxylated cannabinoids, which is a basic step in the process of making full-spectrum products."

(a) Comment: Dee Dee Taylor, Board member Kentucky Hemp Association and CEO/Founder 502 Hemp Wellness Center, commented: "There is one thing in the regs that says the product has to be from an approved source. How do you become an approved source?"

(a) Comment: Katie Moyer, President, Kentucky Hemp Association, commented: "The definitions of key terms, such as 'Adult-use cannabinoid', are too broad, and includes non-intoxicating products like CBD. We propose defining a list of allowable and not allowed cannabinoids, or limiting key definitions to products that are intoxicating. This is consistent with 2023 RS HB 544, which adopted intoxicating language, and was the product of negotiation and compromise with numerous stakeholders.

"That's going to be a big challenge for anybody that is selling products that don't include any delta-8 or has a full-spectrum product that is less than 0.3 percent THC, delta-9 THC. We're concerned about those who are not interested in entering the adult use market or having adult use products."

(a) Comment: Matthew Bratcher, Executive Director, Kentucky NORML (National Organization for the Reform of Marijuana Laws), Director, Kentucky Cannabis

Foundation, and Owner, One Love Hemp Dispensary, commented: "I think we would probably be good with a clarification 'through approved source'. It makes it sound like if a manufacturer is out of stat that you would not be able to purchase form them. I think that there needs to be some clarification there, so out of state manufacturers and processors have a route to get into the market here also."

(a) Comment: Charles George, Executive Director, Wine and Spirits Wholesalers of Kentucky, commented: "For intoxicating products, there should be a higher level of regulation, as is attempted here. We just want to make sure that the definition of adult use is appropriate and doesn't lump in products that are not intoxicating into the intoxicating space."

(a) Comment: Joe Bilby, General Counsel, and Keith Rogers, Chief of Staff for the Kentucky Department of Agriculture, commented: "It would reduce confusion to eliminate the regulation's use of 'adult-use cannabinoid product' as a defined term and replace it with three defined terms that logically build on each other, like this:

a. "Cannabinoid" means a compound found in the plant Cannabis sativa which can join to the cannabinoid receptors of the body.

b. "Intoxicating cannabinoid" means any naturally occurring cannabinoid or artificially derived cannabinoid that is reasonably determined by the cabinet to have an intoxicating effect when consumed, including without limitation: tetrahydrocannabinols or tetrahydrocannabinolic acids, isomer of tetrahydrocannabinols or tetrahydrocannabinolic acids, delta-8 tetrahydrocannabinol, delta-9 tetrahydrocannabinol, delta-10 tetrahydrocannabinol, and hexahydrocannabinol.

c. "Adult-use cannabinoid product" means a product which contains a quantity of intoxicating cannabinoids that is greater than or equal to 2.5 milligrams per package.

"With this tiered approach to defined terms, members of the public will more readily understand that every 'intoxicating cannabinoid' is also a 'cannabinoid', but not every 'cannabinoid' is an 'intoxicating cannabinoid'.

"Similarly, every 'adult-use cannabinoid product' contains 'intoxicating cannabinoids' but not every product containing 'intoxicating cannabinoids' is an 'adult-use cannabinoid product'.

"Other than in the definitions section, the term 'approved source' appears only three times in the regulation. Because it appears only three times, we believe it would reduce confusion to eliminate it altogether and instead insert the phrase 'person or entity possessing a permit issued by the cabinet pursuant to Section 2 of this administrative regulation'. In addition to eliminating the need to consult the definitions section to learn what an 'approved source' is, this revision would make it clear that, regardless of whether a cannabinoid product is sourced from a person or entity holding a license issued by the Kentucky Department of Agriculture, a retailer or food service establishment must ensure that the cannabinoid product was obtained from a person or entity possessing a permit from the Cabinet for Health and Family Services."

(a) Comment: Jonathan Miller, General Counsel, U.S. Hemp Roundtable, commented: "The regulation creates a category for adult-use cannabinoid, a new term. As written, the term would apply to a product with any amount of THC. Most, if not all, non-

intoxicating hemp-derived CBD products, including full-spectrum and broad-spectrum hemp extract, contain delta-9 THC.

"If the definition of adult-use cannabinoid is intended to apply to a product that contains any amount of any THC, it would be devastating for the industry. We suggest modifying the definition to only include a product containing more than 5 mg per serving of an adult-use cannabinoid or combination of adult-use cannabinoids.

"Section 1(2)'s definition of artificially derived cannabinoid also raises concerns. Unlike other states, the definition does not contain any exceptions. We request that the definition be modified to include exceptions for naturally occurring chemical substances separated by a chemical or mechanical extraction process, as well as cannabinoids produced by decarboxylation from naturally occurring cannabinoid acid without the use of a chemical catalyst.

"Sections 1(8) and 1(16) define the terms cosmetic and topical separately and differently. This is likely to cause confusion because topical products are generally considered to be cosmetics. We recommend that the definition of topical be deleted or, if a separate definition is deemed necessary, that the definition of cosmetic be modified as follows: 'cosmetic' is defied by KRS 217.015(7) and includes a topical hemp-derived cannabinoid product intended to be applied to the skin or hair.

"The term edible product is not defined within the regulation and is a term more closely associated with marijuana products. The term ingestible is more appropriate and would include products such as capsules and tinctures."

(a) Comment: Christopher M. Ware, Founder and CEO, KCA Labs, commented: "It is unclear whether the hemp-derived cannabinoids are limited to 'adult-use cannabinoids' or are all hemp-derived cannabinoids included in these regulations?

"Is there a list of all 'artificially derived cannabinoids' that are covered by this rule? Does the testing laboratory bear the burden of determining whether a substance is an 'artificially derived cannabinoid?

"Add approved testing facility licensed by the Kentucky Department of Agriculture.

"This regulation makes 79 reference to 'hemp-derived substances' or 'hemp-derived cannabinoids' but doesn't define the term. The regulations therefore require a definition of the term 'hemp-derived'.

"The term 'processing chemicals' appears nine times in this regulation but the term is not defined. Are 'processing chemicals' limited to those solvents and reagents that were used in the extraction and synthesis of hemp-derived cannabinoid or are synthetic impurities encompassed in the term 'processing chemicals'? Is the testing laboratory responsible for determining whether a detected substance is a processing chemical under this regulation?

"Why are 'tentatively identified compounds' limited to residual solvent analysis?"

(b) Response: The cabinet appreciates all who commented and provided suggested revisions to the defined terms. The cabinet agrees revisions can be made to several definitions to provide clarity.

The cabinet is amending this administrative regulation in response to some of these comments.

(11) Subject: Packaging and labeling requirements

(a) Comment: Jim Higdon and Eric Zipperle, Co-founders of Cornbread Hemp, commented: "There are some concerns in Section 5 regarding product packaging and labeling. We are concerned that by following passage in Section 5, paragraph 3(e) could be interpreted as to disallow the use of the Kentucky Proud logo that we have on Cornbread Hemp products. And it also could call into question the use of the USDA organic seal, which is fundamental and vital to our marketing to our customers, as we go through great lengths to ensure the integrity of the USDA organic program and the USDA organic seal on our packaging and labeling is very important to us.

"Paragraph 4 could be interpreted as the product must include the exact amount of CBD as reported on the lab report instead of within a range of 10 percent above or below, as per the standards for U.S. pharmacopedia guidelines for drug labeling.

"Paragraph 4(c) could be interpreted that the packaging requirements say that all minor cannabinoids other than CBD and THC must be expressed on the label. This is a concern because of the small nature of the limited amount of real estate on our packaging. We have a QR code that links to the lab report so that anyone at point of purchase can see the exact nature of all of the cannabinoids present in our products. And we hope that QR codes for this purpose are acceptable to the cabinet when revised rules are put into place. QR codes are important because they give as much information to consumers, to regulators, and to buyers at retail as possible without sacrificing limited packaging real estate.

"Paragraph (5) in section 5 is confusing. It does not appear to be a complete sentence. We hope Cornbread Hemp's current packaging is considered to be in compliance.

"Paragraph 6, we're interpreting these rules to mean that Cornbread Hemp's non-intoxicating full-spectrum CBD products are not bound by the rules governing intoxicating cannabinoids because our products are not intoxicating."

(a) Comment: Phyllis Smith, PJ Smith Enterprises, LLC, DBA Essentially Hemp, commented: "My husband and I have been growers and now processors since 2016 and 2017. We sell retail full-spectrum CBD products.

"I believe Annie Rouse and Jim Higdon both covered most of the sections I was concerned about, especially the labeling for full-spectrum versus the adult use. I think it is just going to be more clarifying bout what's adult use and what's not.

"I will just confer to what they have had to say as being also what I was wanting to point out today."

(a) Comment: Dee Dee Taylor, Board member Kentucky Hemp Association and CEO/Founder 502 Hemp Wellness Center, commented: "It said for hemp-derived cannabinoid product that is a cosmetic in the topicals to be child-resistant packaging. I don't think that needs to be there. I have topicals. The have the evidence seal. But to be in child-resistant packaging, that's further expenses that aren't needed.

"On the label requirements, it is extremely cumbersome to try and get all of the language listed on page 24, (20)(a), (b), (c), (d), (e), (f), all on one label. You have to put the U.S., FDA notice on there, you have to be the 21 and up. I think we can abbreviate

a lot of that to make it where it will fit. And I already have labels on my packages that don't have all of this. When will that take effect? Will that just be new products coming forward? Or will I have to take all of my labels off and put new labels on?

"I think the QR code could be mandatory on every package. That way it takes you to the specific webpage that shows you all of the certificates of analysis."

(a) Comment: Katie Moyer, President, Kentucky Hemp Association, commented: "We find Section 5(3) regarding package requirements is broad and arbitrary. Sections 5 regarding font size, 6 the precise warning list are outside the current industry standard practices and would make many products out of compliance for sale in Kentucky.

"We think the QR codes go a long wat to making sure you can have the appropriate amount of information without having to squeeze it all in to a tiny label. That is a challenge that manufacturers always have to deal with. We think that technology and QR codes have going a long way into making it more possible to share and educate their consumers without making them get a magnifying glass out to read the labels."

(a) Comment: Matthew Bratcher, Executive Director, Kentucky NORML (National Organization for the Reform of Marijuana Laws), Director, Kentucky Cannabis Foundation, and Owner, One Love Hemp Dispensary, commented: "For current products that are noncompliant, I imagine an exit bag that is childproof would work for products that don't have the child-resistant packaging."

(a) Comment: Dana Emmitt-Hall commented: "I'm an advocate for individuals with disabilities. A lot of child safety packaging our individuals with disabilities, they're not going to be able to open the package."

(a) Comment: Bill Peterson, CEO, Alice Peterson, President, Bobby Gaffney, Chief Science Officer, Jennifer Lantz, Director of Compliance and Quality, and Sam Burney, Director of Partnerships, Kentucky Heritage Hemp (KHH) Company, commented: "We believe the requirements for product packaging and labeling as outlined in the rule are good and reasonable; limited thought our retail business is, our ingestible products are in full compliance already.

- We feel especially strongly that hemp products containing any level of intoxicating properties cannot be offered in packaging that mimics candy brands of which targets and appeals to children.

"We are in favor of full disclosure of ingredients, processes, and other consumer information, yet there is not enough room on labels to put everything that would be desirable to know. Accordingly, we believe a QR code could be required on all labeling, linking the consumer with third party testing, Certificates of Analysis (which lists all cannabinoids present), and other information.

"We want to be sure we will be allowed to display the USDA organic seal on products which have been vetted and granted organic status. This seal stands for quality and it is sought increasingly by educated consumers."

(a) Comment: Liz Burrows, Region 6 KY Agency for Substance Abuse Policy (KY ASAP) Local Board, and Barry D. Lee, Superintendent, Casey County Schools, commented: "All inspected hemp-based THC products should bear distinctive

packaging so they can be easily identified by retailers and consumers. This would allow the consumer to know which products have been inspected and have met the legal safety requirements. It would also facilitate enforcement efforts as it would make it easier to distinguish legal products from illegal products on the shelf."

(a) Comment: Jane Harrod, Early Bird CBD, commented: "I have small label from my farm, Early Bird CBD, and it's strictly oil and some sav. It's only the cannabinoids with the federally-regulated amount of THC, below that.

"For my tiny, tiny business, the packaging requirements are very concerning. I don't make a special box for my bottles that I mail out. They go in packaging material to be shipped.

"Every bit of information has to be on my tiny label that's on a one ounce bottle or a tiny sav jar. The folks that I ship to are people mostly with arthritis and that are my age. If we require childproof...folks I ship to cannot open those."

(a) Comment: Charles George, Executive Director, Wine and Spirits Wholesalers of Kentucky, commented: "We support the warning label requirements in Section 5(6) ."

(a) Comment: Joe Bilby, General Counsel, and Keith Rogers, Chief of Staff for the Kentucky Department of Agriculture, commented: "We did not observe a provision that 'prohibits covered product packaging, labeling, or advertising material from bearing any implicit or explicit health claims stating that the covered product can diagnosis, treat, cure, or prevent any disease', as required by HB 544. We recognize, however, we may have overlooked this item in our review of the regulation or that the Cabinet believes the substance of that restriction is set forth elsewhere in the law or an administrative regulation. If this mandate is not set forth elsewhere, we believe HB 544 requires that the health claims prohibition must appear in this regulation.

"Section 5(4)(a) requires product labels to state total THC and total CBD 'as milligrams per serving' or 'milligrams per package'. But Section 5(4)(b) and 5(4)(c) take a different, percentages-focused approach for 'hemp derived cannabinoid concentrates' and 'all other hemp derived cannabinoids'. We believe that quantities, not percentages, is the information consumers should see on their labels.

"If the Cabinet's intent was to require both quantities and percentages to appear on product labels for products identified in Sections 5(4)(b) and 5(4)(c), we believe it would improve the regulation's clarity to say so explicitly."

(a) Comment: Jonathan Miller, General Counsel, U.S. Hemp Roundtable, commented: "Section 5(2) expands existing requirements to now require a tamper-evident seal and child-resistant packaging for all hemp-derived cannabinoid products, including cosmetics. Child-resistant packaging is not warranted for cosmetic products. We appreciate that the regulation's child-resistant packaging standard is more lenient than the Federal Poison Prevention Packaging Act's standards that we proposed, the requirement should only apply to ingestible hemp-derived cannabinoid products that are considered adult-use—not all hemp-derived cannabinoid products.

"We fully agree with the intent of the packaging restrictions in Section 5(3). We recommend the regulation include explicit language clarifying the use of seals associated with federal programs and used in accordance with federal law and

regulations, such as the U.S. Department of Agriculture organic seal. We recommend that the use of the Kentucky Proud® logo is not prohibited, if used in accordance with the program's requirements.

"The label requirements in Section 5(4) relating to the total amount of hemp-derived cannabinoid per serving and total amount per container are unnecessarily confusing. For ingestible hemp-derived cannabinoid products, we urge the Cabinet to include a simple requirement to list the amount of (i) total THC in milligrams preserving, (ii) CBD in milligrams per serving, and (iii) any other marketed cannabinoids in milligrams pers serving if applicable. For cosmetics, we urge the Cabinet to restore the previous requirement that the label include the total amount of cannabinoids per container and a state that the product is within the federal legal limit of 0.3% delta-9 THC.

"Section 5(4) requires product labels to include the total amount of hemp-derived cannabinoids per service and per container 'as reported by the testing facility'. This language appears to be taken from medical cannabis regulations. It is not appropriate for mass packaging where the concentration or amount of cannabinoid is already printed on the label or packaging. We request the deletion of 'as reported by the testing facility', or clarify that including a web address, or QR code or other scannable code on the label or packing that provides access to the Certificate of Analysis with testing results is sufficient.

"We also recommend the deletion of the product modifier in Section 5(5). We are not aware of any state that requires hemp-derived cannabinoid products to include a modifier such as 'Delta-8 THC' or 'CBD' product.

"Sect 5(6) of the regulation includes warnings that go beyond what other states require for potentially impairing or intoxicating hemp products. For all ingestible adult-use cannabinoid products, we propose requiring the following statements:

- Warning: Contains THC.
- A statement indicating the product should be kept out of reach of children and animals.
- A statement indicating the product should not be used by individuals under 21, those who are pregnant, nursing, taking medication, or have medical conditions.
- A statement such as 'May cause drowsiness or impairment. Do not drive or operate heavy machinery while taking this product'.

"The statement proposed in the regulation would be unique to Kentucky and would require unnecessary, burdensome, and costly label changes.

"Section 5 uses undefined terms such as hemp-derived cannabinoid infused edible product and hemp-derived cannabinoid concentrate that are likely to cause confusion. The regulation should define the latter term, or it should be removed, and as noted the term edible should be replaced with ingestible."

(a) Comment: Christopher M. Ware, Founder and CEO, KCA Labs, commented:

"Section 5(4): What precision should be expressed on the label for the amount per serving and the total amount per container? Nearest whole mg?"

(b) Response: All cannabinoid products are required to be labeled in accordance with 2023 Ky. Acts ch. 78 (House Bill 544), and this administrative regulation. However, the

cabinet understands the concerns regarding the amount of information required to be available to the consumer on the label. The cabinet agrees a quick response or QR code could provide the consumer with the required information and still meet the intent of House Bill 544 and this administrative regulation.

The cabinet is amending this administrative regulation in response to some of these comments.

(12) Subject: Certificate of analysis and testing requirements

(a) Comment: Dee Dee Taylor, Board member Kentucky Hemp Association and CEO/Founder 502 Hemp Wellness Center, commented: "On the certificate of analysis, it should only be applied to the distillate. If the distillate is being checked and verified and tested for all of the contaminates and everything, heavy metals and all of that stuff, it should not also be tested per batch. The batch testing should just be on the milligrams and to verify that what you say, within the 10 percent variance, as Mr. Higdon reported, that should have that. Every batch that is made from that exact same distillate should not have to be retested again and again and again for contaminates. The reason being, one, it is redundant. Two, it's going to be extremely costly for a lot of small batch customers, or that create those batches that aren't even created in Kentucky, that they're made elsewhere, they're not going to batch every test, every single product that comes from that same distillate. It is extremely expensive, about $500 to $700 for a full panel test."

(a) Comment: Katie Moyer, President, Kentucky Hemp Association, commented: "The list of required tests per product is onerous and contains a number of required tests that are more suited for commercial grade hemp flower than for any product that would be legal for sale under current Kentucky law. We propose that the tests be limited to potency of cannabinoids (heavy metals, mycotoxins, pesticides, and residual solvent under the same levels as current Kentucky Hemp regulations). This will accomplish the objectives of the General Assembly in 2023 RS HB 544 but not unduly burden small/batch product manufacturers. A full panel test as proposed in the new regulations would cost over $1,000 per test and would make operating smaller manufacturers impossible. If the same batch of hemp oil is being used in 10 different products there is no need to do redundant tests.

"If you have a batch of distillate, which is the extract from, let's say it's delta-8 distillate and you're adding it to a variety of different products, that distillate is all tested for the solvents, the residuals, any of the bad stuff, then any of the products that it goes into should also be okay. Those tests do get very expensive. We're still testing each individual product for the potency to make sure that they're accurate and that what is on the label is accurate to what's inside the bottle. Once it is tested for residual solvents and contaminates, pesticides and things like that, that is sort of giving the all clear."

(a) Jim Higdon and Eric Zipperle, Co-founders of Cornbread Hemp, commented: "Section 3, paragraph (13)(a), the table on page 16 shows the maximum allowable concentration of ethanol to be 1,000 parts per million, which is five times more strict than the standard for candy and confections that use ethanol-suspended fruit flavorings.

The limit on ethanol content in candy in Kentucky is 0.5% or 5,000 ppm, which is five times higher than these emergency regulations allow."

(a) Comment: Joe Bilby, General Counsel, and Keith Rogers, Chief of Staff, for the Kentucky Department of Agriculture, commented: "We suggest the following revisions to language within the administrative regulation:

"Section 3(8)(b)(7): suggested revision: 'The results of all other hemp-derived cannabinoids contained in that product [~~analyzed on the COA~~]...'.

"Testing facilities should report all cannabinoids that were found to be present so a manufacturer cannot fail to disclose intoxicating cannabinoids whose presence are known.

"Section 3(8)(e): suggested revision: 'Adult-use hemp-derived cannabinoid products shall not contain a total delta-9 tetrahydracannabinol concentration (measured post decarboxylation) of more than three-tenths of one percent (0.3%) on a dry weight basis'.

"The regulation should make clear that the measurement of a substance's intoxicating potential must take into account delta-9 THC acid as well as its delta-9 THC.

"Section 3(17)(a): suggested revision: 'The testing facility shall provide the processing or manufacturing facility and the cabinet with a complete report of an TICs identified'.

"Without a requirement that this information be promptly reported to the Cabinet, the Cabinet will not be able to undertake the investigation and other steps identified in Section 3(17)(e) ."

(a) Comment: Jonathan Miller, General Counsel, U.S. Hemp Roundtable, commented: "We appreciate Section 3's incorporation of comprehensive testing and contaminant limits. However, the testing requirements in this section use terms such as infused hemp-derived cannabinoid product, hemp-derived cannabinoid concentrate, and cannabinoid extract that are not defined. We request these terms be deleted from the regulation or defined appropriately to avoid confusion.

"The arsenic limit is extremely low and does not reflect industry practices, putting a strain on Kentucky hemp manufacturers. We recommend the arsenic limit for ingestible products be revised from 0.4 ppm to 1.5 ppm."

(a) Comment: Christopher M. Ware, Founder and CEO, KCA Labs, commented:

"Section 3(2): Testing performed by an approved source licensed by the Kentucky Department of Agriculture.

"Section 3(6)(a): This accreditation requirement is necessary but insufficient requirement to assure that laboratories are performing tests correctly. Is there any provision for inspection of laboratories or subjecting them to blind sample analysis? What provisions are there for assuring that testing will be performed and that results are accurate and precise?

"Section 3(6)(b): Be licensed by the Kentucky Department of Agriculture.

"Section 3(6)(b)2.a.: It is imperative that laboratories use methods that are specific and are able to differentiate Delta-8-THC and Delta-9-THC from synthetic by

products, such as Delta-8-iso-THC and Delta-4(8)-iso-THC, which are known interfering chromatographic peaks using HPLC analysis.

"Section 3(6)(b)2.f.: Who is responsible for specifying which 'processing' chemicals require testing?

"Section 3(6)(c)2.: The accrediting body does not attest to the laboratory's competence. The accrediting body merely issues a certificate that states that the laboratory is accredited to perform certain tests which are identified on the laboratory's certificate. This is a public document that can be provided by the laboratory or obtained online.

"Section 3(7)(a): Using an approved and licensed laboratory by the Kentucky Department of Agriculture.

"Section 3(7)(b)1.: The hemp-derived cannabinoids are being produced semi-synthetically and completely synthetically. These synthetic processes produce synthetic impurities that are new chemical entities that have not be subjected to toxicity testing. Do the laboratory testing requirements include requirements for testing for these substances and are there limits on the maximum amounts of such substances?

"Section 3(7)(d): Who or what entity is responsible for complying with this requirement? The testing laboratory cannot be responsible for assessing whether the addition of ingredients or processing practice crease a reasonable or foreseeable microbial impurity, mycotoxin, residual pesticide, heavy metals, or processing chemicals hazard. Recommend relocating the requirement to the applicable section.

"Section 3(8)(b)1.: Does total tetrahydrocannabinol include the concentrations of delta-9-trans-tetrahydrocannabinol plus that of delta-9-trans-tetrahydrocannabinol or is it limited to delta-9-trans tetrahydrocannabinol??

"Section 3(8)(b)2.: Needs further clarification. Delta-9-THC acid?

"Section 3(8)(b)3 and 4: Needs further clarification. #3 says Total CBD which would include CBD acid.

"Section 3(8)(b)7.: Does this requirement include cannabinoid side-products found in the hemp-derived cannabinoids? These substances are products of the synthesis and are not found in plant materials and therefore could be termed 'other hemp derived cannabinoid.

"Section 3(8)(e): How does the laboratory report the delta-9-tetrahydrocannabinol concentration in a water-based beverage?

"Section 3(8)(f): This requirement does not belong in the testing section. This requirement applies to the manufacturer.

"Section 3(9)(c): Microbial testing should also include Total Coliforms, Listeria spp, Total Yeast and Mold, Total Aerobic Bacteria when appropriate.

"Section 3(11)(a), myclobutanil: This requirement needs a limit or laboratories will likely use the 0.2 ppm limit.

"Section 3(13): How are these substance defined? Are reaction side-products included as 'processing chemicals'? If not, where are these impurities found in the regulation?

"Section 3(13)(a), any other solvent not permitted for use pursuant to this regulation: A limit of 'none detected' for any other solvent not permitted for use pursuant to this regulation is vague. Recommend using the criteria established by USP 467 for residual solvents.

"Section 3(15)(b): This promotes laboratory shopping. Consider revising this requirement to permit reanalysis at the original KDA approved laboratory.

"Section 3(15)(f): Mixed products should not be considered adulterated if they meet regulatory acceptance criteria. Products can be reformulated and reprocessed with dilution and adding ingredients to make initially non-compliant products meet regulatory acceptance criteria for cannabinoid concentration and safety compliance limits. What are the maximum limits for reaction side-products in hemp-derived cannabinoids and hemp-derived products? The laboratories need these limits so they can adjust the sensitivities of their test for the side-products.

"Section 3(17)(a): The definition of TICs limits them to those substance tentatively identified by GC-MS analysis if residual solvents. However, a testing laboratory may encounter other substances in other tests and not just for residual solvents. Is there a requirement or provision for reporting these other substances?

"Section 3(17)(b): Is this requirement sufficient to protest consumers? Is the manufacturer required to file a hazard analysis with the agency?

"Section 3(17)(d): Does the presence of a new chemical entity that has not been subjected to toxicity testing in a hemp-derived cannabinoid meet the definition of 'adulterated' under this administrative regulation?

"Section 3(18)(b)6.: This does not make sense. Is this a reference to control samples and an attestation that the results of control sample analyses met criteria for acceptance? If so, this requirement should be rephrased to reflect the specific samples that are covered by this administrative regulation.

"Section 3(18)(b)7.: This does not make sense. How are these substances to be identified in the report if they are unknown or unidentified? Should identified substances that are produced as side-products in the synthesis of hemp-derived cannabinoids be reported or not? What threshold, if any, should be used by the testing laboratory when reporting unidentified or tentatively identified substances?

"Section 3(18)(c)4.: Needs clarification. How do results of cannabinoids differ from other analytes?

"Section 3(18)(f): Only the customer can provide approval for the testing lab to relinquish their sample to another party.

"Section 3(19)(a): Are products manufactured outside the Commonwealth eligible for sale in the state? Most products sold in Kentucky are not being manufactured within the State and therefore would not be subject to these regulations."

(b) Response: The cabinet appreciates the thorough review of the testing requirements and certificate of analysis. The cabinet believes the testing requirements are necessary to comply with HB 544 Section 1(3)(e). The intent is not to be overly burdensome to manufacturers and processors but to ensure products are safe for human consumption.

The cabinet is amending this administrative regulation in response to some of these comments.

(13) Subject: General comments and suggestions for amendments to the administrative regulation

(a) Comment: Chris Lindsey, Director of State Advocacy and Public Policy, ATACH, commented: "The American Trade Association for Cannabis & Hemp ("ATACH") is a 501(c)(6) trade organization and we have members that manufacture and distribute both cannabis and hemp products. We were founded in 2014 to support and protect regulated cannabis and hemp businesses, promote consumer safety or marijuana and hemp products at the state and federal levels, and promote the expansion, protection, and preservation of businesses engaged in the state-legal trade of medical and recreational cannabis and hemp based products.

"There are two suggestions we would offer in support of the Cabinet's efforts:

"I. The first is to suggest that you include ASTM International's D9448 standards for cannabis products, which includes a monogram for labels, which can help consumers.

"II. Second suggestion is to specifically define "cannabinoid concentration" in addition to "total cannabinoid concentration" in order to capture all intoxicant, including those that are not technically defined at THC. Our concern is that while "all other hemp-derived cannabinoids" are included in the testing results in Section 8(b)(7), they might not be required to contribute to the "total cannabinoid concentration" in 2(b), which is a potency calculation, unless they are defined as part of the cannabinoid concentration. In other words, it might be possible for a manufacturer to emphasize minor cannabinoids that are intoxicating and under-report potency, which still complying with the testing requirement for "total cannabinoid concentration". ATACH believes that under-reporting the potency of a product could be harmful for consumers, and we suggest the language be amended if the Cabinet agrees with our interpretation.

"It is worth noting that in addition to the cannabis product monogram mentioned above, ASTM International is also working on a standard to identify when a cannabinoid is intoxicating as well as ensuring that all intoxicating cannabinoids that appear in a cannabinoid product are captured through a concept called Total Intoxicating Cannabinoid Content (TICC). These standards are in process but which might be useful.

"Considering the many unknown compounds that are created in these processes and the research that is being uncovered, it will be interesting to see how the requirements of Section 2(16) related to hazard analysis will apply. We hope the system will be workable for businesses that seek to comply with requirements and urge the Cabinet to work with licensed businesses to find solutions if needed."

(a) Comment: Bill Peterson, CEO, Alice Peterson, President, Bobby Gaffney, Chief Science Officer, Jennifer Lantz, Director of Compliance and Quality, and Sam Burney, Director of Partnerships, Kentucky Heritage Hemp (KHH) Company, commented: "The emergency rule is a valuable step in establishing a safe marketplace for the manufacture and sale of ingestible and topical products containing hemp-derived cannabinoids.

"KHH provides organic hemp-derived products for health and wellness. Delta-8 is sought for its intoxicating effects.

"There is a *de minimis* amount of naturally occurring Delta-8 in every hemp variety. However, the D-8 which is blanketing the Kentucky market is made synthetically. Synthetic Delta 8 deploys harsh, toxic and often carcinogenic elements to knock a molecule off of CBD to result in Delta 8.

"Because the federal government has not regulated D-8, we think it is more than appropriate, even urgent, for the State of Kentucky to step in and restrict it.

"KHH does not manufacture D-8. We are concerned that the lack of clarity in the current wording of the emergency regulations "throws the baby out with the bathwater". Even though D-8 is not our focus, if it is properly regulated, we have no issue with its production. What we can't get on board with is sweeping *all* intoxicating hemp elements, whether phytocannabinoids or synthetic ones, into new rules.

"1. KHH would like to work with you to establish the state of Kentucky as synonymous with safe, high quality hemp products. We can do this. When a consumer in any part of the world sees Kentucky origins on a hemp label, it should connote immediately that it's a good product – because Kentucky hemp is subjected to rigorous standards and regulations rendering it safe and efficacious. We must do this in a way that does not inhibit retail sales, or which could put Kentucky in an inferior position relative to other states.

"2. Above all, we must avoid the temptation to over-regulate. There are many examples of where state' overreach backfired and created a stronger black market. This would be very bad for all of us. Peterson Farms and KHH have been pioneers in the hemp industry in Kentucky. Now, even as we rein in D-8, we'd like to state focused on creating a viable marketplace for safe, health-focused and quality-oriented CBD, CBG and other hemp products."

(a) Comment: Shannon Stiglitz, Senior VP of Governmental Affairs, Kentucky Retail Federation, commented: "Other concerns or questions:

"*Section 1* Definitions: this section contains no definition of hemp-derived products, but in *Section 6* all retailers selling hemp-derived products will be required to register with DPH.

"*Section 6 (a),* requires retailers to purchase products only from an approved source. Will the Department for Public Health publish a readily accessible list of approved sources? If yes, where would a retailer locate such a list? If not, how will a retailer know they are purchasing from an approved source?

"*Section 6(8)* states that "All products not in compliance with the administrative regulation may be seized and destroyed by cabinet or its duly authorized agent." At the time an inspection is conducted, an inspector could destroy any product in violation of the regulations. What recourse would a retailer have if they disagreed with the inspector's claim that the product is non-compliant? What due process rights would a retailer have to challenge such action and assertion? If an inspector improperly destroyed retailer inventory, how would they recover the cost of this loss?

"*Section 7 (5)* requires a restaurant serving hemp-derived cannabinoid enhanced food or drink products to report adverse reactions within one business day of the knowledge about the adverse reaction. Could this be expanded to two business days to accommodate restaurant operating hours on weekends, where they may be required to report an adverse reaction, but no one is available to report it?

"*Section 8(1):* Again, we would encourage the cabinet to remove the ability of its inspection staff to inspect any and all retailers selling hemp-derived products such as CBD. It will only cause confusion and dilute the ability of inspection staff to root out bad actors. Given that the regulation states that "...the cabinet shall conduct an onsite inspection..." this means the cabinet is required to inspect everyone selling a hemp-

derived product, it further demonstrates the difficulty the cabinet will have inspecting all these entities.

"Section 8(2): requires the cabinet to inspect vehicles utilized to transport products—does this requirement extend to retailers delivering to the end consumer? If so, how would a retailer provide inspection of what may be personal vehicles of employees or contracted third parties that would have no way of knowing which vehicle would be delivering on any given day."

(a) Comment: K. Brad Oakley, Member, Jackson Kelly, PLLC, Kentucky Beer Wholesalers Association (KBWA), commented: "Based on our reading of the e-regulation, we believe its intent is to create a comprehensive framework for regulating certain hemp-derived substances, primarily products containing intoxicating amounts of Delta-8 THC. The KBWA agrees with your efforts to regulate Delta-8 THC in any amount that is intoxicating just as other intoxicating substances are heavily regulated within the Commonwealth. However, as drafted, it is the KBWA's opinion that the e-regulation needs additional controls put in place to regulate intoxicating amounts of Delta-8 THC (or any other intoxicating hemp-derived product) to adequately protect the safety and health of the public. In this regard, we believe the regulatory framework for the taxation, licensing, production, distribution, sale, and consumption of alcohol provides the type and scope of regulatory oversight and control that is needed for intoxicating hemp-derived products. The Commonwealth's regulatory framework controlling all aspects of alcoholic beverages, specifically including, but not limited to, the alcohol licensing process (including thorough background checks – see KRS 243 generally) and the limitations on shipping/delivering alcohol beverages directly to consumers (see KRS 243.027 and 243.028), is the type of regulatory oversight that needs to be in place so that the Cabinet has the ability to adequately protect the safety and health of the Commonwealth's citizens.

"Additionally, the e-regulation is not clear on which agency is responsible for enforcing its requirements. The e-regulation should specifically identify which agency has enforcement authority and the consequences for failing to comply with all requirements.

"In short, the KBWA believes that any product containing an intoxicating amount of hemp-derived products (including, but not limited to, Delta-8 THC) should be taxed and regulated in a manner that is no less strict than the current regulatory scheme for alcoholic beverages."

(a) Comment: Liz Burrows, Region 6 KY Agency for Substance Abuse Policy (KY ASAP) Local Board, and Barry D. Lee, Superintendent, Casey County Schools, commented: "Set a maximum threshold of THC per edible dose, vape cartridge or capsule at 20 milligrams."

(a) Comment: Joe Bilby, General Counsel, and Keith Rogers, Chief of Staff for the Kentucky Department of Agriculture, commented: "Section 3(14) of the regulation establishes certain requirements for '[p]lant material, such as flower, shake, and plant trim'. We believe the regulation should not contain any mention of 'flower, shake, and plant trim', however, because KRS 260.858(2) states: 'It is unlawful for a person who

does not hold a license issued by the department, or who is not an agent of a licensee, to cultivate, handle, process, or market living hemp plants or viable seeds, leaf materials, or floral materials derived from hemp'. The statute adds: 'Penalties for persons who cultivate, handle, process, or market living hemp plants or viable seeds, leaf materials, or floral materials derived from hemp without a licensed are the same as those penalties that are applicable to persons who violate KRS Chapter 218A, relating to marijuana'. Because products containing left and flower cannot lawfully be distributed in Kentucky, we believe that Section 3(14) should be deleted. Additionally, the explicit prohibition of products containing hemp leaf or flower would provide clarity and consistency with existing law.

"We understand that some retailers in Kentucky currently sell cannabinoid products that are intended to be smoked. We believe a consumer's use of such products creates additional health risks that warrant their prohibition. We urge the Cabinet to exercise its regulatory authority be including within this regulation a explicit prohibition against 'smokable' products containing cannabinoids, including without limitation: cigarettes, cigars, pre-rolls, and joints; and chews, dips, and chaws."

(a) Comment: Christopher M. Ware, Founder and CEO, KCA Labs, commented:

"Section 2(1): Is a 'person located in Kentucky' required to be a resident or to have a permanent address in Kentucky?

"Section 2(7): Is the processing or manufacturing facility responsible for having the product tested for non-cannabinoid additives, caffeine, and nicotine? Who or what entity is responsible for assessing carcinogenicity or cardiac effects?

"Section 2(8): Change 'disbursement' to 'dispersion' or 'distribution'.

"Section 2(9): Is 'hydrogenation' included in these processes?

"Section 2(10): Recommend deletion of the modifier 'vegetable' before 'glycerin'.

"Section 2(20)(a): Recent research indicates that all acetates (not just Vitamin E acetate) produce ketene during pyrolysis and that this substance is implicated in vaping use-associated lung injury. If so, shouldn't all acetate be prohibited in vaping products?"

(b) Response: The cabinet appreciates the thorough review and suggestions provided. The intent is not to overregulate or cause an undue burden to all those involved in the cannabinoid market.

The cabinet is amending this administrative regulation in response to some of these comments.

(14) Subject: Retail permit

(a) Comment: Dee Dee Taylor, Board member Kentucky Hemp Association and CEO/Founder 502 Hemp Wellness Center, commented: "Retail establishments are going to have to get a permit. I filled out the paperwork to be—apply for the permit. I have not received anything back.

"Gas stations, are they going to have to be permitted? Are you actually going to go in to every gas station that is selling these products and test all of their products as well or look to see if they have certificate of analysis in a booklet?"

(b) Response: The current emergency administrative regulation requires retail establishments to register with the department. A retail permit is not issued at this time. The intent of the registration is to allow the department to know what type of products are being sold at retail establishments.

The cabinet is not amending this administrative regulation in response to this comment.

(15) Subject: Formula

(a) Comment: Katie Moyer, President, Kentucky Hemp Association, commented: "Section 3(8)(c) includes the inaccurate and arbitrary measurement for calculating Total THC by multiplying THCa by 0.877 and adding Delta 9 THC. This measurement has never demonstrated any benefit to the hemp industry, its consumers, retailers or farmers. In fact, as a measurement of price for products the Total THC equation is confusing, does not account for changes in weight of the products as they undergo combustion or vaporization, and often causes products to be undervalued. This means significantly less revenue for retailers and ultimately reduces state sales taxes. Regulations should be amend to label products accurately for Delta-9 THC specifically, or other cannabinoids (such as Delta-8 THC, or Delta-10 THC, rather than using flawed math to arbitrarily guess the levels of 'Total THC'.

"We think it would be more important to label the products accurately for delta-9 THC and delta-8 THC and the specific items that are considered adult use, rather than just sort of doing some math and then hoping that that's accurate."

(b) Response: The cabinet appreciates the concern regarding the inaccuracy of the suggested formula.

The cabinet is amending this administrative regulation in response to this comment.

(16) Subject: Approved products list

(a) Comment: Katie Moyer, President, Kentucky Hemp Association, commented: "We suggested an approved products list that would define specifically what is considered adult use and intoxicating. If you count delta-8 as adult use, delta-9 as adult use, delta-10, and be very specific about those items.

"Adopting either the West Virginia approach or limiting language to cabin the regulation to intoxicating products allows the regulations to be abbreviated significantly, while streamlining the enforcement process and reducing the burden for retailers.

"An Approved Products Program of product registration to certify adult-use products approved for sale in Kentucky would solve a number of problems that we foresee that will arise under the current regulation as written.

"Manufacturers can have a clear answer on packaging as to what is allowed, regulator and gents of the cabinet will not be asked to make arbitrary decisions which will undoubtedly lead to conflicting decisions, which leads to unnecessary litigation arising from ad-hoc enforcement.

"Adopt the current industry package warning labels using California standards.

"Having an Approved Products Program can be funded through fees to the manufacturers and the program will pay for itself.

"An Approved Products Program would make enforcement easier, as agents could merely scan each product's UPC code to ensure compliance.

"The Approved Products Program should contain a system for any non-approved product to be added to the registry and given an opportunity at compliance before it is confiscated or destroyed.

"Any ambiguity or arbitrariness in Section 6(1)(a) and (b) would be removed by using the Approved Products Program. Such a program would also remove the extremely onerous requirement contained in Section 6(1)(c) and would prevent bad actors from passing off faked lab results. The Approved Products Program should require that test results be submitted directly from an approved laboratory to prevent fraudulent test results."

(b) Response: The cabinet agrees that having an approved products list may simplify the processing, manufacturing, and inspection processes, and remove any ambiguity or arbitrariness in the regulation. However, the cabinet is not in a position to implement an Approved Products Program as suggested.

The cabinet is amending this administrative regulation in response to some of these comments.

(17) Subject: Fiscal note

(a) Phyllis Smith, PJ Smith Enterprises, LLC, DBA Essentially Hemp, commented: "One of the things that struck me is the very last page, the fiscal note. It's going to be about the cost of this being an entity to be able to be a processor or a retailer. I think most of us probably here have already signed up for and paid that 125. I had of course because of my facility being regulated already.

"It also states in here several different places in this that the minimum fee is 125, the maximum is a thousand, about the hiring of additional health inspectors for $125,000 a year, four of them. And the cost of this program to watch after or to do this administrative prat of this seem to be quite...it's going to increase things quite a bit.

"My concern is, as a small processor, how much is going to be my permitting fees form here on out? Am I going to have to try and cover the cost of these administrative fees? Is that going to hit me, another big fee annually? Because our KDA hemp program, we already have to pay a large fee and it's not based on anything other than being a processor.

"I'd like for it to be considered in this, also, that based on your sales and your production is how this fee will be considered and not to be lumped in with the larger corporations."

(b) Response: The cabinet is aware of the multiple entities that assess fees on processors. Kentucky Department of Agriculture assesses fees on hemp growers, processors, and handlers under 302 KAR 50:060, Fees for the Hemp Licensing Program. All revenue received from hemp processors under that administrative regulation are retained by the Department of Agriculture. The Kentucky Department for

Public Health also regulates hemp processors under 902 KAR 45:190E. The fee referenced in this administrative regulation is found in 902 KAR 45:180. The lowest fee will be $125 and the highest would be $1,000 under 902 KAR 45:180.

The cabinet is not amending this administrative regulation in response to this comment.

(18) Subject: Enforcement procedures

(a) Comment: Liz Burrows, Region 6 KY Agency for Substance Abuse Policy (KY ASAP) Local Board, and Barry D. Lee, Superintendent, Casey County Schools, commented: "The regulations do not expressly state that violators can have their permit revoked. It only says, "they shall be provided notice of the violations" and "all products not in compliance with this administrative regulation may be seized and destroyed by the cabinet or its duly authorized agent." The regulations should contain language that allows for the cabinet or its duly authorized agent to fine the retailers found in violation of law. The same fines for tobacco violations should be used. $1000 fine to the store owner on the first offense and $100 fine to the clerk. This could increase if the same retailer was issued a second violation within a 12-month period. There should also be language that allows for a temporary suspension of the retailer's permit to sell hemp-based THC products after a set number of repeated violations. For the sake of comparison, the FDA issues a no sell order to tobacco retailers who incur five violations within a 36 month period. In determining the length of the no sale order the following factors must be considered: *the nature, circumstances, extent, and gravity of the violations and, with respect to the violator, any history of prior such violations, the degree of culpability, and such other matters as justice may require*."

(a) Comment: Katie Moyer, President, Kentucky Hemp Association, commented: "Section 6(8), products not in compliance due to record keeping, registration, or other administrative requirements, should be provided an opportunity to comply, including to be added to the Approved Products Registry before destruction, and a reasonable opportunity to obtain the return of seized products after a reasonable period to come into compliance."

(a) Comment: Launi Gum, Program Director/Project Coordinator, Champions for a Drug Free Grant County, commented: "We appreciate the following regulations that align with best practice for youth substance use prevention:

- Definition of hemp-derived products as adult-use for individuals 21 years of age and older
- Addition of product testing requirements
- Requirement to register with the Cabinet for Health & Family Services
- Requirement of security measures to prevent theft and youth access
- Requirement of child-resistant packaging and the prohibition of packaging that appeals to children and young adults

"However, we strongly believe the success of these regulations would greatly increase with the addition of penalties for businesses that are non-compliant. This is a precedent that has been established by both the Food & Drug Administration with

compliance of nicotine product regulations and Kentucky's Department of Alcoholic Beverage Control with the compliance of alcohol product regulations. There is simply no incentive to comply with regulations that, without penalties for non-compliance, become interpreted as recommendations or guidelines."

(a) Comment: Joe Bilby, General Counsel, and Keith Rogers, Chief of Staff for the Kentucky Department of Agriculture, commented: "Section 6 requires certain retail establishments to register with the cabinet within ninety (90) days of its effective date. But as far as we can tell, a retailer that fails to comply with this registration faces no consequence. To increase compliance with this retailer registration requirement, we recommend imposing a financial penalty for retailers found to be offering cannabinoid products for sale to the public without having made the required registration with the cabinet.

"Additionally, we recommend that a registration fee be imposed for retailers to help offset the costs of the required inspections."

(a) Comment: Christopher M. Ware, Founder and CEO, KCA Labs, commented:

"Section 8(9): Must include a violation for any instances of altering, modifying, or falsifying a Certificate of Analysis provided by the approved laboratory."

(b) Response: The cabinet appreciates the suggestions to strengthen enforcement procedures related to the manufacture, processing, and sale of hemp-derived cannabinoid products. However, the cabinet is limited to the statutory allowances for enforcement and penalties under KRS 217.992.

The cabinet is not amending this administrative regulation in response to these comments.

(19) Subject: Record keeping

(a) Comment: Christopher M. Ware, Founder and CEO, KCA Labs, commented: "How much variance from the target concentration is permitted? Is there any requirement for the manufacturer to submit master formulation records to the agency for approval or is it sufficient to merely maintain the records?"

(b) Response: The cabinet has not included any variance from the requirements of this administrative regulation. However, the cabinet is aware of the need to amend the regulation for clarity.

The cabinet is amending this administrative regulation in response to this comment.

(20) Subject: Recommended revisions to the administrative regulation

(a) Comment: Annie Rouse, Co-founder and Chief Operating Officer, OP Innovates, provided a detailed revision to the administrative regulation. This includes several new

defined terms, amended processing and manufacturing requirements, amended testing requirements, amended packaging and labeling requirements, and amended retail and food service establishment requirements. Many of these suggested changes incorporate the recommendations made during her testimony at the public hearing and her written comments.

(b) Response: The cabinet appreciates Ms. Rouse's thorough review and thoughtful recommendations. The cabinet will consider these suggested edits and revise this administrative regulation where applicable.

The cabinet is amending this administrative regulation in response to some of these comments.

Summary of Statement of Consideration
and
Action Taken by Promulgating Administrative Body

A public hearing on 902 KAR 45:190E was held on September 25, 2023, at 9 a.m. via the Zoom Cloud Meetings platform. In addition to those who attended the public hearing, written comments were received during the public comment period.

The Cabinet for Health and Family Service, Department for Public Health responded to the comments and amends the administrative regulation as follows:

Page 2
Section 1(1)
Line 7

After ""Adult-use cannabinoid" means", insert the following:

<u>a product with intoxicating properties that changes the function of the nervous system and results in alterations of perception, cognition, or behavior</u>

Delete the following:

tetrahydrocannabinols, tetrahydrocannabinolic acids that are artificially or naturally derived, delta-8 tetrahydrocannabinol, delta-9 tetrahydrocannabinol, the optical isomers of delta-8 tetrahydrocannabinol or delta-9 tetrahydrocannabinol, and any artificially derived cannabinoid that is reasonably determined to have an intoxicating effect

Retain the period

Page 2
Section 1(2)
Line 12 to 15

After "(2)", delete the following:

"Artificially derived cannabinoid" means a chemical substance that is created by a chemical reaction that changes the molecular

structure of any chemical substance derived from a plant of the genus Cannabis.
(3)

Page 2
Section 1(3)
Line 18

After "the applicable jurisdiction;", delete "or"

Line 20

After "Department for Public Health"; insert the following:

; 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

Pages 2 and 3
Section 1(4) to (9)
Lines 21 to 9

Renumber these seven subsections by inserting "(3)", "(4)", "(5)", "(6)", "(7)", "(8)", and "(9)", respectively, and by deleting "(4)", "(5)", "(6)", "(7)", "(8)", "(9)", and "(10)", respectively.

Page 2
Section 1(4)
Line 24

Amend the newly renumbered subsection (4) by inserting the following after "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

Page 3
Section 1
Line 10

Insert the following new subsection:

(10) "Hemp-derived cannabinoid" means an ingestible, inhalable, or cosmetic product that is processed or derived from hemp.

Page 3
Section 1
Line 11

After "(12)", insert the following:

"Hydrogenation" means the chemical reaction between molecular hydrogen (H_2) and another compound or element.
(13)

Line 12

Insert the following new subsections:

(14) "Infused" means adding a cannabinoid concentrate 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)

Page 3
Section 1(14)-(15)
Lines 13-14

Renumber these two subsections by inserting "(17)", and "(18)", respectively, and by deleting "(14)", and "(15)", respectively.

Page 3
Section 1
Line 15

Insert the following new subsection:

(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)

Page 3
Section 1(16)
Line 16

After "sample", delete the following:

using gas chromatography mass spectrometry

Line 17

After "analytes", delete the following:

for the residual solvent analysis

Page 3
Section 1(17)
Lines 18-19

Delete subsection (17) in its entirety

Page 3

Section 2
Line 20

After "Section 2.", insert the following:

Permit and Product Registration

Delete the following:

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

Page 3
Section 2(1)
Line 22

After "(1)", insert the following:

In-state permit.

(a)

Page 3
Section 2(1)
Line 23

After "distribute hemp-derived", insert "cannabinoid products".

Delete "cannabinoids".

Page 4
Section 2(2)
Line 3

Renumber this subsection by inserting "(b)", respectively, and by deleting "(2)", respectively.

Page 4
Section 2(2)(a)-(c)
Lines 4-6

Renumber these three paragraphs by inserting "1.", "2.", and "3." respectively, and by deleting "(a)", "(b)", and "(c)", respectively.

Line 5

Amend the newly numbered subparagraph "2." by deleting "and" after "facility;".

Page 4
Section 2(3)
Line 7

Insert "4. Include", delete "(3)".

Lines 8-10

Renumber these three paragraphs by inserting "a.", "b.", and "c.", respectively, and by deleting "(a)", "(b)", and "(c)", respectively.

Page 4
Section 2(3)(c)
Line 10

After "food service establishment, insert "; and".

Page 4
Line 11

After the newly renumbered subparagraph "c.", insert the following new language:

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 less than three tenths of one percent (0.3%) Total THC;

3. Delta-8-tetrahydrocannabinol (Delta-8-THC);

4. Delta-9-tetrahydrocannabinolic acid A (THCA-A) with less than three tenths of one percent (0.3%) 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)

Page 4
Section 2(4)
Line 11
Delete "(4)".

Page 4
Section 2(5)-(6)
Lines 14 and 16
Renumber these two subsections by inserting "(2)", "(3)", respectively, and by deleting "(5)", "(6)", respectively.

Page 4
Section 2
Line 16
For the newly renumbered subsection (3), insert the following:
(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

Delete the following:

(6) An adult-use hemp-derived cannabinoid processing or manufacturing facility, or distributor, shall not employ anyone under twenty-one (21) years of age

Retain the period.

Page 4
Line 18

After "twenty-one (21) years of age or older"; insert the following new subsections:

(4) Non-intoxicating cannabinoid products shall:
(a) Have at least a twenty-five (25) 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.

Page 4
Section 2(7)
Line 18

Renumber this subsection by inserting "(6)", respectively, and by deleting "(7)", respectively.

Page 4
Section 2(7)
Line 19

Delete the following:

, concentrate, cannabinoid extract, or edible product

Page 4
Section 2(7)(a)
Line 21

After "or addictive potential,", insert "excluding caffeine".

Section 2(7)(b)
Line 22

After "(b)", insert "Alcohol".

Delete "Caffeine".

Page 5
Section 2(8), (9), (10), (11), (12), (13), (14)
Lines 1, 3, 5, 10, 13, 18, 22

Renumber these subsections by inserting "(7)", "(8)", "(9)", "(10)", "(11)", "(12)", and "(13)", respectively, and by deleting "(8)", "(9)", "(10)", "(11)", "(12)", "(13)", "(14)", respectively.

Page 5
Section 2(8)
Line 1
After "All", delete "edible".
After "uniform", insert "distribution".
Delete "disbursement".

Page 5
Section 2(9)
Line 4
After "catalyzation,", delete "or".
After "distillation", insert the following:
, hydrogenation, or other refinement

Page 5
Section 2(10)
Line 6
After "solvents: water,", delete "vegetable".
Line 8
After "prohibited unless", insert "preapproved".
Delete "approved".

Page 5
Section 2(13)(a)
Line 18
After "stored in", insert "food".
Delete "medical".

Page 6
Section 2(15), (16), (17), (18), (19), (20)
Lines 1, 4, 6, 8, 11, and 19
Renumber these six subsections by inserting "(14)", "(15)", "(16)", "(17)", "(18)", "(19)", respectively, and by deleting "(15)", "(16)", "(17)", "(18)", "(19)", "(20)", respectively.

Page 6
Section 2(19)(a)
Line 11
After "cannabinoid manufacturer", insert the following:
may use terpenes or other hemp essential oil but
Line 14
After "in the manufacture of", insert "inhalable".

Page 6
Section 2(20)(a)
Line 21
After "(a)", insert "Acetates".
Delete "Vitamin E acetate (VEA)".

Page 7
Section 2(20)(e)
Line 1
After "(e)", insert the following:
Diketones:
1.
After "butanedione (Diacetyl);", insert the following:
2. 2,3-pentanedione (acetylpropionyl); and
3. 3-hydroxybutanone (acetoin);
Delete "and".
Line 2
After "(f) Myclobutanil", insert the following:
;
(g) Artificial food coloring; and
(h) Benzoic acid
Retain the period.

Page 7
Section 3
Line 3
After "Section", insert "4".
Delete "3".

Page 7
Section 3(5)(a)
Line 19
After "(a)", delete "For".
After "cannabinoid", insert "product".
Delete the following:
concentrates, extracts, and edible products,
Line 20
After "shall consist of enough", insert "material".
Delete "samples".

Page 8
Section 3(5)(b)
Lines 1 and 2
After "hemp-derived cannabinoid", delete the following:
concentrates, extracts, and edible

Page 8

Section 3(6)
Line 4

After "(6)", insert the following:

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)

Page 8
Section 3(6)(a)
Line 6

After "facility shall be", insert the following:

an independent third-party,

Page 8
Section (3)(6)(b)f.
Line 17

After "Residual solvents", delete "and processing chemicals".

Page 8
Section 3(7)
Line 24

Renumber this subsection by inserting "(8)", respectively, and by deleting "(7)", respectively.

Page 9
Section 3(7)(a)
Line 2

After "hemp-derived cannabinoid", insert "product".
Delete the following:

concentrate, extract, or edible products

Page 9
Section 3(7)(b)

Line 4

After "(b)", insert the following:

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)

Page 9
Section 3(7)
Line 4

After "Hemp-derived cannabinoid", delete the following:

concentrate, extract, or edible

Page 9
Section 3(7)(b)6.
Line 11

After "Residual solvents", delete "and processing chemicals".

Page 9
Section 3(7)
Line 12

Renumber this paragraph by inserting "(d)", respectively, and by deleting "(c)", respectively.

Page 9
Section 3(7)(c)
Lines 13 and 14

After "heavy metals, or", insert "residual solvents".

Delete "processing chemicals".

Line 17

After "heavy metals,", insert "residual solvents".

Delete "processing chemicals".

Page 9
Section 3(7)
Line 19

Renumber this paragraph by inserting "(e)", respectively, and by deleting "(d)", respectively.

Line 21

After "heavy metals, or", insert "residual solvents".

Delete "processing chemicals".

Page 9
Section 3(7)
Line 22

Renumber this paragraph by inserting "(f)", respectively, and by deleting "(e)", respectively.

Line 23

After "shall be tested for", insert "Acetates".

Delete "Vitamin E Acetate".

Pag 10
Section 3(7)
Line 1

Renumber this paragraph by inserting "(g)", respectively, and by deleting "(f)", respectively.

Page 10
Section 3(8)
Line 3

Renumber this subsection by inserting "(9)", respectively, and by deleting "(8)", respectively.

Page 10
Section 3(8)(b)3.
Line 12

After "3.", delete the following:

Total CBD concentration, calculated in accordance with paragraph (d) of this subsection and reported in percentages;
4. CBD-A concentration;
5.

Page 10
Section 3(8)
Line 15

After "total tetrahydrocannabinol and", insert the following:

the primary cannabinoid marketed, excluding cosmetics

Delete "total CBD".

Page 10
Section 3(8)
Line 16

Renumber this subparagraph by inserting "4.", respectively, and by deleting "6.", respectively.

After "total tetrahydrocannabinol and", insert the following:

the primary cannabinoid marketed, excluding cosmetics

Delete "total CBD".

Page 10
Section 3(8)
Line 18

Renumber this subparagraph by inserting "5.", respectively, and by deleting "7.", respectively.

Line 19

After "a percentage and", delete "in either".

After "milligrams per gram (mg/g)", delete the following:

if by weight or milligrams per milliliter (mg/mL) if by volume

Retain the period.

Page 10
Section 3(8)(c) and (c)1.
Lines 21 and 22
After "calculating total tetrahydrocannabinol", delete the following:
:
1. For
Line 24
After "(mg/g)", delete "; or".

Page 11
Section 3(8)
Lines 1-3
Delete subparagraph 2. in its entirety but retain the period.

Page 11
Section 3(8)(d)
Line 4
After "cannabinoid infused products,", insert "excluding cosmetics,"
Line 5
After "total tetrahydrocannabinol and", insert the following:
the primary cannabinoid marketed, excluding cosmetics
Delete "total CBD".

Page 11
Section 3(8)(e)
Line 6
After "(e)", delete "Adult-use hemp-derived".

Page 11
Section 3(9)
Line 11
Renumber this subsection by inserting "(10)", respectively, and by deleting "(9)", respectively.
Line 12
After "Hemp-derived cannabinoid", delete the following:
concentrate, extract, or edible

Page 11
Section 3(9)(b)3.
Line 18
After "detected in one (1) gram", delete "and".
Line 20
After "detected in one (1) gram", insert the following:
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

Retain the period.

Page 11
Section 3(9)(c)
Line 21

After "The sample of", insert "ingestible or cosmetic".

Delete "non-inhalable hemp-derived".

Page 12
Section 3(9)(c)2.
Line 1

After "detected in one (1) gram", delete "and".

Line 2

After "detected in one (1) gram", insert the following:

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

Retain the period.

Page 12
Section 3(9)(e)
Line 6

Before "concentrate or extract", insert "product".

Delete "concentrate or extract".

Page 12
Section 3(9)(f)
Line 10

After "microbiological contaminants,", insert "and".

Line 11

After "residual solvents", delete ", and processing chemicals".

Page 12
Section 3(10)
Line 16

Renumber this subsection by inserting "(11)", respectively, and by deleting "(10)", respectively.

Page 12
Section 3(10)(a)
Line 17

After "Hemp-derived cannabinoid", delete the following:

concentrate, extract, or edible

Page 13

Section 3(11)
Line 4
Renumber this subsection by inserting "(12)", respectively, and by deleting "(11)", respectively.

Page 13
Section 3(11)
Line 5
After "Hemp-derived cannabinoid", delete the following:
concentrate, extract, or edible

Page 14
Section 3(12)
Line 4
Renumber this subsection by inserting "(13)", respectively, and by deleting "(12)", respectively.

Page 15
Section 3(12)(a)
Line 1
After "Hemp-derived cannabinoid", delete the following:
concentrate, extract, or edible

Page 15
Section 3(12)(a)
Line 4
After "allowable concentration:", insert the following:
one and five tenths (1.5)
Delete "zero and four-tenths (0.4)".

Page 15
Section 3(13)
Line 18
Renumber this subsection by inserting "(14)", respectively, and by deleting "(13)", respectively.
After "residual solvents", delete "and processing chemicals".
Line 19
After "Hemp-derived cannabinoid", delete the following:
concentrate, extract, or edible
Line 20
After "residual solvents", delete "and processing chemicals".
In the chart at the bottom of page 15
After "Solvent", delete "or processing chemical".

Page 16
Section 3(13)(a)
In the chart for "Ethanol", insert "5,000".

Delete "1,000".
In the chart for "Any other solvent not permitted for use pursuant to this regulation", insert "1 ppm", delete "None Detected".

Page 17
Section 3(14)
Line 14
Renumber this subsection by inserting "(15)", respectively, and by deleting "(14)", respectively.

Page 17
Section 3(15)
Line 19
Renumber this subsection by inserting "(16)", respectively, and by deleting "(15)", respectively.

Page 18
Section 3(15)
Line 16
After "hemp-derived cannabinoid", delete the following:
concentrate, extract, or edible

Page 18
Section 3(16)
Line 20
Renumber this subsection by inserting "(17)", respectively, and by deleting "(16)", respectively.

Page 19
Section 3(16)(b)
Line 3
Insert the following new subsection
(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)

Delete the following:

(17) Tentative identification of compounds (TICs).
(a) The testing facility shall provide the processing or manufacturing facility with a complete report of any TICs identified.
(b) The processing or manufacturing facility shall conduct a hazard analysis in accordance with the requirements of 902 KAR 45:160 Section 2(1)(u) to identify and evaluate based on experience, illness data, scientific reports, and other information known or reasonably foreseeable hazards associated with any reported TICs.
(c) 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 a preventive control.
(d) A processing or manufacturing 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 will not be adulterated.
(e)

Page 19
Section 3(17)(e)
Line 17

After "of a processing", delete "or manufacturing".

Line 18

After "as a result of", insert the following:

a by-product or compound with no toxicity study or

Page 19
Section 3(18)
Line 22

Renumber this subsection by inserting "(19)", respectively, and by deleting "(18)", respectively.

Page 20
Section 3(18)(b)1.
Line 7

After "manufacturer's name,", insert "and".
After "premises address", delete ", and permit number".

Page 20
Section 3(18)(b)5.

Line 17

After "limits of quantitation (LOQ);", insert "and".

Lines 18-21

After "6.", delete the following:

An attestation from the testing facility supervisory or management employee that all LOQ samples required by this administrative regulation were performed and met the acceptance criteria; and

7.

Page 21

Section 3(18)(f)

Line 20

Insert "(20)", delete the following:

(f) The testing facility shall provide the reserve sample to the cabinet upon request.

(19)

Page 22

Section 3(19)

Line 1

After "testing", insert "and labeling".

Line 2

After "receiving state", insert "or jurisdiction".

After "does not have testing", insert "or labeling".

Line 3

After "receiving state's", insert "or jurisdiction's".

After "testing and", insert "labeling".

Line 4

After "testing", insert "and labeling".

Page 22

Section 3(19)

Line 5

Insert the following new subparagraph:

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.

Page 22

Section 4

Line 7

Renumber this section by inserting "5", respectively, and by deleting "4", respectively.

Page 23

Section 5

Line 10

Renumber this section by inserting "6", respectively, and by deleting "5", respectively.

Page 23
Section 5(2)
Line 14

After "Each container of", insert "adult-use".
Delete the following:
ingestible or cosmetic hemp-derived

Page 23
Section 5(3)
Line 18

After "(3)", insert the following:
Each container of non-intoxicating cannabinoid product or cosmetic shall have a tamper-evident seal.
(4)
Delete "Ingestible hemp-derived".

Page 24
Section 5(3)(e)
Line 4

After "thereof", insert the following:
excluding the use of seals associated with state or federal programs used in accordance with state or federal law and regulations.
(5)

Line 5

Delete "(4)".

Page 24
Section 5(4)
Line 6

After "per container", insert the following:
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
Delete the following:
"as reported by the testing facility"

Page 24
Section 5(4)(a)
Line 7

After "hemp-derived cannabinoid", insert "ingestible or inhalable".
Delete "infused edible".

Line 8

After "total tetrahydrocannabinol", insert the following:
the primary cannabinoid marketed
Delete "total CBD".

Line 9

After "total tetrahydrocannabinol", insert the following:

the primary cannabinoid marketed; and

(b)

Lines 9-12

Delete the following:

total CBD, as applicable;

(b) For hemp-derived cannabinoid concentrates total tetrahydrocannabinol and total CBD, as applicable shall be labeled in percentages; and

(c) The results of all

Capitalize "Other".

Page 24
Section 5(4)(c)
Line 12

After "hemp-derived cannabinoids", insert "labeled".

Delete the following:

as a percentage, in either

Line 13

After "milligrams per gram (mg/g)", insert the following:

per serving, excluding cosmetics, and milligrams per package, if listed on the label.

(6) All cannabinoid products shall include the common cannabinoid description in the product name, such as "Delta-8 THC gummies" or "Full-spectrum CBD extract" using the same or larger font than the product name.

(7) Adult-use

Lines 13-18

Delete the following:

if by weight, or milligrams per milliliter (mg/mL) if by volume, as applicable.

(5) The name of the hemp-derived cannabinoid product that includes a product modifier such as "Delta-8 THC product," or "CBD product" using the same or larger font than the product name.

(6) Adult-use

Page 24
Section 5(6)
Line 18

After "hemp-derived cannabinoid", delete "ingestible".

Page 24
Section 5(6)(c)
Line 24

After "product for", insert "those".

Delete "women".

After "who are pregnant", insert "nursing".
Delete "breastfeeding".

Page 25
Section 5(6)(e)
Line 2
After "(e)", insert the following:
May cause drowsiness or impairment.
After "operate", insert "heavy".

Page 25
Section 5
Line 4
Insert the following new subsection:
(8) 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.

Page 25
Section 6
Line 4
Renumber this section by inserting "7", respectively, and by deleting "6", respectively.

Page 25
Section 6(2)
Line 9
After "Retail establishments", insert the following:
and food service establishments
After "offering", insert "adult-use".

Page 25
Section 6(3)
Line 12
After "(3)", insert the following:
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)

Page 25

Section 6(3)
Line 12

After "Only", insert the following:

non-intoxicating and cosmetic cannabinoids

Delete "cannabidiol".

Page 25
Section 6
Lines 14 and 19

Renumber these two subsections by inserting "(6)" and "(7)", respectively, and by deleting "(4)" and "(5)", respectively.

Pages 25 and 26
Section 6(5)(b)
Lines 23, 1-2

After "Adult-use only", insert a close quotation mark.

Delete the following:

, adult signature (21 years of age or over) required" and request adult-signature-only service from the carrier.
(6) The cabinet or its duly authorized agent shall inspect retail establishments for compliance with this administrative regulation.
(7) A retail establishment not in compliance with this administrative regulation shall be provided notice of the violation.
(8) All products not in compliance with this administrative regulation may be seized and destroyed by the cabinet or its duly authorized agent.

Page 26
Section 6
Lines 3, 5, and 7

Renumber these three subsections by inserting "(8)", "(9)", and "(10)", respectively, and by deleting "(6)", "(7)" and "(8)", respectively.

Page 26
Section 7
Line 9

Renumber this section by inserting "8", respectively, and by deleting "7", respectively.

Page 26
Section 7
Line 10

After "Establishments.", insert the following:

(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

Page 27
Section 7(1)
Line 12

Delete the following:

(1) Only cannabidiol or CBD

Page 27
Section 7
Lines 15, 16, 18

Renumber these three subsections by inserting "(4)", "(5)", and "(6)", respectively, and by deleting "(2)", "(3)" and "(4)", respectively.

Page 27
Section 7(2)
Line 15

After "The", insert "non-intoxicating".
Delete "hemp-derived".
After "cannabinoid", delete "ingredient".

Page 27
Section 7(4)
Line 21

After "service establishment offering", insert "non-intoxicating cannabinoid".
Delete "cannabidiol or CBD".

Page 28
Section 7
Line 2

Renumber this subsection by inserting "(7)", respectively, and by deleting "(5)", respectively.

Page 28
Section 7(5)
Line 4

After "should have been aware of any", insert "serious adverse event".
Delete "adverse reactions".

Page 28
Section 8
Line 8

Renumber this section by inserting "9", respectively, and by deleting "8", respectively.

Page 28
Section 8(1)
Line 10
After "storage warehouses," insert "and".
Lines 10 and 11
After "distribution centers", delete ", and retail establishments".

Page 28
Section 8(2)
Line 12
After "(2)", insert the following:

(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)

Page 28
Section 8(3), (4), (5)
Lines 15, 18, and 20
Renumber these three subsections by inserting "(4)", "(5)", and "(6)", respectively, and by deleting "(3)", "(4)", and "(5)", respectively.

Page 29
Section 8(6)-(12)
Lines 3, 9, 11, 14, 17, 19, and 23
Renumber these seven subsections by inserting "(7)", "(8)", "(9)", "(10)", "(11)", "(12)", and "(13)", respectively, and by deleting "(6)", "(7)", "(8)", "(9)", "(10)", "(11)", and "(12)", respectively.

Page 29
Section 8(8)
Line 12
After "aware of any", insert "serious adverse event".
Delete "adverse reactions".

Page 30
Section 8(13)
Line 5
Renumber this one subsection by inserting "(14)", and by deleting "(13)".