BEFORE THE DEPARTMENT OF REVENUE
OF THE STATE OF MONTANA

In the matter of the amendment of ARM 42.39.601, 42.39.603, 42.39.610, and 42.39.614 pertaining to revised marijuana sampling protocols and quality assurance testing requirements	))))))	NOTICE OF AMENDMENT

TO: All Concerned Persons

1. On May 24, 2024, the Department of Revenue (department) published MAR Notice No. 42-1071 pertaining to the public hearing on the proposed amendment of the above-stated rules at page 1172 of the 2024 Montana Administrative Register, Issue Number 10.

2. On June 18, 2024, the department held a public hearing to consider the proposed amendment. The following commenters appeared and provided oral testimony to the proposed rulemaking: Susan Stanley, Sensicare Dispensary; Adam Arnold, Collective Elevation; Joanna Barney, Sacred Sun Farms; Kate Cholewa, Montana Cannabis Industry Association (MTCIA); Mariah Bond, Soultonix and Euphoria Wellness; Sahil Mehta, Soultonix and Euphoria Wellness; Christina Johnson, Nordic Labs; Jerry Spurlock, Firefly Dispensary; and Jennifer Hensley, Hensley and Associates on behalf of Fidelity Diagnostics Laboratory (Fidelity). The department received written comments from Evan Kajander, Apogee Gardens; Erica Siate; Susan Stanley; Kate Cholewa, MTCIA; Jennifer Hensley, Hensley and Associates for Fidelity; Pepper Petersen, Montana Cannabis Guild; Anthony Saur, The Green Bee; Jay Bostrom, Dancing Goat Gardens; and Keith Erwin, Integrity Analytics.

3. The department has amended ARM 42.39.603 as proposed.

4. The department has amended ARM 42.39.601, 42.39.610, and 42.39.614 as proposed, but with the following changes from the original proposal, new matter underlined, deleted matter interlined:

42.39.601 DEFINITIONS As used in this subchapter; the following definitions apply:

(1) through (7) remain as proposed.

~~(8) "As received" means the mass of the marijuana item as determined by the testing laboratory with no dry weight calculation applied.~~

(9) through (14) remain as proposed but are renumbered (8) through (13).

~~(15) "Container" means the vessel or receptacle that comes into physical contact with the marijuana item.~~

(16) through (23) remain as proposed but are renumbered (14) through (21).

~~(24)~~ (22) "Harvest lot" means the specifically identified quantity of marijuana provided in SOP-001 that is cultivated utilizing the same growing practices, harvested within a 72-hour period at the same location, and cured under uniform conditions. A harvest lot may contain multiple strains until ~~[one day less than six months from date of adoption]~~ February 23, 2025. Effective ~~[six months from date of adoption]~~ February 24, 2025, a harvest lot must not contain multiple strains and must be identical in strain.

(25) through (72) remain as proposed but are renumbered (23) through (70).

AUTH: 16-12-202, 16-12-209, MCA
IMP: 16-12-202, 16-12-209, MCA

42.39.610 QUALITY ASSURANCE SAMPLING PROTOCOL (1) through (13) remain as proposed.

(14) The department adopts and incorporates by reference the "Quality Assurance Sampling Protocol for Usable Marijuana, Marijuana Concentrates and Extracts, Marijuana-Infused Products, and Marijuana Pre-Rolls" SOP-001 (Version 3.0) (~~[date of adoption]~~ August 24, 2024), which describes the sampling protocol for marijuana, marijuana concentrates and extracts, marijuana-infused products, and marijuana pre-rolls. A copy of SOP-001 is available from the department electronically at www.mtrevenue.gov/cannabis and may also be obtained at 125 N. Roberts St., Helena, MT 59601.

AUTH: 16-12-202, 16-12-209, MCA
IMP: 16-12-202, 16-12-209, MCA

42.39.614 QUALITY ASSURANCE TESTING REQUIREMENTS (1) All marijuana items intended for final sale or transfer to a customer shall be tested in its final form. The addition of any ingredient or reagent after final quality assurance testing will require retesting with respect to the mandatory quality assurance testing requirements provided in the Quality Assurance Testing Requirements Appendix and the marijuana laws. The department adopts and incorporates by reference the Quality Assurance Testing Requirements Appendix (Version 1.0) (~~[date of adoption]~~ August 24, 2024), which provides quality assurance testing requirements from marijuana item classifications and subcategories and details specific contaminant testing requirements for these items. A copy of the Appendix is available from the department electronically at www.mtrevenue.gov/cannabis and may also be obtained at 125 N. Roberts St., Helena, MT 59601.

~~(2) All laboratory test sample results shall be reported into the seed-to-sale tracking system on an "as received" basis. Dry weight reporting or corrections are not permitted.~~

(3) remains as proposed but is renumbered (2).

~~(4)~~ (3) Composite laboratory test samples from the same or different harvest lots and test batches therein are strictly prohibited. Effective ~~[six months from the date of adoption]~~ February 24, 2025, multi-strain harvest lots and multi-strain composite laboratory test samples are prohibited.

~~(5)~~ (4) Usable marijuana: a licensee shall submit for testing all harvest lots and test batches therein of usable marijuana for the analyses required in Table 1.0a of the Appendix prior to final sale to a customer. Usable marijuana, including trim or manicure, shall also be tested for the analyses provided in Table 1.0a of the Appendix prior to use in the production of marijuana pre-rolls and direct marijuana-infused products. A licensee may ~~forgo~~ forego testing of usable marijuana, including trim and manicure, only if that usable marijuana is subjected to solvent or non-solvent-based extraction for the production of marijuana concentrates and extracts.

(6) through (9) remain the same but are renumbered (5) through (8).

~~(10)~~ (9) Use of any untested marijuana item ~~as an ingredient~~ in the production of ~~marijuana concentrates and extracts,~~ marijuana-infused products~~,~~ and marijuana pre-rolls~~, or any marijuana item therein~~ is prohibited. Use of any untested marijuana item, except for usable marijuana – including trim and manicure – in the production of concentrates and extracts is prohibited.

(11) and (12) remain the same but are renumbered (10) and (11).

~~(13)~~ (12) The laboratory test sample and related lot or test batch fail quality assurance testing for filth and foreign matter screening if the results are greater than the following action levels:

(a) 5.0 percent of stems 3mm or more in diameter; ~~and~~ or

(b) 2.0 percent of seeds or other foreign matter.

(14) through (19) remain the same but are renumbered (13) through (18).

AUTH: 16-12-202, 16-12-209, MCA
IMP: 16-12-202, 16-12-209, MCA

5. The department has thoroughly considered the comments and testimony received. A summary of the comments received, and the department's responses are as follows:

COMMENT 1: Ms. Stanley commented that the department has gone too far with the statement of reasonable necessity for the definitions of "harvest lot" and "process lot"; that the current definition of "harvest lot" allows for egregious sample compositing by diluting contaminants to below the sensitivity of the analytical instrumentation, which drastically increases the probability of contaminated product entering the market. Ms. Stanley continued that it would be impossible and costly to dilute a contaminated sample into a five-pound lot to the point that you could not even detect it on analytical instrumentation; and provided examples of batch strains and composites with various parts per million Spinosad. This is an insult to the industry to imply that there are cultivators and manufacturers who are egregiously diluting contaminated products into composite test batches that cannot be detected by sensitive analytical instrumentation.

RESPONSE 1: The department is mandated to ensure product safety and consumer protection, and Ms. Stanley does not have the benefit of the department's testing or sampling experiences and perspective. The department stands by the statement of reasonable necessity provided for in the rulemaking.

Compositing numerous individually sold strains of either marijuana flower or process lots of concentrates and extracts into laboratory test sample(s) for contaminant testing increases the probability of contaminated product entering the market. And larger numbers of individual products composited together further increase that risk. Though it appears that pesticides are the focus of Ms. Stanley's discussion, equally important are mycotoxin exposure, residual solvents, and microbiological contamination; each with varying action limits that must be met to ensure consumers are provided with access to safe products.

Ms. Stanley's examples in her comments also mischaracterize the sample compositing process which occurs in the laboratory. Sample compositing is done at a 1:1 ratio, and not by how many pounds of different strains a licensee puts into a harvest lot test batch. Many laboratory extraction procedures use anywhere between 0.2 grams to 1.0 grams of product per individual sample extraction. If ten samples are composited together at a 1:1 ratio for a 0.5-gram laboratory extraction sample, only 0.05 grams of each strain is making up that 0.5 gram extracted sample to be run on the analytical instrumentation. This equates to a ten times dilution factor which is applied to each of the results of the ten strains. Should any of those strains have a contaminant issue that is at, or above, a given contaminant action level, the other strains in the laboratory extraction sample have effectively diluted and masked the issue. If that strain or process lot had been tested individually, the problem product would have been easily identified and marked as "test failed" in the seed-to-sale tracking system.

COMMENT 2: All commenters provided feedback to the department's proposed revisions to the definition of "harvest lot" in ARM 42.39.601, which currently allows for multi-strain compositing for testing but will not be allowed six months from adoption of this rulemaking in favor of a single-strain lot requirement.

Comments expressed objection or reservation to single-strain harvest lot test batch provided in Section 7.1.1 of the Quality Assurance Sampling Protocol for Usable Marijuana, Marijuana Concentrates and Extracts, Marijuana-Infused Products, and Marijuana Pre-Rolls SOP-001 document (SOP-001).

Commenters contend that smaller cultivators focus on providing more marijuana strains in smaller quantities and it is that variety that separates them from larger cultivators who are able to scale production to fit single-strain harvest lot requirements. These commenters also suggested the department allow limited, multi-strain harvest lots for smaller (e.g., tier 1 and tier 2) producers.

Mr. Kajander questions whether single-strain testing applies only to flower. Does the requirement apply to single strain testing of concentrates? Mr. Kajander opines that single-strain flower testing may be palatable but single-strain concentrate testing will be costly.

Comments were also received stating that the elimination of multi-strain testing puts pressure on testing costs that could be offset by larger harvest lot sizes–another suggestion of the commenters.

RESPONSE 2: Single-strain testing requirements have been proposed before – albeit withdrawn – and have been previously discussed with industry. Based on that prior feedback, the department proposed a six-month transition period

in this rulemaking before the new requirement becomes enforceable. The department believes the transition provides licensees time to analyze and adjust their business practices to comply with the new testing standard.

The department is aware of industry concerns that additional testing requirements affect product pricing and industry ability to compete with the black market. The issue is not unique to Montana. The department has observed other states' cannabis regulatory processes, and believes the proposed requirements are a good balance between maintaining public health and limiting the illicit market. The department notes that states which mandated single-strain testing and additional pesticide and contaminates did so because medical and adult-use consumers primarily desire quality products.

As for allowing small producers to continue under multi-strain harvest lots, the department responds that the benefits of such a proposal do not justify the increased difficulty of administering multiple testing requirements for licensees given the number of strains and harvest lots grown and regularly changing tier sizes of cultivators. Licensed laboratories each use different methodology and instrumentation as well, making that approach unnecessarily complicated and difficult to regulate.

The department is also monitoring multiple lawsuits that are likely to open the state to interstate commerce and other states' products which already meet the expanded testing protocols proposed in this rulemaking. The department reiterates that this rulemaking is necessary to position Montana marijuana producers so they will be able to compete in an expanded industry instead of pursuing after-the-fact solutions to a newly opened market.

The department responds to Mr. Kajander that the rules do not prevent manufacturers from using multiple strains of marijuana within a process lot of concentrate and extract. The definition of "process lot" provides that "test batches from the same or different harvest lots" can be used in a process lot of marijuana concentrate or extract. However, laboratory test samples composed of different process lots cannot be composited together for the purposes of quality assurance compliance testing under ARM 42.39.614(3).

The department addresses harvest lot size comments in Response 3.

COMMENT 3: As an extension of Comment 2, the department received multiple comments that an increase in the size of the harvest lot test batch size in Section 7.1.1 of SOP-001 is necessary – especially with the adoption of the single-strain harvest lot testing requirement. Most commenters provided some version of their own proposed resolutions, like in Comment 2, or compared other states' protocols and suggested that Montana should adopt a harvest lot size of 20 to 25 pounds, if a "no limit" harvest lot size cannot be considered.

The department also received comments that advocated for the department to take a cautionary approach before increasing harvest lot test batch sizes because larger test batch sizes will negatively impact smaller cultivators, who focus on a larger variety of strains from smaller harvests versus larger cultivators who produce fewer strains to scale.

RESPONSE 3: The harvest lot test batch size has been in place since SOP-001 was adopted by the Cannabis Laboratory Program while at the Department of Public Health and Human Services. Test batch size, while related to multi-batch/single-strain quality assurance testing, was not proposed for amendment by the department in this rulemaking, and comments regarding non-proposed changes are outside the scope of this rulemaking.

Even if the department were amenable to making such a change in response to the comments, it could not be accomplished under the Montana Administrative Procedure Act (MAPA) without adversely affecting the timely implementation of these rules and adoption of SOP-001 and Appendix before the closure of most agency rulemaking in the final quarter-year preceding a legislative session (see 2-4-305(11), MCA).

The department continues its willingness to engage with industry stakeholders and policymakers about future adjustments to harvest lot sizes. But the department and industry need to analyze the data and outcomes from the implementation of this rulemaking, the revised marijuana product testing standards, and the actual fiscal impact from the five-pound test batch under the new quality assurance testing requirements before any proposal to adjust test batch size is developed.

COMMENT 4: The department received multiple comments regarding the proposed definition for "as received" in ARM 42.39.601(8), which would exclude dry weight correction of potency results in the testing of marijuana flower.

Many comments questioned the benefit to changing the system and believe the disallowance of dry-weight reporting is a disservice to the consumer because dry-weight reporting provides the consumer with a consistent parameter when making purchase decisions. If marijuana potency is based on "as received" reporting, it is variable/relative to the moisture content of the marijuana submitted for testing. Commenters fear adding more variability to the system will act as an incentive for some licensees to dry out their product, which would result in an inferior product with higher THC and will only result in increased sales of inferior product.

Some testing laboratory comments offered that changing the way that labs calculate potency is also not consistent with federal guidelines for hemp.

Mr. Erwin commented his belief that reporting on a dry weight basis increases the potency, and as a result, consumers will dose more than intended.

Commenters requested the department remove the proposed definition upon adoption of the rulemaking.

RESPONSE 4: Based on the comments, the department has removed the definition from ARM 42.39.601(8) and the reference from ARM 42.39.614(2).

COMMENT 5: The department received comments from MTCIA and Fidelity regarding ARM 42.39.614(5) and (10). The commenters believe the two sections contradict one another, and they request additional clarification. Section (5) allows usable marijuana to be untested if it is subjected to extraction for extracts and concentrates, and (10) prohibits untested marijuana to be used as an ingredient in concentrates and extracts.

Fidelity sees the inclusion of the phrase "as an ingredient" as creating the disconnect.

While Fidelity expressed its support for the term "usable marijuana" used throughout the rulemaking proposal and the existing rules, it notes there is no stated definition provided for it. While the term may be inferred from ARM 42.39.614(5), an actual definition is preferred because of its frequency of use.

Mr. Bostrom proposes the removal of much of ARM 42.39.614 regarding marijuana pre-rolls, usable marijuana, and the prohibition of untested marijuana.

The department also received a comment of a typographic error in (5) for the word "forego."

RESPONSE 5: The comments are well taken and based on the comments, the department has amended ARM 42.39.614(10), renumbered as (9), to rectify the problematic phrasing.

Regarding Fidelity's request for a definition of "usable marijuana" the term is defined in 16-12-102(42)(a) and (b), MCA. The language " . . . and includes trim and manicure . . ." found in ARM 42.39.614(9) was added to provide additional clarity as to what usable marijuana encompasses.

While the department appreciates Mr. Bostrom's comments, the department declines to implement those changes in lieu of the above-described amendments to ARM 42.39.614.

The department has also corrected the typographic error.

COMMENT 6: MTCIA, Ms. Barney, and Mr. Spurlock commented that marijuana tinctures are not adequately defined or qualified under the rules and SOP-001. Ms. Barney comments that SOP-001 v.1 and v.2 identified a tincture as a concentrate, but tincture is also included as an example in the definition of an "edible marijuana infused product (edible)." Ms. Barney opines that a concentrate is a concentration of the resin from the marijuana plant; it is not the concentrate that is diluted in a carrier oil or another substance that would be safely assumed as an edible or ingestible product. Further, a concentrate needs to be an infused-edible.

Ms. Barney also commented that department enforcement of packaging for tinctures has been inconsistent. Ms. Barney noted her experience that department inspectors requested the repackaging and retesting of her tinctures as a concentrate to an edible.

MTCIA and Ms. Barney request tinctures be removed from the definition of "solvent-based marijuana concentrate and extract" in ARM 42.39.601, or in the alternative, distinguish tinctures (alcohol vs. olive oil base, for example) in the concentrate and infused-edible definitions. Similarly, Mr. Spurlock questions whether two rules for solvent-based products and edibles are necessary to provide adequate guidance to licensees who manufacture tinctures as the two different product types.

MTCIA and Ms. Barney also note that the proposed definition change has a significant impact on packaging and possession limits as tinctures are customarily sold in a one-ounce (30 ml) size and inclusion of tinctures here would create a limit of 8 ml.

RESPONSE 6: The commenters are correct that tinctures may be a concentrate and an edible. Proper classification of a tincture (concentrate or edible) and its potency are a fact-dependent analysis, as the commenters recognize. The definition correctly identifies where a tincture should be placed, particularly for the purposes of testing. Additionally, the department disagrees that an olive oil-based product falls under the purview of a tincture. Olive oil-based products made by incorporating a solvent-based or non-solvent based marijuana concentrate and extract into olive oil would be considered an indirect marijuana-infused product.

Tincture potency remains governed by 16-12-224, MCA, but the inclusion of tincture as an example of an edible marijuana-infused product in ARM 42.39.102(12) was implemented to clarify tinctures' statutory potency variation allowance enacted under HB 229 (2023) amendments to 16-12-224, MCA. The department understands this unintentionally created conflicting language under what product type tinctures fall.

The department disagrees that removing tincture from the definition of solvent-based concentrate and extract solves this issue. In fact, tinctures are only referred to in statute once – in 16-12-224(8)(iii), MCA – regarding an 800mg/package THC limit.

However, a tincture as an edible extract has different serving size and package limitations, as found in 16-12-224(8)(iv) MCA, and also allows for a ten percent manufacturing variance in potency.

ARM 42.39.102 is not proposed for amendment in this rulemaking and the department is unable to clarify those definitions at this time for the reasons expressed in the second paragraph of Response 3. The department also prefers a legislative change to the MMRTA to clarify tinctures. However, should the conflicting language remain after the passing of the 2025 Legislature, the department is amenable to correction through future rulemaking.

Finally, the department understands Ms. Barney's comments regarding tinctures and packaging enforcement, her concerns for clarity and consistency of terms, and that a lack of clarity could have operational impacts for licensees. While the department does not have any details of Ms. Barney's encounter as of this date, the department is willing to respond to Ms. Barney independently from this rulemaking if her issues remain.

COMMENT 7: Several comments were received about the proposed definitions of "final form" and "final packaging" in ARM 42.39.601. The comments indicate an inconsistency between what is proposed in the rule and what is provided in SOP-001. Ms. Barney commented that SOP-001 states that edibles need to be tested in final packaging vs. final form, infused pre-rolls do not have to be in final packaging before being tested, and vape cartridges do not have to be in final packaging before being tested.

Mr. Mehta commented his desire for increased clarity on final form packaging requirements because businesses are trying to scale up production and final packaging affects equipment purchases. He notes if tests are required in the final packaging, labeling machines cannot be run which increases costs to manufacturers.

Fidelity commented its support the definition of "final form" as it eliminates potential confusion. While Fidelity supports all the other definitions, they elevate the importance of keeping this proposed definition in the adopted version of rules.

RESPONSE 7: The department believes SOP-001 is clear as to which marijuana items need to be in final packaging prior to sample collection for testing. All marijuana items intended for sale to consumers must be in final form per ARM 42.39.614(1). Section 7.5.1 of SOP-001 (concerning marijuana-infused products) states ". . . the process lot shall be in its final packaging and a serving size shall be designated by the licensee." It is the department's intent to test marijuana-infused products from their final packaging to ensure contamination from the packaging is not imparted onto the product itself.

Section 7.4.1 of SOP-001 (concerning vapor cartridges) makes no indication of final package, but instead states " . . . the process lot shall be packaged into cartridges by the licensee prior to laboratory test sample collection and final quality assurance compliance testing." It is the department's intent to test marijuana vapor products from the cartridge to ensure contamination from the cartridge is not imparted into the product itself.

Given the nature of how pre-rolls are constructed, typically with a paper wrapping, the department does not believe that the inclusion of final packaging is required at this time. Therefore, a final packaging designation was not included in Section 7.6.1 of SOP-001.

COMMENT 8: Mr. Mehta questions the accuracy of the department's economic impact statement used in the proposal notice. He questions the analysis of the data, whose business model was used, and which test methods were used.

Ms. Johnson also commented that she conducted an internal analysis of her largest and smallest clients, most of which use multi-strain harvest lots. The results were that testing costs would increase by 66 percent. Ms. Johnson also commented that laboratories should look at the laboratory's current testing methods and decide whether they can actually do an interim period that allows for people to actually expand, grow, and get some help with that transition period.

RESPONSE 8: As a response to Mr. Mehta, specifically, but also for the benefit of all commenters regarding testing cost increases associated with single-strain testing, the department's economic impact statement was developed by reviewing seed-to-sale tracking laboratory testing data from calendar year 2023 to estimate how many flower and concentrate testing samples represented composited strain test samples. This was done to project an annual increase in flower and concentrate test counts in an environment where composite testing was no longer allowed.

After reviewing the 2023 testing data, the department estimated that 66.1 percent of test samples were composited. The cost estimation model utilized the composite sample estimate and projected a downward strain consolidation factor of 33 percent. This consolidation factor was estimated due to the likelihood that cultivators and manufacturers will adjust their harvests and production in an environment of non-composite test samples to focus on their highest yield and most

efficiently produced strains. This 33 percent strain consolidation factor reduced the projected annual statewide test count increase for flower and concentrate from 66.1 percent to the 44.3 percent statewide test count increase that was used to estimate cost impacts in the study (66.1 x 33 downward factor = 44.3 percent increase).

The department determined it was not feasible to calculate a custom projected, non-compositing test count increase for each licensee based on 2023 harvest, manufacturing, and testing data. For this reason, the non-compositing cost estimation model applied the projected 44.3 percent annual flower and concentrate test count increase proportionately to all licensees' 2023 flower and concentrate test counts. These estimated test count increases by license were then multiplied by market test pricing (i.e., tests conducted by licensed marijuana testing laboratories at their designated cost, outside of the department), establishing a low and high projected annual cost range. Finally, licensee groupings were determined by 2023 annual dispensary revenue ranges as provided in the original economic impact statement, to model and estimate potential testing cost increases for the industry in an environment with non-composite testing.

The department produced estimates to project cost impacts due to this rulemaking and respects Nordic Labs conducting its own due diligence and providing public comment on their calculations.

Given that the department's own cost impact model first identified a potential test count increase of 66 percent (if no adjustments were made to strain counts in an environment of non-composite testing), before projecting the potential for industry strain consolidation to arrive at an estimated annual statewide flower and concentrate test count increase of 44.3 percent; a projected 66 percent test count increase is feasible.

The department reiterates that any projected costs paid by licensees to the licensed testing laboratory of their choice are only estimates, and the department does not control what licensees are charged for testing. Projected test count increases may prove to not be proportionate to projected test cost increases.

In a testing environment where annual test count volume may increase for flower and concentrate in an approximate range of 44.3 percent to 66.1 percent, testing labs may decide to lower their prices given a significant increase in testing volume. Any downward adjustment in testing fees would influence the department's cost impact study to overestimate actual cost. The department reiterates that this cost impact statement is an estimate, and actual testing cost increases in the environment of non-composited test samples may vary.

As for Ms. Johnson's comments regarding laboratory testing practices or perceived efficiencies, those fall outside the scope of the rulemaking and the department declines to respond.

COMMENT 9: The department also received comments relative to what the commenters refer to as "double testing" or "redundant testing" requirements. The commenters ask for clarification whether marijuana joints are required to be tested twice; the same question applies to infused pre-rolls.

RESPONSE 9: There is no requirement in statute or rule, nor a definition, for double testing or redundant testing, and the department refers these commenters to ARM 42.39.614, which provides the necessary guidance.

The department notes that producers often test bulk marijuana flower before it is used in intermediate products like concentrates and extracts. Depending on a product life cycle, intermediate products may have their own testing requirements before they may be sold to a consumer. So additional testing in this scenario – and associated testing costs – are a byproduct of the producer's independent business decision to have the source marijuana flower tested, arguably prematurely, depending on the parameters provided in ARM 42.39.614 and SOP-001.

But a positive aspect of testing marijuana flower before its use in any intermediate product is the assurance that the flower meets initial testing requirements, where absent a first test, an intermediate product's quality assurance testing is unknown.

COMMENT 10: Mr. Arnold commented objection to harvest lot size and single strain lot requirements, as stated in Comments 2 and 3, and that the implementation of industry regulation is akin to " . . . death by 1,000 cuts." Mr. Arnold continued commentary outside the scope of the rulemaking but indicated his willingness to engage in litigation with others in industry against the department to resolve their issues with agency rulemaking.

RESPONSE 10: All department rulemaking is conducted in compliance with MAPA, and the promulgation of cannabis industry rules and regulations is a task delegated to the department by the legislature, which the department pursues considering the needs and public policy goals stated in the Montana Marijuana Regulation and Taxation Act (MMRTA). If Mr. Arnold believes that any rulemaking was not adopted in substantial compliance with the MMRTA and MAPA, then he has recourse in the court system to pursue his complaint, and where the department will assert its defense.

COMMENT 11: Fidelity supports the proposed definition of contaminant in ARM 42.39.601(16) and proposes a change in the test failure provisions in ARM 42.39.614(13) by changing " . . .; and" at the end of (a) to " . . .; or." Otherwise, samples that are 80 percent 3mm or more stems or 80 percent seeds or other foreign matter could pass testing. Then Fidelity suggests removing (13) altogether to better align with contaminants under 16-12-209, MCA.

RESPONSE 11: The department finds the comments compelling but does not fully agree. Based on the comments, the department has amended ARM 42.39.614(13)(a) and (b) to change the connector to "or" instead of "and."

The department partially agrees that filth and foreign matter are not contaminants. The current thresholds for seed and stems may not present an inherent health concern on par with other mandated testing. However, they influence quality measures for product entering the market. Fidelity proposed only removing the seed and stem threshold, but did not provide a suggestion for other elements that could be assessed to satisfy the department's statutory obligation to

determine the presence of levels of foreign matter. The department is aware of other filth and foreign matter components such as animal excrement, hair, insects, and microplastics that could have compliance thresholds. However, implementing these changes cannot be accomplished at this time for the reasons expressed in the second paragraph of Response 3.

It is also worth noting that a "test failed" status for filth and foreign matter does not mean the flower in question must be destroyed. The flower could be remediated by processing it into a concentrate or extract, thereby reducing financial burden(s) for a test failed result. The department believes the current threshold for seeds and stems is adequately set and also notes a low failure rate for filth and foreign matter testing.

COMMENT 12: Fidelity requested clarity regarding the proposed amendments for new ARM 42.39.614(11)(f). Fidelity asks whether the department is asking for all of the cannabinoids that appear on the certificate of analysis in addition to those required in (11)(a) through (e) to be reported to METRC. If yes, Fidelity contends the change would require testing labs to make significant and time-consuming changes to their data reporting systems–if it is even possible given the current METRC configuration.

RESPONSE 12: The department responds that the requirements are clear. Further, METRC is capable of this functionality. However, given that testing laboratories may benefit from a transition period to implement this requirement, the department will delay implementation of the requirement until September 24, 2024, which is 30 days from adoption of this rulemaking.

COMMENT 13: The department received extensive commentary via email from Ms. Siate, which could be generally categorized as strong advocacy against industry use of pesticides at all levels. Ms. Siate is also a strong advocate for random blind sampling of marijuana cultivators and the work of the marijuana testing laboratories.

The department notes that despite the proposed rulemaking and expanded quality assurance testing requirements in the rules, SOP-001, and the Appendix, Ms. Siate objects to the rulemaking as not going far enough because the department is not fulfilling its "mandate to ensure safety and keep up with national knowledge and trends." In support of her position, Ms. Siate submitted a lengthy newspaper article from the Los Angeles Times newspaper dated June 14, 2024, titled "The Dirty Little Secret of California's Legal Weed." Ms. Siate requested that agency and Cannabis Control Division management read the article and that it be entered into the record as a part of her testimony.

Ms. Siate proceeded to give a recitation of personal events related to the cannabis industry in Montana and provided several lengthy comments, a number of which fall outside the scope of the rulemaking.

RESPONSE 13: The department thanks Ms. Siate for her comments and for provision of the newspaper article which can be viewed online at

https://www.latimes.com/california/story/2024-06-14/the-dirty-secret-of-californiaslegal-weed or in the department's rulemaking file.

Since many of Ms. Siate's comments fall outside the scope of the rulemaking, the department declines to respond. The remainder of Ms. Siate's comments have been aggregated with other comments to this rulemaking.

COMMENT 14: Fidelity commented under SOP-001, Pesticide Action Levels, that the footnote to this table instructs that "pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1, and jasmolin 1 (CAS numbers 121-21-1, 25402-06-6, and 4466-14-2 respectively)." As cinerin 1 and jasmolin 1 traditionally make up a statistically insignificant amount of pyrethrins, we suggest that they should be measured as the cumulative residues of pyrethrin 1 and pyrethrin 2, which are the majority of the insecticide constituents.

Fidelity also requested a change to Section 6.3.1 of SOP-001 to begin with " . . . is an employee of the testing laboratory and . . . (continue the text of the subsection)."

RESPONSE 14: The department understands that cinerin I (CAS 25402-06-6) and jasmolin I (CAS 4466-14-2) constitute a small portion of the cumulative of pyrethrins. However, this does not necessarily mean the results of these components are insignificant. Other states that test for pyrethrins test for cinerin I, jasmolin I, and pyrethrins I, or pyrethrin I and pyrethrin I, or cinerin I, jasmolin I, pyrethrin I, cinerine II, jasmolin II, and pyrethrin II. At this time, the department believes maintaining the pesticide list in the Appendix is satisfactory and is not out of step with other state's marijuana regulations.

The department believes the suggestion for section 6.3.1 of SOP-001 is unnecessary, and refers Fidelity to the new term "testing laboratory sampler" in ARM 42.39.601 which includes language clarifying a testing laboratory sampler is an employee of the testing laboratory.

COMMENT 15: Several commenters expressed objection to the requirement that a testing laboratory sampler must physically verify the count of a package submitted for testing. The perspectives came from testing laboratories as well as cultivators, manufacturers, and dispensaries, but shared the opinion that the requirement is an administrative burden due to the amount of time that it takes to physically verify products submitted for testing, such as marijuana pre-rolls. Further, monitoring, inspecting, and regulating are the job of the department and its inspectors, and it is the job of the department to interpret laws and rules and apply those interpretations to the industry.

Mr. Erwin commented that the requirement creates a clear conflict of interest between a testing laboratory and its customer.

Commenters have requested the removal of the requirement or the easing of the requirement such that the department is satisfied that product is not being deviated from testing while taking time constraints of all of the parties concerned into account.

RESPONSE 15: The department disagrees and notes that the requirements have been in place since SOP-001 was first adopted under the Department of Public Health and Human Services. Verifying that an entire test batch is presented to the testing laboratory sampler ensures that a truly random and representative sample is collected from the entire test batch; and doing so provides the most representative sample from which test results are derived and further ensures that the label on the marijuana item accurately reflects the product.

In Section 7.1.4 of SOP-001, the weight confirmation for flower test batches was reduced from all flower test batches to one to reduce the time burden on laboratories while also spot checking the process.

Pre-rolls are addressed in Section 7.6 of SOP-001, and those sample increments are specified and very clear.

The department disagrees with Mr. Erwin that marijuana testing laboratories are put in a conflicting position because they fulfill a specific role in Montana's marijuana regulatory construct under 16-12-202, 16-12-206, and 16-12-209, MCA. The department contends that testing laboratories are aware of their unique position in the industry because they effectively implement the department's quality assurance testing protocols and indirectly affect what product can be sold in Montana with the safety of Montana consumers as a primary mission.

COMMENT 16: In addition to shared comments previously responded to, Mr. Saur commented concerns with heavy metals testing, pre-roll testing for potency, and sample sizes for vape cartridges and edibles.

Mr. Kajander shared Mr. Saur's question about the changes to heavy metals testing.

Mr. Saur also requested the department define the term "increment." He states that the term is used consistently by the department but is not clearly defined. He adds that he wants to calculate how much a testing laboratory will take before sampling and it is necessary in the calculation of the cost of goods sold. Is one serving an increment, or is one package an increment?

Mr. Erwin also commented to the proposed definition of "increments" and "container." For container, it is unclear to Mr. Erwin how this is supposed to work with prepackaged products. Does each product have its own "container," or is the individual product package considered the "marijuana item"? For increments, how does this definition apply in SOP-001 regarding sampling required "increments"?

RESPONSE 16: The department responds to Messrs. Saur and Kajander that the only change to heavy metal testing was a minor word change – "will" to "shall" – and there has been no substantive change to heavy metal testing protocols from current requirement or how a random test might occur.

The department agrees that a general definition of "sample increment" may be helpful for clarity, particularly for licensees other than laboratories. However, even though ARM 42.39.614 was a part of the this rulemaking, the suggested definitional change cannot be accomplished at this time for the reasons expressed in the second paragraph of Response 3.

The existing tables 1.0, 2.0, 3.0, 4.0, 5.0, and 6.0 along with Sections 7.4.8, 7.5.7, and 7.6.7 in SOP-001 also direct the reader as to what and how much a sample increment is per product type.

The department agrees that the term "container," as proposed, may cause confusion with regards to product packaging. The department has removed the term from ARM 42.39.601 and will work within the existing terms for product packaging.

COMMENT 17: Mr. Bostrom commented strong support for the rulemaking. He states that these amendments are essential for improving marijuana product testing protocols to ensure the highest safety standards for Montana's consumers. He commends the department's initiative to expand, improve, and clarify these rules to address the evolving marijuana industry in Montana.

Mr. Bostrom continued by emphasizing the importance of testing pre-rolls in final form. He asks how industry can be certain that the flower claimed to be in the final pre-roll is actually what is present, especially since typical practice involves using leftover flower from larger testing lots designated for sale as flower the practice can result in significant discrepancies in potency and quality. Mr. Bostrom quotes evidence of discrepancy research from California and highlights the necessity of final form testing.

Mr. Erwin also shares many of the concerns with Mr. Bostrom and posits whether the definition of "pre-roll" may be too broad. Mr. Erwin states that under the definition, you can make different pre-rolls that are likely to yield different test results but meet the definition as proposed since batches of pre-rolls could be made in a 48-hour period that have the same strain but different amounts of each strain.

Regarding marijuana pre-rolls, Messrs. Saur and Kajander commented the protocol needs to clarify when pre-rolls should be tested for potency. The current wording suggests retesting is needed if potency is expected to change, likely referring to infused pre-rolls and strain blends. Is compliant, tested flower that is simply ground and rolled into pre-rolls expected to change the potency?

Do licensees have to test pre-rolls if the material has aged and licensees are suspicious that the THC has potentially degraded? Or does this just apply if a licensee infuses or otherwise alters the joints, or combines materials in a way that would result in different expected testing results than the tested flower batch being used to make the joints?

Messrs. Saur and Kajander claim it is crucial to define these scenarios clearly to avoid redundant testing.

RESPONSE 17: The department thanks Mr. Bostrom for his support of the rulemaking and appreciates his position regarding current practices and issues with pre-roll testing, in which the department agrees.

The department disagrees with Mr. Erwin that the definition of "pre-roll" is too broad. Additionally, small differences in the amount of single strain ground flower between individual pre-rolls of the same process lot is not expected to affect the potency results of the product as potency for this product type is reported as a percentage and is not weight dependent. ARM 42.39.614(8) provides typical examples of when the potency of a pre-roll is expected to change, including multi-strain pre-rolls and all infused pre-rolls. However, other scenarios may exist, and

considerations may need to be given to the age or storage conditions of the flower used. Compliantly tested single-strain flower that is ground and manufactured into pre-rolls is not expected to change the potency.

The department responds to Messrs. Saur and Kajander, that yes, a licensee must test pre-rolls if the material has aged and if THC has potentially degraded. As to the second question, ARM 42.39.614(8) provides specific examples: " . . . include mixing multiple strains of usable marijuana into a process lot of pre-rolls and all process lots of infused pre-rolls."

COMMENT 18: As an extension of Comment 17, Mr. Bostrom also made several comments relative to public marijuana policy, truth in labeling laws, consumer trust and market growth, and public trust and good manufacturing practices – all of which set high expectations and goals of building Montana's cannabis industry.

RESPONSE 18: The department appreciates Mr. Bostrom's remaining comments. However, they are matters of public policy and are outside the scope of this rulemaking. Accordingly, the department declines to respond.

COMMENT 19: Ms. Johnson commented her opinion that the pesticides in the proposed list are not "compatible with each other" and discussed the increased number of continuing calibration verifications testing labs will need to run and the amount of time each requires, saying that expanded testing equals fewer tests completed in a day.

Ms. Johnson also suggested that the department adopt the Department of Agriculture's pesticide registry for all farming and commerce and that the department should require cultivators to register with that agency.

Ms. Johnson also made several comments that are outside the scope of this rulemaking.

RESPONSE 19: While the department generally agrees with Ms. Johnson regarding expanded pesticides requiring more testing time, substantial delays could equally be the result of not maximizing efficiencies in running QC samples and instruments. The department's Cannabis Laboratory Program has discussed this issue previously with other testing labs, and based on the limited amount of information provided, the issue may be isolated to the commenter.

Regarding Ms. Johnson's suggestion about the Department of Agriculture's pesticide registry, the department notes, as of this rulemaking, there is no authorized pesticide list and usage that applies to marijuana. Further, the requested change likely requires statutory implementation or clarification by the legislature before the department could implement any expanded testing protocols.

As some of Ms. Johnson's comments are outside the scope of this rulemaking, the department declines to respond.

/s/ Todd Olson
Todd Olson
Rule Reviewer

/s/ Brendan Beatty
Brendan Beatty
Director of Revenue

Certified to the Secretary of State August 13, 2024