DRAFT – NOT FOR FILING

3796:1-1-01 Definitions.

...

(49) "Tetrahydrocannabinol" or "THC" means all naturally or artificially derived tetrahydrocannabinols, or any structural, optical or geometric isomers or analogs of tetrahydrocannabinols. this includes, but is not limited to,Delta-1 tetrahydrocannabinol; Delta-6 tetrahydrocannabinol; Delta 3,4 tetrahydrocannabinol; Delta-8 tetrahydrocannabinol; Delta-9 tetrahydrocannabinol; Delta-10 tetrahydrocannabinol, and any other cannabinoid that the Department determines to have an intoxicating or psychoactive effect.

(50) "Tetrahydrocannabinol content" or "THC content" means the sum of the amount of the tetrahydrocannabinol (THC) and 87.7 per cent of the detectable amount of tetrahydrocannabinolic acid (THCA) present in the product or plant material.

(51~~0~~) "Unique plant identifier" means a numeric or alphanumeric sequence, as determined by the department, that is assigned to an individual plant when a plant reaches twelve inches in height or is transplanted from a cloning medium or apparatus into a growth medium or apparatus intended for the vegetative or flowering stages of the growth cycle, whichever occurs sooner, to allow for inventory and traceability in the inventory tracking system.

(52~~1~~) "Vegetative stage" means the stage of cultivation where and when a marijuana plant is propagated to produce additional marijuana plants or reach a sufficient size for production. This includes "seedlings," "clones," "mothers," and other immature marijuana plants identified by: (a) having no more than two stigmas visible at each internode of the marijuana plant and if the marijuana plant is in an area that has not been intentionally deprived of light for a period of time intended to produce flower buds and induce maturation; or (b) any marijuana plant that is cultivated solely for the purpose of propagating clones and is never used to produce any medical marijuana.

3796:2-2-02 Cultivator and plant-only processor packaging and labeling.

(A) A cultivator distributing plant material to a processor shall meet the following requirements:

(1) A cultivator shall place plant material in a tamper-evident, light-resistant package approved by the department prior to distributing plant material to a processor. Approved packaging shall maintain the integrity and stability of the plant material.

(2) A label shall be affixed to every package and state in legible English:

(a) The name and license number of the cultivator where the packaged material was cultivated and harvested;

(b) The name and license number of the processor facility receiving the shipment;

(c) The product identifier;

(d) The registered name of the medical marijuana that was registered with the department;

(e) A unique identification number that will match the medical marijuana with a batch and batch number to facilitate any warnings and recalls the department deems appropriate;

(f) The date of harvest, final testing, and packaging;

(g) The total weight in grams of plant material in each package;

(h) The identification of the independent testing laboratory;

(i) The laboratory analysis, profile and a list of all active ingredients, including the percentage content by weight for the following cannabinoids, at a minimum:

(i) Delta-8-tetrahyrocannabinol;

(ii) Delta-8-tetrahydrocannabinolic acid;

(~~i~~iii) Delta-9-tetrahydrocannabinol ~~(THC)~~;

(iv~~ii~~) Delta-9-tetrahydrocannabinolic acid ~~(THCA)~~;

(v~~iii~~) Cannabidiol (CBD); ~~and~~

(vi~~iv~~) Cannabidiolic acid (CBDA);

(vii) THC Content as Defined in 3796: 1-1-01; and

(viii) any other cannabinoid determined by the Department.

(j) The expiration date, which shall not exceed one calendar year from the date of harvest; and

(k) A statement with the following language: "This product is for medical use and not for resale or transfer to another person. This product may cause impairment and may be habit-forming. This product may be unlawful outside of the State of Ohio."

(B) A cultivator with a plant-only processor license distributing plant material to a dispensary shall meet the following requirements:

(1) A cultivator shall place plant material in a child-proof, tamper-evident, light-resistant package approved by the department prior to distributing plant material to a dispensary. Approved packaging shall maintain the integrity and stability of the plant material.

(2) A label shall be affixed to every package and state in legible English:

(a) The name and license number of the cultivator where the packaged material was cultivated and harvested;

(b) The name and license number of the dispensary receiving the shipment;

(c) The product identifier;

(d) The registered name of the medical marijuana that was registered with the department;

(e) A unique identification number that will match the medical marijuana with a batch and batch number to facilitate any warnings or recalls the department deems appropriate;

(f) The date of harvest, final testing and packaging;

(g) The total weight in grams of plant material in each package;

(h) The identification of the independent testing laboratory;

(i) The laboratory analysis, profile, and a list of all active ingredients, including the percentage content by weight for the following cannabinoids, at a minimum:

~~(i) Delta-9-tetrahydrocannabinol (THC);~~

~~(ii) Delta-9-tetrahyrdrocannabinolic acid (THCA);~~

~~(iii) Cannabidiol (CBD); and~~

~~(iv) Cannabidiolic acid (CBDA);~~

(i) Delta-8-tetrahyrocannabinol;

(ii) Delta-8-tetrahydrocannabinolic acid;

(iii) Delta-9-tetrahydrocannabinol;

(iv) Delta-9-tetrahydrocannabinolic acid;(v) Cannabidiol (CBD);

(vi) Cannabidiolic acid (CBDA);

(vii) THC Content as Defined in 3796: 1-1-01; and

(viii) any other cannabinoid determined by the Department.

(j) The expiration date, which shall not exceed one calendar year from the date of harvest; and

(k) A statement with the following language: "This product is for medical use and not for resale or transfer to another person. This product may cause impairment and may be habit-forming. This product may be unlawful outside the State of Ohio."

(C) A label may contain the approval or certification logo of a third-party certifier of cultivation practices if:

(1) The third-party certifier does not have a direct or indirect financial interest in any medical marijuana entity licensed in the state of Ohio; and

(2) The certification protocols used by the third-party certifier have been reviewed and approved by the department.

(D) A label shall not contain any of the following:

(1) Any false or misleading statement or design;

(2) Depictions of the product, cartoons, or images that are not registered with the department, which includes any insignia related to a governmental entity;

(3) Any sum totals of cannabinoids or terpenes, except THC content as defined in rule 3796:1-1-01 of the Administrative Code; or

(4) Any information that would violate paragraph (F) of rule 3796:5-7-01 of the Administrative Code.

(E) A cultivator may provide a dispensary free samples of plant material sold at the dispensary. A free sample shall be packaged in a sample jar protected by a plastic or metal mesh screen to allow patients and caregivers to smell the plant material before purchase. A sample jar may not contain more than three grams of a particular strain of plant material. The sample jar and the plant material within may not be sold to a patient or caregiver and shall be destroyed by the dispensary after use by the dispensary. The dispensary shall document the destruction of every free sample in accordance with the rules established pursuant to Chapter 3796. of the Revised Code.

(F) It is prohibited for anyone to knowingly or intentionally alter, obliterate, or otherwise destroy any container or label attached to an approved container. In the event a container or label is altered, obliterated, or otherwise destroyed, the department may act in accordance with rule 3796:5-6-01 of the Administrative Code.

3796:2-2-06 Laboratory testing.

(A) An employee of a licensed testing laboratory shall select a random sample of adequate weight from every batch of medical marijuana cultivated at the facility that is sufficient to perform the required tests, prior to packaging any plant material intended to be sold to a patient or caregiver through a dispensary licensed under Chapter 3796. of the Revised Code. Every sample shall be tested by a licensed testing laboratory in accordance with testing standards established for testing laboratories in the rules promulgated pursuant to Chapter 3796. of the Revised Code. At a minimum, a testing laboratory shall test every sample for the following:

(1) Microbial contaminants;

(2) Mycotoxins;

(3) Moisture content;

(4) Foreign matter contamination;

(5) Heavy metals, including, at a minimum, arsenic, cadmium, lead, and mercury;

(6) Pesticide and fertilizer residue; and

(7) Cannabinoid potency, including, at a minimum, the following:

(a) Delta-8-tetrahyrocannabinol;

(b) Delta-8-tetrahydrocannabinolic acid;

(c) Delta-9-tetrahydrocannabinol;

(d) Delta-9-tetrahydrocannabinolic acid;

(e) Cannabidiol (CBD);

(f) Cannabidiolic acid (CBDA);

(g) THC Content as Defined in 3796: 1-1-01; and

(h) any other cannabinoid determined by the Department.

~~(a) Delta-9-tetrahydrocannabinolic acid (THCA);~~

~~(b) Delta-9-tetrahydrocannabinol (THC);~~

~~(c) Cannabidiolic acid (CBDA); and~~

~~(d) Cannabidiol (CBD).~~

(B) An employee of a licensed testing laboratory shall select a random sample of adequate weight from every batch of medical marijuana cultivated at the facility that is sufficient to perform the required tests, prior to packaging any plant material that shall be used in the manufacture of medical marijuana products by a processor licensed under Chapter 3796. of the Revised Code. Every sample shall be tested by a licensed testing laboratory in accordance with testing standards established for testing laboratories in the rules promulgated pursuant to Chapter 3796. of the Revised Code. At a minimum, a testing laboratory shall test every sample for the following:

(1) Pesticide and fertilizer residue;

(2) Moisture content;

(3) Foreign matter contamination; and

(4) Cannabinoid potency, including, at a minimum, the following:

(a) Delta-8-tetrahyrocannabinol;

(b) Delta-8-tetrahydrocannabinolic acid;

(c) Delta-9-tetrahydrocannabinol;

(d) Delta-9-tetrahydrocannabinolic acid;

(e) Cannabidiol (CBD);

(f) Cannabidiolic acid (CBDA);

(g) THC Content as Defined in 3796: 1-1-01; and

(h) any other cannabinoid determined by the Department.

~~(a) Delta-9-tetrahydrocannabinolic acid (THCA);~~

~~(b) Delta-9-tetrahydrocannabinol (THC);~~

~~(c) Cannabidiolic acid (CBDA); and~~

~~(d) Cannabidiol (CBD)~~

(C) A licensed testing laboratory shall submit to the cultivator an analysis of every sample of medical marijuana tested by the testing laboratory in accordance with the rules promulgated pursuant to Chapter 3796. of the Revised Code. A cultivator shall not sell or otherwise distribute medical marijuana unless the medical marijuana meets the standards set forth by the department and the package or label contains the analysis from a licensed testing laboratory.

3796:3-2-02 Processor packaging and labeling.

(A) A processor distributing medical marijuana to a dispensary shall meet the following requirements:

(1) A processor shall place medical marijuana in a child-proof, tamper-evident, light-resistant package approved by the department prior to distribution to a dispensary. Approved packaging shall maintain the integrity and stability of the medical marijuana, and shall comply with the rules promulgated by the state of Ohio board of pharmacy pursuant to Chapter 3796. of the Revised Code.

(2) A label shall be affixed to every package and state in legible English:

(a) The name and license number of the cultivator where the packaged plant material was cultivated or the name and license number of the processor where the medical marijuana products were manufactured;

(b) The name and license number of the dispensary facility receiving the shipment;

(c) The product identifier;

(d) The registered name of the medical marijuana plant material strain that was registered with the department or the registered name, form, and dose of the medical marijuana product that was registered with the department;

(e) A unique batch or lot number as defined in paragraph (A) of rule 3796:1-1-01 of the Administrative Code that will match the medical marijuana or medical marijuana products with a batch or lot, in order to facilitate any warnings or recalls the department deems appropriate;

(f) The dates of manufacture, final testing, and packaging;

(g) The total weight in grams of medical marijuana or medical marijuana products in each package;

(h) The name and license number of the independent testing laboratory that performed the required tests on the batch or lot from which the medical marijuana or medical marijuana products in the package were taken;

(i) The laboratory analysis and cannabinoid profile, including the percentage content by weight or total milligrams and milligrams per unit for:

(a) Delta-8-tetrahyrocannabinol;

(b) Delta-8-tetrahydrocannabinolic acid;

(c) Delta-9-tetrahydrocannabinol;

(d) Delta-9-tetrahydrocannabinolic acid;

(e) Cannabidiol (CBD);

(f) Cannabidiolic acid (CBDA);

(g) THC Content as Defined in 3796: 1-1-01; and

(h) any other cannabinoid determined by the Department.

~~(i) Delta-9-tetrahydrocannabinol (THC);~~

~~(ii) Delta-9-tetrahydrocannabinolic acid (THCA);~~

~~(iii) cannabidiol (CBD); and~~

~~(iv) cannabidiolic acid (CBDA).~~

(j) The expiration date, which shall not exceed one calendar year from the date of manufacture;

(k) If the product is edible, the following additional information:

(i) A list of all ingredients and subingredients, providing that all ingredients comply with the standards of identity under rule 901:3-1-12 of the Administrative Code;

(ii) A list of all major food allergens as identified in 21 USC 343; and

(iii) A statement with the following language: "Caution: When eaten or swallowed, the effects and impairment caused by this drug may be delayed."

(l) If a marijuana extract was used in the manufacture of the product, a disclosure of the type of extraction process and any solvent, gas, or other chemical used in the extraction process or any other compound added to the extract; and

(m) A statement with the following language: "This product is for medical use and not for resale or transfer to another person. This product may cause impairment and may be habit-forming. This product may be unlawful outside the State of Ohio."

(n) If the product was manufactured using plant material that was acquired from a dispensary pursuant to paragraph (B) of rule 3796:3-2-01 of the Administrative Code, a statement with the following language: "This product was manufactured using medical marijuana that exceeded the expiration date defined in OAC 3796:1-1-01."

(o) The intended method of administration of the medical marijuana product.

(B) A processor that elects to or is required to determine portions for an edible medical marijuana product under rules promulgated by the state of Ohio board of pharmacy pursuant to Chapter 3796. of the Revised Code shall apply a universal symbol that denotes that the product contains medical marijuana as an ingredient, as determined by the department, to each portion of the medical marijuana product, in accordance with the following:

(1) If the medical marijuana product is presented as separate single portions, the processor shall apply the universal symbol to each single portion;

(2) If the medical marijuana product is presented as a single unit comprised of more than one portion, the processor shall make clearly visible lines of demarcation between portions and apply the universal symbol to each portion; and

(3) The size of the universal symbol marking shall be determined by the size of the portion instead of the overall product size, and shall not be less than one-fourth inch by one- fourth inch.

(C) The label may contain the approval or certification logo of a third-party certifier of manufacturing or cultivation practices if:

(1) The third-party certifier does not have a direct or indirect financial interest in any medical marijuana entity licensed in the state of Ohio; and

(2) The certification protocols used by the third-party certifier have been reviewed and approved by the department.

(D) A label shall not contain:

(1) Any false or misleading statement or design;

(2) Depictions of the product, cartoons, or images that are not registered with the department, which includes any insignia related to a governmental entity;

(3) Any sum totals of cannabinoids or terpenes, except as defined in paragraph (A)(49) of rule 3796:1-1-01 of the Administrative Code; or

(4) Any information that would violate paragraph (E) of rule 3796:5-7-01 of the Administrative Code.

(E) A processor may provide a dispensary free samples of plant material sold at the dispensary. A free sample shall be packaged in a sample jar protected by a plastic or metal mesh screen to allow patients and caregivers to smell the plant material before purchase. A sample jar may not contain more than three grams of a particular strain of plant material. The sample jar and the plant material within may not be sold to a patient or caregiver and shall be destroyed by the dispensary after use by the dispensary. The dispensary shall document the destruction of every free sample in accordance with the rules established pursuant to Chapter 3796. of the Revised Code.

(F) It is prohibited for anyone to knowingly or intentionally alter, obliterate, or otherwise destroy any container or label attached to an approved container. In the event a container or label is altered, obliterated, or otherwise destroyed, the department may act in accordance with rule 3796:5-6-01 of the Administrative Code.

3796:3-2-04 Processor inventory control and storage.

(A) A processor shall track and submit into the inventory tracking system any information the department determines necessary for maintaining and tracking medical marijuana extract and medical marijuana products.

(1) Upon completion of each iteration of an approved extraction process, the processor shall securely attach a label to the container of medical marijuana extract that includes, at a minimum, the following information:

(a) The processor's name and license number;

(b) The batch numbers of any batches of plant material used in the extraction;

(c) The registered strain names of any plant material used during the extraction;

(d) The batch number assigned to the batch of medical marijuana extract;

(e) The date of extraction; and

(f) The net weight and volume of medical marijuana extract.

(2) Upon completion of each iteration of an approved manufacturing process, the processor shall securely attach a label to the container of medical marijuana products that includes, at a minimum, the following information:

(a) The processor's name and license number;

(b) The registered product name;

(c) The batch numbers of any batches of medical marijuana extract used in the manufacturing process;

(d) The date of manufacture; and

(e) The net weight and unit count of medical marijuana products prepared or packaged for sale to a licensed dispensary.

(B) Prior to commencing business, each processor shall establish ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of medical marijuana, medical marijuana

extract, and medical marijuana products for traceability in the department's inventory tracking system, which shall enable the processor to detect any diversion, theft, or loss in a timely manner.

(C) Upon commencing business, each processor shall prepare a weekly inventory of medical marijuana at the facility, which shall include, at a minimum:

(1) The date of the inventory;

(2) The amount of medical marijuana on hand, which shall include:

(a) The net weight of plant material;

(b) The net weight and volume of medical marijuana extract;

(c) The net weight and unit count of medical marijuana products prepared or packaged for sale to a dispensary;

(d) The results from a testing laboratory indicating the amounts of ~~delta-9~~ tetreahydrocannabinol(THC) and cannabidiol, if available; and

(e) The registered strain or product names and batch or lot numbers of plant material, medical marijuana extract, and medical marijuana products.

(3) The amount of medical marijuana and medical marijuana products sold since previous weekly inventory, which shall include:

(a) The date of sale;

(b) The name of the dispensary to which the medical marijuana and medical marijuana products were sold;

(c) The lot number, strain or product name, and quantity sold.

(4) The date, quantity, and method of disposal of any plant material, medical marijuana extract, and medical marijuana products, if applicable;

(5) A summary of the inventory findings; and

(6) The name, signature and title of the type 1 or type 2 employees who conducted the inventory and oversaw the inventory.

(D) On an annual basis and as a condition for renewal of a processor license, a processor shall conduct a physical, manual inventory of plant material, medical marijuana extract, and medical marijuana products on hand at the processor and compare the findings to an annual inventory report generated using the inventory tracking system. If any discrepancies are discovered outside of loss standard to the industry due to moisture loss and handling, the processor shall report such findings to the department in accordance with rule 3796:5-4-01 of the Administrative Code.

(E) All inventories, procedures, and other documents required by this chapter shall be maintained on the premises and made available to the department at all times.

(F) A processor is authorized to store plant material, medical marijuana extract, and medical marijuana product inventory on the premises in a designated, enclosed, locked area identified in the processor's plans and specifications submitted to the department and accessible only by authorized individuals. Notwithstanding the requirements of this chapter nothing shall prohibit members of the department, the department's designee, law enforcement, or other federal, state, or local government officials from entering any area of a processor facility if necessary to perform their governmental duties.

3796:3-2-06 Laboratory testing.

(A) Prior to the sale of any medical marijuana product to a dispensary licensed under Chapter 3796. of the Revised Code, an employee of a licensed testing laboratory shall select a random sample from every lot of medical marijuana products at the facility that is of sufficient quantity to perform the required tests. Every sample shall be tested by a licensed testing laboratory in accordance with the testing standards established for testing laboratories in the rules promulgated pursuant to Chapter 3796. of the Revised Code. At a minimum, a testing laboratory shall test every sample for:

(1) Microbial contaminants;

(2) Cannabinoid potency including, at minimum:

(a) Delta-8-tetrahyrocannabinol;

(b) Delta-8-tetrahydrocannabinolic acid;

(c) Delta-9-tetrahydrocannabinol;

(d) Delta-9-tetrahydrocannabinolic acid;

(e) Cannabidiol (CBD);

(f) Cannabidiolic acid (CBDA);

(g) THC Content as Defined in 3796: 1-1-01; and

(h) any other cannabinoid determined by the Department.

~~(a) TDelta-9-tetrahydrocannabinolic acid (THCA);~~

~~(b) TDelta-9-tetrahydrocannabinol (THC);~~

~~(c) Cannabidiolic acid (CBDA); and~~

~~(d) Cannabidiol (CBD).~~

~~(e) Any additional cannabinoid determined by the Department.~~

3796:4-2-04 Testing laboratory analysis requirements.

(A) A testing laboratory shall analyze a sample of at least one half of one percent of the net weight of the batch from each batch of dried, cured plant material intended to be sold to a dispensary licensed by the state of Ohio board of pharmacy for, at minimum:

(1) Moisture content;

(2) Water activity;

(3) Cannabinoid potency including, at minimum:

(a) Delta-8-tetrahyrocannabinol;

(b) Delta-8-tetrahydrocannabinolic acid;

(c) Delta-9-tetrahydrocannabinol;

(d) Delta-9-tetrahydrocannabinolic acid;

(e) Cannabidiol (CBD);

(f) Cannabidiolic acid (CBDA);

(g) THC Content as Defined in 3796: 1-1-01; and

(h) Cannabinol (CBN)

(i) any other cannabinoid determined by the Department. ~~(a) Delta-9-tetrahydrocannabinolic acid (THCA);~~

~~(b) Delta-9-tetrahydrocannabinol (THC);~~

~~(c) Cannabidiolic acid (CBDA);~~

~~(d) Cannabidiol (CBD); and~~

~~(e) Cannabinol (CBN);~~

(4) Foreign matter contamination;

(5) Microbial contamination;

(6) Mycotoxin contamination;

(7) Heavy metal contamination including, at a minimum, arsenic, cadmium, lead, and mercury; and

(8) Pesticide and fertilizer residue.

(B) A testing laboratory shall analyze a sample of at least one half of one percent of the net weight of the batch from each batch of plant material intended to be sold to a processor licensed by the department for use in the manufacture of medical marijuana products for, at minimum:

(1) Pesticide and fertilizer residue; and

(2) Cannabinoid potency for, at a minimum:

(a) Delta-8-tetrahyrocannabinol;

(b) Delta-8-tetrahydrocannabinolic acid;

(c) Delta-9-tetrahydrocannabinol;

(d) Delta-9-tetrahydrocannabinolic acid;

(e) Cannabidiol (CBD);

(f) Cannabidiolic acid (CBDA);

(g) THC Content as Defined in 3796: 1-1-01; and

(h) Cannabinol (CBN)

(i) any other cannabinoid determined by the Department.~~(a) Delta-9-tetrahydrocannabinolic acid (THCA);~~

~~(b) Delta-9-tetrahydrocannabinol (THC);~~

~~(c) Cannabidiolic acid (CBDA);~~

~~(d) Cannabidiol (CBD); and~~

~~(e) Cannabinol (CBN);~~

(C) A testing laboratory shall analyze a sample of one unit of the same size, weight, and volume intended to be packaged and sold to a licensed dispensary from each lot of medical marijuana products prior to sale to a dispensary licensed by the state of Ohio board of pharmacy for, at minimum:

(1) Cannabinoid potency including, at minimum:

(a) Delta-8-tetrahyrocannabinol;

(b) Delta-8-tetrahydrocannabinolic acid;

(c) Delta-9-tetrahydrocannabinol;

(d) Delta-9-tetrahydrocannabinolic acid;

(e) Cannabidiol (CBD);

(f) Cannabidiolic acid (CBDA);

(g) THC Content as Defined in 3796: 1-1-01; and

(h) Cannabinol (CBN)

(i) any other cannabinoid determined by the Department.~~(a) Delta-9-tetrahydrocannabinolic acid (THCA);~~

~~(b) Delta-9-tetrahydrocannabinol (THC);~~

~~(c) Cannabidiolic acid (CBDA);~~

~~(d) Cannabidiol (CBD); and~~

~~(e) Cannabinol (CBN);~~

(2) Foreign matter contamination;

(3) Microbial contamination;

(4) Mycotoxin contamination, if a medical marijuana extract was used in the manufacture of the product that was not previously tested for mycotoxin contamination by a licensed testing laboratory;

(5) Heavy metal contamination including, at a minimum, arsenic, cadmium, lead, and mercury, if a medical marijuana extract was used in the manufacture of the product that was not previously tested for heavy metal contamination by a licensed testing laboratory;

(6) Pesticide and fertilizer residue, if a medical marijuana extract was used in the manufacture of the product that was not previously tested for pesticide or fertilizer residue contamination by a licensed testing laboratory; and

(7) Residual solvents, if a hydrocarbon-based medical marijuana extract was used in the manufacture of the product that was not previously tested for residual solvent contamination by a licensed testing laboratory.

(D) A testing laboratory may perform analysis on marijuana-derived ingredients used in the manufacture of medical marijuana products, including but not limited to medical marijuana extract. When performing analysis on medical marijuana-derived ingredients, the following sample sizes and required tests shall apply:

(1) A sample of at least one half of one percent of the net weight of the batch from a batch of medical marijuana extract derived from a system utilizing hydrocarbon solvents for, at minimum:

(a) Pesticide and fertilizer residue; and

(b) Cannabinoid potency including, at minimum:

(i) Delta-8-tetrahyrocannabinol;

(ii) Delta-8-tetrahydrocannabinolic acid;

(iii) Delta-9-tetrahydrocannabinol;

(iv) Delta-9-tetrahydrocannabinolic acid;

(v) Cannabidiol (CBD);

(vi) Cannabidiolic acid (CBDA);

(vii) THC Content as Defined in 3796: 1-1-01; and

(viii) Cannabinol (CBN)

(ix) any other cannabinoid determined by the Department.~~(i) Delta-9-tetrahydrocannabinolic acid (THCA);~~

~~(ii) Delta-9-tetrahydrocannabinol (THC);~~

~~(iii) Cannabidiolic acid (CBDA);~~

~~(iv) Cannabidiol (CBD); and~~

~~(v) Cannabinol (CBN);~~

(c) Mycotoxin contamination;

(d) Heavy metal contamination including, at a minimum, arsenic, cadmium, lead, and mercury; and

(e) Residual solvents.

(2) A sample of at least one half of one percent of the net weight of the batch from a batch of medical marijuana extract derived from a system utilizing carbon dioxide for, at minimum:

(a) Pesticide and fertilizer residue; and

(b) Cannabinoid potency for, at a minimum:

(i) Delta-8-tetrahyrocannabinol;

(ii) Delta-8-tetrahydrocannabinolic acid;

(iii) Delta-9-tetrahydrocannabinol;

(iv) Delta-9-tetrahydrocannabinolic acid;

(v) Cannabidiol (CBD);

(vi) Cannabidiolic acid (CBDA);

(vii) THC Content as Defined in 3796: 1-1-01; and

(viii) Cannabinol (CBN)

(ix) any other cannabinoid determined by the Department.~~(i) Delta-9-tetrahydrocannabinolic acid (THCA);~~

~~(ii) Delta-9-tetrahydrocannabinol (THC);~~

~~(iii) Cannabidiolic acid (CBDA);~~

~~(iv) Cannabidiol (CBD); and~~

~~(v) Canabinol (CBN);~~

(c) Mycotoxin contamination; and

(d) Heavy metal contamination including, at a minimum, arsenic, cadmium, lead, and mercury.

(3) A sample of at least one half of one per cent of the net weight of the batch from a batch of medical marijuana extract derived from a method that does not involve the use of a hydrocarbon or carbon dioxide as a solvent for, at a minimum:

(a) Cannabinoid potency including, at minimum:

(i) Delta-8-tetrahyrocannabinol;

(ii) Delta-8-tetrahydrocannabinolic acid;

(iii) Delta-9-tetrahydrocannabinol;

(iv) Delta-9-tetrahydrocannabinolic acid;

(v) Cannabidiol (CBD);

(vi) Cannabidiolic acid (CBDA);

(vii) THC Content as Defined in 3796: 1-1-01; and

(viii) Cannabinol (CBN)

(ix) any other cannabinoid determined by the Department.~~(i) Delta-9-tetrahydrocannabinolic acid (THCA);~~

~~(ii) Delta-9-tetrahydrocannabinol (THC);~~

~~(iii) Cannabidiolic acid (CBDA);~~

~~(iv) Cannabidiol (CBD); and~~

~~(v) Canabinol (CBN);~~

(b) Foreign matter contamination;

(c) Microbial contamination;

(d) Mycotoxin contamination;

(e) Heavy metal contamination including, at a minimum, arsenic, cadmium, lead, and mercury; and

(f) Pesticide and fertilizer residue.

(E) A testing laboratory may request additional sample material in excess of the amounts listed in this rule if necessary for completion of the required quality assurance tests.

(F) For the purposes of microbial contamination analysis, a sample provided to a testing laboratory shall be deemed to have passed if it satisfies the standards set forth in Table 9 of the "Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control" (2014) monograph.

(1) If a batch of plant material is not deemed to have passed testing for microbial contamination, that batch may be designated for extraction by hydrocarbon-based or carbon dioxide-based methods

(2) Medical marijuana extract derived from a batch of plant material not deemed to have passed testing for microbial contamination must be tested for microbial contamination prior to use in the manufacture of medical marijuana products.

(G) For the purposes of mycotoxin contamination analysis, a sample provided to a testing laboratory pursuant to this rule shall be deemed to have passed if:

(1) The total of the detected amounts, if any, of aflatoxin B1, aflatoxin B2, aflatoxin G1, and aflatoxin G2 is less than twenty micrograms per kilogram; and

(2) The detected amount, if any, of ochratoxin A is less than twenty micrograms per kilogram.

(H) For the purposes of heavy metal contamination analysis, a sample provided to a testing laboratory shall be deemed to have passed if:

(1) The detected amount of arsenic, if any, is less than 0.14 micrograms per kilogram.

(2) The detected amount of cadmium, if any, is less than 0.09 micrograms per kilogram.

(3) The detected amount of lead, if any, is less than 0.29 micrograms per kilogram.

(4) The detected amount of mercury, if any, is less than 0.29 micrograms per kilogram.

(I) For the purposes of pesticide residue analysis, a sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for an approved pesticide chemical residue in a food item as set forth in Subpart C of 40 C.F.R. Part 180, as effective on September 8, 2017. A sample shall automatically be deemed to have failed if residue is detected from any pesticide not on the approved pesticide list maintained by the department, regardless of the detected level of residue.

(J) Except as provided in paragraph (G)(1) of this rule, if a sample is deemed to have failed tests for any contaminants listed in this rule, the cultivator or processor that provided the sample must immediately destroy the corresponding batch of plant material or extract or lot of medical marijuana products and document the destruction in the inventory tracking system.

3796:4-2-05 Testing laboratory reporting.

(A) A testing laboratory performing analysis on medical marijuana shall input the results of analysis into the inventory tracking system. The department may require a testing laboratory to submit, in portable document format (.pdf), an electronic copy of the results of analysis of any batches and lots tested to an email address specified and maintained by the department.

(B) A testing laboratory performing analysis on medical marijuana shall create a unique certificate of analysis for each batch or lot tested, which shall include, at minimum:

(1) The name and license number of the testing laboratory where the analysis was performed;

(2) The name and license number of the cultivator or processor from whom the sample was received;

(3) The registered name of the medical marijuana strain or medical marijuana product that was registered with the department;

(4) A unique batch or lot number as defined in rule 3796:1-1-01 of the Administrative Code that will match the sample of medical marijuana or medical marijuana products with a batch or lot, in order to facilitate any warnings or recalls the department deems appropriate;

(5) The date or dates on which each test was performed;

(6) A grid or table listing all tests performed, and indicating "pass" or "fail" for each, as defined in rule 3796:4-2-04 of the Administrative Code.

(7) The cannabinoid profile of the sample, including the percentage content by weight for, at minimum:

(a) Delta-8-tetrahyrocannabinol;

(b) Delta-8-tetrahydrocannabinolic acid;

(c) Delta-9-tetrahydrocannabinol;

(d) Delta-9-tetrahydrocannabinolic acid;

(e) Cannabidiol (CBD);

(f) Cannabidiolic acid (CBDA);

(g) THC Content as Defined in 3796: 1-1-01; and

(h) Cannabinol (CBN)

(i) any other cannabinoid determined by the Department.~~(a) Delta-9-tetrahydrocannabinol (THC);~~

~~(b) Delta-9-tetrahydrocannabinolic acid (THCA);~~

~~(c) Cannabidiol (CBD);~~

~~(d) Cannabidiolic acid (CBDA); and~~

~~(e) Cannabinol (CBN);~~

(8) Moisture content;

(9) Water activity;

(10) Results of analysis for foreign matter contamination;

(11) Quantitative results of analysis for microbial contamination;

(12) Quantitative results of analysis for heavy metal contamination;

(13) Quantitative results of analysis for pesticide and fertilizer residue;

(14) Quantitative results of analysis for mycotoxins;

(15) Quantitative results of analysis for residual solvents; and

(16) The signature of the laboratory manager or scientific director certifying the analysis.

(C) The certificate of analysis may contain the following:

(1) Results of quantitative analysis of additional cannabinoids for which the laboratory is able to obtain a standard for comparison;

(2) Results of quantitative analysis of terpenes for which the laboratory is able to obtain a standard for comparison;

(D) A certificate of analysis shall not contain any sum totals of cannabinoids or terpenes, except THC content as defined in paragraph rule 3796:1-1-01 of the Administrative Code.