COLORADO
Department of Revenue
Marijuana Enforcement Division

June 2, 2023

INDUSTRY BULLETIN: 23-02

RE: Implementation of Rule Changes

Dear Stakeholders:

The intention of this bulletin is to highlight certain rules that were previously adopted by the State Licensing Authority on October 11, 2022 and will become effective in the coming months.

Mandatory Reporting for Test Sample Adulteration:

Effective July 1, 2023, per Rule 4-115(C)(3) Regulated Marijuana Testing Facilities will be required to notify the Division and quarantine any Test Batches that they suspect, or have reason to suspect, may be adulterated. The Division is working with Metrc to create a reporting adulteration option within the inventory tracking system to create efficiencies in the reporting process. More information will be provided through an inventory tracking software bulletin as we approach July 1, 2023.

Examples of suspected adulteration may include:

- Discoloration such as bleaching or dark brown appearance
- Unusual smell
- Inconsistent texture of samples submitted from the same harvest batch

The Marijuana Enforcement Division has identified many examples of Regulated Marijuana Businesses adulterating Test Batches in order to pass required testing which has led to administrative actions, penalties, and in some cases Health and Safety Advisories. Adulterating or altering Test Batches is a significant public safety concern because the Test Batch is no longer representative of the Harvest or Production Batch it was pulled from. If the Division finds evidence of willful or deliberate Test Batch adulteration or alteration, it will recommend the strictest penalties possible to the State Licensing Authority which may include suspension or revocation of license, and fines of up to $100,000 per violation. In addition, Rule 4-110(A)(3) states that adulteration or alteration of test batches is a violation affecting public safety and constitutes a class 2 misdemeanor.

Use-by Date Information:

This section is intended to provide information and guidance regarding shelf stability testing contemplated in Rule 3-1015, 1 CCR 212-3. On October 11, 2022, the State Licensing Authority adopted amended Rule 3-1015(2)(a.5), which requires:

> Effective January 1, 2024, a product use-by date, upon which the Regulated Marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Product will no longer be fit for consumption, or upon which

> the Regulated Marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Product will no longer be optimally fresh. Once a label with a use-by date has been affixed to a Container containing Regulated Marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Product and any Marketing Layer, a Licensee shall not alter that use-by date or affix a new label with a later use-by date. *The **use-by date shall not be longer than nine months** from the harvest or production date, **unless shelf stability testing**, including but not limited to potency, microbial, and water activity testing, **supports a longer shelf life***. All use-by dates must be entered into the Inventory Tracking System prior to Transfer. Prior to Transfer to a patient or consumer, a Regulated Marijuana Store or Accelerator Store must inform the patient or consumer if the Regulated Marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Product is past its use-by date.

The following information is intended to assist licensees in determining how to conduct shelf stability testing to establish use-by dates in accordance with the Rule.

Shelf Stability Testing Requirements & Expectations:

The purpose of stability testing is to determine how long a product will stay within product quality and safety specifications while considering a variety of factors such as temperature, humidity, light, packaging, etc. Stability testing is used, in part, to determine an appropriate use-by or expiration date, as well as to identify appropriate storage conditions and packaging.

Required Tests: Regulated Marijuana Businesses that produce Regulated Marijuana are expected to base the expiration or use-by date on a reasonable assessment of the Regulated Marijuana packaging, storage conditions (e.g. temperature, humidity), possible contaminants, and possible changes to cannabinoid content (potency) and terpene content. These studies should, to the extent possible, follow standard practices for such determinations. Guidance documents and best practices on stability testing, such as this document from the FDA, may be used to inform approaches taken by Regulated Marijuana Businesses.

- Vaporizer Delivery Devices (VDDs) and Pressurized Metered Dose Inhalers (PMDIs): Per MED Rule 3-335(M)), Marijuana Products Manufacturers that produce VDDs or PMDIs are required to include all contaminant and potency tests required for those product types, as detailed in 4-115, 4-120, and 4-125, in their determination of an expiration date. The expiration date must also consider the interaction of the marijuana with the hardware and packaging and the ideal storage conditions. Per MED Rule 3-1010(C)(3)(k), the expiration date and storage conditions must be included on the label.
- Inhaled Product (other than Vaporizers and Inhalers): Per MED Rule 3-1015(B)(2)(a.5), **effective January 1, 2024,** marijuana with an intended use of "Inhaled Product" must include a use-by date "upon which the [marijuana] will no longer be fit for consumption or…optimally fresh." This date must be no longer than nine months from the harvest or production date, unless shelf stability

testing supports a longer shelf life. Stability testing supporting a use-by date of longer than nine months requires the demonstration that the following properties are sustained:

  - Potency
  - Acceptable microbial contaminant levels
  - Water activity

Additionally, if a use-by date longer than nine months is used, the label on the marijuana must include the storage conditions as determined by the business that cultivated or manufactured the marijuana.

- Oral Consumption (Edible Products) and Skin and Body Products (Topicals and Transdermals): Per MED Rule 3-1015(B)(3) and (4), products for oral consumption or skin and body products must include an expiration or use-by date. MED rules do not specify a maximum expiration date or shelf life, however any product that is not past its expiration or use-by date is expected to pass any potency or contaminant testing applicable to the product type.

Conducting Shelf Stability Studies:

Shelf stability testing is performed to determine how long a product will stay within product quality and safety specifications when stored according to the manufacturer's instructions.

- *How is a shelf stability study performed?* In its simplest form a shelf stability study would include initial tests, performed upon the completion of all manufacturing and packaging steps for a product. The batch, or a portion of the batch, is stored in accordance with storage conditions for the product, and then re-tested at a later date or dates. A portion of the batch that passes testing after being stored for 3 months could be determined to have an expiration date of 3 months. Subsequent passing test results for samples that have been aged for 6, 9, and 12 months from the production date would extend the expiration date to 6, 9, or 12 months, respectively. Failing test results would typically indicate that the product's expiration date should be equal to or less than the interval between the production date and the last passing test result (i.e., if the 9 month test passed and the 12 month test failed, the expiration might be set at 9 months). It is up to the manufacturer to determine the appropriate type of tests, number of tests, aging periods, and storage conditions used in a stability study.
- *What are accelerated stability studies?* Accelerated stability studies age the product under conditions expected to deteriorate the product at a much faster rate than if it was stored under the labeled storage conditions. This typically involves elevated temperatures and humidity, but the determination of these conditions must be considered separately for each product type. Accelerated stability studies allow the manufacturer to extrapolate an expiration date that is longer than the aging period. For example, if a product aged for 3 months at high temperature, humidity, and exposure to UV light passes testing, a manufacturer might determine the expiration date to be 6 months based on trends in the potency and contaminant test results of 7, 14, 21, 28, 42, 56, 70, and 84-day old samples. Calculating expiration dates based on accelerated studies is challenging and involves a thorough understanding of the degradation mechanisms in the product

and how those mechanisms are affected by the harsher aging conditions. Accelerated stability studies are typically supplemented by conventional long term stability studies.

- *How often do I have to perform shelf stability studies?* Shelf stability studies should be performed on each product that is manufactured and when bringing a new product to market. Stability studies should be revisited every time there is a significant change in the product formulation, standard operating procedures (SOPs), or a change in the packaging.
- *How many tests need to be performed to complete a stability study?* The amount of tests required to be performed for stability study may be determined by the business that is making the product. A minimum of two tests for each test type being performed would be required, but many more tests are often necessary to establish the behavior of the product over time.
- *How do I determine which and how many Harvest Batches or Production Batches to test?* The use-by or expiration date for each product or strain should be supported by an applicable stability study. There is not a specific number of tests or batches that are required, but the more tests that are performed in a study, the more robust the study will be.
- *Do I need to do a stability study for each strain of marijuana that I cultivate?* Different types and amounts of cannabinoids or terpenes, differences in moisture content, and other factors may have a significant impact on the stability of different strains of marijuana. However, a well-designed shelf stability study may incorporate multiple strain types into the same study. If the study indicates that one strain degrades faster than another strain, either the strains should have separate use-by dates or the shorter of the two dates should be used.
- *Do I need to do stability studies for each flavor of product that I produce?* Similar to strains, the effects of different flavorings, ingredients, or processes may have a significant impact on the shelf stability of different products, but a single stability study *could* be designed to assess multiple flavors.
- *How do I submit Test Batches for stability study testing?* The use of R&D testing is generally recommended, but licensees should decide which testing options make the most sense for their procedures. We also encourage licensees to communicate with their Testing Facility when submitting stability studies.

Pesticide Test Panel:

July 1, 2023 the pesticide panel expands as detailed in Rule 4-115(D)(5)(b). Testing facilities will be required to be certified for the following analytes at the action limits listed below.

Substance	Action Limit (PPM)
Abamectin	< 0.1
Azoxystrobin	< 0.02
Bifenthrin	< 1.0
Bifenazate	< 0.02
Boscalid	< 0.02
Carbaryl	< 0.05

Chlorpyrifos	< 0.04
Clothianidin	< 0.05
Lambda-Cyhalothrin	< 0.25
Dichlorvos	< 0.1
Dimethoat	< 0.02
Dinotefuran	< 0.1
Diuron	< 0.125
Etoxazole	< 0.02
Imazalil	< 0.05
Imidacloprid	< 0.02
Malathion	< 0.02
Metalaxyl	< 0.02
Myclobutanil	< 0.02
Permethrins	< 0.5
Propiconazole	< 0.1
Pyriproxyfen	< 0.01
Spinosad	< 0.1
Spiromesifen	< 3.0
Spirotetramat	< 0.02
Tebuconazole	< 0.05
Thiabendazole	< 0.02
Thiamethoxam	< 0.02