May 25, 2017
MEDICAL MARIJUANA INFORMATION BULLETIN 2017-05

Subject: Summary of Division 7 Rule Changes Effective May 31, 2017

Below is a summary of the cannabis testing and labeling rule changes. The testing rules aim to balance the need for ensuring a reasonably safe product for patients and consumers, protecting public health, and the cost to producers and processors. In developing the rule changes, the Oregon Health Authority considered the cost of a potential testing procedure and how that cost will affect the cost to the ultimate consumer of the marijuana item as required under ORS 475B.555(8).

Of significant note, the Authority did not implement the proposal of a once annual randomized pesticide testing scheme for concentrates and extracts and did not reduce the frequency of pesticide testing on usable marijuana being supplied into the adult use market. Most of the revised testing rules make permanent temporary testing rules adopted in December of 2016. Some additional changes that should alleviate costs to producers and processors include, making the control study rule permanent, increased batch sizes for usable marijuana, reduced testing for cannabinoid products that have passed a control study, opportunities for product remediation, and greater flexibility on product labeling.

The information provided below is just a summary of the changes made to division 7 regarding labeling and testing. The full rule text should be reviewed in its entirety. The rules may be found at: healthoregon.org/ommprules.

Summary of Division 7 Testing Changes

Definitions: OAR 333-007-0310

- New definitions were added to help better clarify testing standards. Includes definitions for: Compliance test, Control study, Field duplicate sample, Level of quantification, Sample increment, Unit of sale.

- Harvest lot – means “a specifically identified quantity of marijuana that is cultivated utilizing the same growing practices, harvested within a 72 hour period at the same location and cured under uniform conditions.” This is an increase from 48 hours to 72 hours for a harvest to be included in a harvest lot.
    - Harvest lot does not mean all marijuana cultivated in a specific location must be harvested within 72 hours. It just includes marijuana that was harvested in that time period under uniform conditions as defined as a “harvest lot.”
    - A harvest lot may contain multiple strains.

Ordering Tests: OAR 333-007-0315

- Outlines the minimum information required to be provided to a laboratory by a registrant or licensee prior to sampling which includes:
    - The registrant or licensee's registrant or license number.
    - The name, address and contact information of the registrant or licensee.
    - Type of marijuana item.
    - Harvest lot number that is associated with the batch numbers, if applicable.
    - Process lot number that is associated with the batch numbers, if applicable.
    - Batch numbers to be sampled.
    - Total mass or volume of each batch to be sampled.
    - For cannabinoid products, the unit of sale.
    - Identification of the test or tests the laboratory is being requested to conduct.
    - Whether the test or tests being requested are compliance tests.
    - Whether the test or tests being requested are quality control or research and development tests.
    - Whether a batch is being re-sampled because of a failed test, the date the failed test result was received by the registrant or licensee and laboratory identification number of the laboratory that conducted the initial test.
    - Whether the marijuana item has a certified control study.

Batch Requirements for Compliance Testing: OAR 333-007-0350

- The size of a batch in a harvest lot was increased from 10 pounds to 15 pounds.
- The size of a process lot of concentrates, extracts or products submitted for sampling and testing for purposes of a control study defines the maximum process lot size for future batch sampling and testing for that item if the control study is certified.
- Cannabinoid products must be separated into process lots of not larger than 35,000 unit batches.

Compliance Testing Requirements for Marijuana or Usable Marijuana: OAR 333-007-0320

- Every batch from a harvest lot of useable marijuana must be tested for pesticides, water activity and moisture content, and potency before being transferred to a processor, processing site, dispensary or retail shop.

  An exception for this is made in 333-007-2000, where OLCC may establish the frequency of pesticide testing required by a producer or wholesaler as long as at least one third of the batches in a harvest lot are tested for pesticides. This rule does not change or reduce the current frequency of pesticide testing on usable marijuana intended for the adult use market.

  This exception does not apply to medical marijuana growers.

Compliance Testing Requirements for Cannabinoid Concentrates and Extracts: OAR 333-007-0330

- The proposed rule changes allowing for once annual random testing of concentrates and extracts were <u>not</u> adopted.

- The rule required every process lot of cannabinoid concentrates or extracts must be tested for pesticides, solvents and potency before being transferred.

Sampling and Sample Size Requirements for Compliance Testing: OAR 333-007-0360

- Samples of different batches of the same harvest lot of usable marijuana may be combined for purposes of testing for potency if the batches are the same strain.

- Samples of different batches of usable marijuana may NOT be combined for purposes of pesticide testing. OAR 333-007-0320 outlines every batch from a harvest lot of marijuana must be tested for pesticides.

- Minimum sample increments for different batch sizes or units of sale for concentrates, extracts and product are in Exhibit B, Table 5 or 6.

- Once a concentrate or extract has a certified control study, the minimum number of samples increments that must be taken for future batches are established in Exhibit B, Table 7. Sample increments may be combined into a primary sample and a field duplicate sample but must be prepared and analyzed separately.

- After a cannabinoid product has successfully passed a control study, at a minimum one unit of sale is required for the primary sample and one unit of sale is required for the field duplicate sample for future batches of that product. Both the primary sample and the field duplicate sample must be prepared and analyzed separately and enough product must be sampled for the laboratory to perform all required tests.

Sampling Personnel Requirements; Sampling Recordkeeping: OAR 333-007-0370

- If a producer or wholesaler transports marijuana or useable marijuana to a laboratory for compliance testing for pesticides all the batch from the harvest lot must be transported so the laboratory can choose which batches to sample from.

- Rules related to laboratory personnel that perform sampling were moved to OAR 333-064-0100(2)(c).

Standards for THC and CBD Compliance Testing: OAR 333-007-0430

- The maximum concentration limit permitted in a package may have a variance of 10 percent over, but no more, as specified in OAR 333-007-0200 to 333-007-0220, as applicable.

Control Study: OAR 333-007-0440

- Rules outlining a control study are made permanent.

- If a processor chooses to perform a control study, every cannabinoid concentrate, extract or product must successfully complete one control study every year.

- During a control study, sample increments must be tested separately to determine if the concentrate, extract or product is uniform.

- Once OHA has certified a control study, future sample increments may be combined into a primary sample for testing and a field duplicate sample must be taken.

- If a sample increment from a control study fails it cannot be remediated and resubmitted for a control study.

- A control study will be valid for one year unless a change to the standard operating procedure or a change in the type of ingredient is made by the processor or processing site.
    - Products that differ only in flavor or color do not need a separate control study as long as the different flavors or colors do not have an effect on the potency.

Failed Test Samples: OAR 333-007-0450

- If after a failed test a registrant wishes to have a sample reanalyzed, the registrant must request a reanalysis within 7 calendar days from the date the laboratory sent notice of the failed test. The reanalysis must be completed by the laboratory within 30 days from the date the reanalysis was requested. If a primary sample or a field duplicate sample fails, both must be reanalyzed. The laboratory that did the initial test may not subcontract the reanalysis.

- If a registrant requested a reanalysis and the sample passes, the registrant has 7 calendar days from the date the laboratory sent notice of the passed test to request that another laboratory resample the batch and confirm the passing test result. The retesting must be completed by the second laboratory within 30 days from the date the retesting was requested. The registrant needs to follow OHA's instructions for reporting reanalysis and subsequent testing results.

- If a batch fails pesticide testing, it may not be destroyed without obtaining permission from the Authority.

- If a batch of usable marijuana fails pesticides testing for piperonyl butoxide or pyrethrins only, and the Oregon Department of Agriculture (ODA) determine that only products from the ODA Guidelist for Pesticides and Cannabis were applied in accordance with the label, the producer or grower may be permitted to remediate the usable marijuana using procedure that would reduce the concentration of pesticides to less than the action levels. A batch of usable marijuana that is remediated must be re-sampled and re-tested for pesticides.

- If a processor or processing site only uses usable marijuana that has passed pesticide testing and a sample from a batch of concentrates or extracts fails pesticide testing, the batch may be remediated using procedures that reduce the concentration of pesticides to less than the action level. A batch that is remediated and after being re-sampled and re-tested fails pesticide testing must be destroyed by obtaining permission from the Authority or Commission.

Audit and Random Testing: OAR 333-007-0480

- A registrant will be required to pay for any audit or random testing if selected. OMMP may obtain a marijuana item from a registrant at any time and have it tested to ensure compliance.

Quality Control and Research and Development Testing: OAR 333-007-0500

- A registrant or a licensee may request a laboratory to conduct a test for the purpose of assuring quality control or for research and development.

- A grower or producer may not request a laboratory to conduct a pesticide test on usable marijuana for purposes of quality control or research and development. A pesticide test on usable marijuana is always considered a compliance test.

- A laboratory result from a quality control or research and development test cannot be used as a compliance test. Only marijuana items with compliance tests may be transferred and sold.

- Laboratory results for all quality control and research and development tests must be maintained by the registrant and licensee for at least two years.

OLCC Licensee Pesticide Testing Requirements: OAR 333-007-2000

- OLCC may establish the frequency of pesticide testing required by a producer or wholesaler as long as at least one third of the batches in a harvest lot are tested.

- If any sample taken from a batch fails a pesticide test, every batch from the harvest lot must be tested for pesticides.

- If all samples from each randomly chosen batch of a harvest lot pass pesticide testing, the entire harvest lot is considered to have passed pesticide testing and may be transferred or sold. A laboratory will not be considered in violation of any accreditation standards for reporting these tests as passing.

Marijuana Item Sampling Procedures and Testing: OAR 333-064-0100

- Language regarding laboratory personnel was moved from division 7 to division 64.

- A laboratory performing tests for medical marijuana registrants must maintain required documentation for three years and provide that information upon request to OMMP.

Reporting Marijuana Test Results: OAR 333-064-0110

- Test reports must clearly indicate whether a sample has failed a test, a pesticide has been detected, include the batch identification number and test batch number associated with the samples tested and indicate if a test is a compliance test or a quality control or research and development test.

- A laboratory's LOQ must be below the action limits established for pesticides and solvents.

Summary of Division 7 Labeling Changes

General Label Requirements; Prohibitions; Exceptions: OAR 333-007-0090

- The THC and CBD amount required to be on a label must be based on the value calculated by the laboratory that did the testing, plus or minus 10 percent except that a label may not have a THC value that exceeds the applicable maximum concentration limit. The THC and CBD may be expressed as a range based on high and low values or an average.

Concentration and Serving Size Limits: OAR 333-007-0210 and 333-007-0220

- A marijuana item that does not fall within a category in the Concentration and Serving Size Limits Table 1 or 2, but is intended for human consumption, must meet the concentration and serving size limits applicable to a cannabinoid edible.