March 31, 2022
MEDICAL MARIJUANA INFORMATION BULLETIN 2022-01 - Revised

Subject: New Cannabis Testing Rules Effective March 31, 2022

The Oregon Health Authority writes rules for testing cannabis that effect both the medical and recreational market. Newly adopted testing rules will go into effect March 31, 2022, that make many changes to testing. This bulletin is a summary of the major changes and should not be relied on solely. You may review the testing rules, found in Division 7 and 64, in full at healtheroregon.org/ommprules.

In addition, guidance documents are available to help understand sampling changes, Metrc changes related to testing, what to do with failed items, and an outline of the new tests along with a timeline. All guides can be found at healthoregon.org/marijuanatesting

Addition of New Tests
Testing for heavy metals, mycotoxins and microbiological contaminants will soon be required. A marijuana item or industrial hemp-derived vapor item will be required to be tested for:

- Mycotoxins, if harvested or manufactured on or after July 1, 2022.
- Heavy metals, if harvested or manufactured on or after March 1, 2023.
- Microbiological containments, if harvested or manufactured on or after March 1, 2023.

For finished inhalable cannabinoid products and finished concentrates and extracts, all testing is to be performed on the finished item. Once the new tests are in effect, no other testing will need to be performed along the way, but licensees may choose to process marijuana that has passed pesticide testing when processing extracts in order to be eligible for remediation. Other finished cannabinoid products will only require a potency test; all other tests will be performed on the cannabinoid concentrate, extract, or marijuana used to make the product. An example of this is that starting March 1, 2023, water activity and moisture content testing will not be required on marijuana or usable marijuana if it will be made into a concentrate or extract. The finished concentrate or extract will be required to be tested for pesticides, solvents (if required), potency, mycotoxins, heavy metals and microbiological contaminants. It should be noted that if an item receives a passing test before it is required, the test result does not transfer to the new item being created.

Rules specific to the standards of compliance testing for microbiological contaminants are found under OAR 333-007-0390, heavy metals are found under OAR 333-007-0415 and mycotoxin are found under OAR 333-007-0425. For an outline of testing requirements for each marijuana item type see the testing guide.

Finished inhalable cannabinoid products
Finished inhalable cannabinoid products is a new category of marijuana items under the testing rules. Rules specific to testing them can be found under OAR 333-007-0341. Examples of items that fit under this category are things like infused pre-rolls or inhalable cannabinoid products with non-cannabis additives. These items will be required to be compliance tested once they are finished, but before they are packaged, for pesticides, solvents (if required), adult use cannabinoids and CBD concentration, mycotoxins if manufactured on or after July 1, 2022, heavy metals contaminants if manufactured on or after March 1, 2023, and microbiological contaminants if manufactured on or after March 1, 2023.

It should be noted that the marijuana or usable marijuana used to make a finished inhalable cannabinoid product must be tested and pass for water activity and moisture content if the finished inhalable cannabinoid product is made before March 1, 2023.

Batching, Sampling and Control Study Changes
Many changes have been made to the rules around batching and sampling for all marijuana item types.

Changes related to marijuana and useable marijuana

- The definition of "harvest lot" is being amended to mean marijuana harvested within a 7-calendar day period instead of a 72 hour-hour period.
- Starting July 1, 2022, a harvest lot of marijuana or usable marijuana may be separated into a maximum of 50.0-pound batches.
    - The whole batch of marijuana or usable marijuana must be made available for sampling and place in containers that hold no more than 15 pounds during the sampling event.
    - Batches from the same harvest lot that are the same strain and appear to be substantially similar in appearance and quality may be combined for testing for adult use cannabinoids and CBD.
        - This generally means that trim and flower should not be combined for potency testing.

Changes related to concentrates, extracts, finished inhalable products and industrial hemp-derived vapor items
Sampling increments required per batch size of concentrates, extracts, finished inhalable cannabinoid products and industrial hemp-derived vapor items are being changed. In most cases, only a primary and duplicate sample will need to be sampled and tested. Once the batch weight is above 12.0 kilograms, additional replicate samples will be required to be sampled and tested for potency and solvents if required. Sample increments required vary depending on the batch weight. See the new Table 7 under OAR 333-007-0360 for details. The whole batch must be available for sampling and each item types has specifications for how they may be batched for sampling.

A batch of concentrate or extract must be produced using a standard operating procedure and result in one finished cannabinoid concentrate or extract that is uniform in texture and form.

A batch of an industrial hemp-derived vapor item must be made from a standard operating procedure and result in one final industrial hemp-derived vapor item that is uniform in flavor, texture, and form.

A batch of a finished inhalable cannabinoid product must be made from a standard operating procedure and result in one finished inhalable cannabinoid product that is uniform in flavor, texture, and form.

Changes related to cannabinoid products

For cannabinoid product sampling, only a primary and duplicate sample will be required. A batch may not consist of more than 35,000 units of sale.

The allowance of unbaked edible items to be sampled will be allowed. Prior to sampling, the processor or processing site must ensure that the entire batch is available to the laboratory and in a form where the only remaining step to complete the edible is baking. If anything is added to the edible after baking, the entire batch must be baked and finished prior to sampling. The sampler must select the unbaked samples and the samples must be baked by the processor at the processing site while the sampler remains at the processing site in order to not brake chain of custody of the sampled item.

A batch of a cannabinoid product must be produced using a standard operating procedure and result in a finished cannabinoid product that is uniform in potency, texture, and weight. A standard operating procedure may use different flavors or colors in a batch if the different flavors or colors:

- Are substituted for one another at a 1:1 ratio; and
- Do not affect the potency, texture, or weight of the finished cannabinoid product.

For the purposes of this rule, "flavor" means:

- The essential oil or essence which contains the flavoring constituents derived from a spice, fruit, fruit juice, vegetable, vegetable juice, herb, root, leaf, or similar plant material.
- Any substance, the function of which is to impart flavor, which is not derived from a spice, fruit, fruit juice, vegetable, vegetable juice, herb, root, leaf, or similar plan material.
- Flavor does not include flavoring constituents derived from the cannabis plant.

Acceptable product variation example:

- A processor makes a batch of two different flavored cake pops. The batter is made and split in two, one lemon flavored and one orange flavored. The flavorings are used

in the same quantity and the end products are consistent in texture and weight. There is no expected change in potency since the only difference is the use of a different flavoring agent. In this case, the two different flavors may be considered one batch and sampled and tested together.

Unacceptable product variation example:

- A processor makes a batch of cookies. Chocolate chip cookies and peanut butter cookies could not be presented as one batch for sampling and testing since there is a texture difference. Each would need to be sampled from individually and have their own potency testing performed.
- A processor makes a batch of cupcakes with frosting. A batch of frosted and unfrosted cupcakes could not be presented as one batch for sampling and testing since there is a weight difference. Each would need to be sampled from individually and have their own potency testing performed.

If a cannabinoid product is or may be sold in different quantities in a unit of sale, then the process lot shall be sampled based on the smallest unit of sale for the purposes of sampling and testing. All proposed units of sales must meet the OLCC's concentration limit rules found in chapter 845, division 26.

Examples:

- If a pack of gummies is sold in a unit of sale that consists of either five gummies in a unit of sale or 10 gummies in a unit of sale, then the process lot should consist of units of sales that consist of five gummies for the purpose of sampling.
- If a tincture is sold in 1-ounce bottles but may also be sold in 4-ounce bottles, then the process lot should be sampled in units of sales that consist of one-ounce bottles.

Control studies

Due to the changes being made to sampling, control studies are being eliminated from rule. Rules around batching and sampling may be found under OAR 333-007-0350 and 333-007-0360. The sampling guide and the Metrc guide may also help explain the sampling changes in more detail. Guides may be found at healthoregon.org/marijuanatesting

New ORELAP sampling protocols

Cannabis testing laboratories should be aware of new ORELAP sampling protocols.
New ORELAP sampling protocols for usable marijuana (ORELAP-SOP-001 Rev. 4.1) take effect July 1, 2022. New ORELAP sampling protocols for cannabinoid concentrates, extracts, inhalable products, products and industrial hemp-derived vapor items (ORELAP-SOP-002 Rev 4.3) is effective with the filing of these rules. Laboratories should ensure their protocols are up to date as soon as possible.

Changes to RSD and RPD

- Modifying standards for solvent compliance testing by indicating a batch fails solvent testing if the RPD or RSD is more than 10% between the samples as appropriate. (OAR 333-007-0410)
- Amending standards for adult use cannabinoid and CBD compliance testing by reducing the RPD or RSD to 10%. (OAR 333-007-0430)

Quality Control or Research and Development Testing

A quality control or research and development testing may be performed for any test that is required. The only exception to this is a quality control or research and development pesticide test is not allowed on marijuana or usable marijuana.

All results from a quality control or research and development test are required to be entered into Metrc. See OLCC's Metrc guide for additional information on how to enter these results in Metrc.

While quality control or research and development testing is not considered a compliance test, a failure for any test performed could mean that the item is now considered adulterated and is not safe for consumption. There may be a means to remediate the item but before doing so a review of the failed testing rules, found under OAR 333-007-0450, should be performed to see how to handle a failed item. Dilution is not considered a form of remediation and should not be done on any item that fails a test. (OAR 333-007-0500)

Laboratory requirements found in division 64

Many of the changes being made to OAR 333-064-0100 will be found in the new cannabis sampling quick guide. Other changes that laboratories should be made aware of include new requirements for quality control (QC) samples for microbiological and chemical tests. This includes new QC acceptance criteria for adult use cannabinoids and CBD, pesticides, solvents, heavy metals, and mycotoxins which are specified in OAR 333-064-0100, Exhibit C, Table 1. The precision of analysis of duplicate samples for RPD or RSD limits will be decreased from 20% to 10%. These changes are effective March 31, 2022, and laboratories should make any changes needed as soon as possible.

Another new requirement indications that a laboratory's limits of quantitation (LOQs) must be less than or equal to one half of the action level for all matrices. This was previously a requirement only for pesticides. An LOQ of less than or equal to 0.15% is also specified for total delta-9 THC and delta-8 THC. This aligns with less than or equal to one half of the federal legal level for THC of 0.3% and is meant to ensure laboratories have adequate sensitivity to analyze hemp and hemp-derived vapor items are below the state and federal legal limit of THC.

Lastly, if a laboratory calculates adult use cannabinoid or CBD results exceed 100% and the difference between the result and 100% is within the laboratory's calculated analytical uncertainty, the laboratory may report the result as 100% with a qualifying statement on the

certificate of analysis or the laboratory may report the calculated result with or without a qualifying statement. If the difference between the result and 100% is outside the calculated analytical uncertainty, the calculated result shall be reported without correction. When calculating RPD or RSD, a laboratory shall use the calculated result and not he adjusted result.

Once the rules take effect on March 31, 2022, the Oregon Secretary of State website will reflect the changes. In the meantime, the copy of the filed rules may be found in full at healthoregon.org/ommprules.