

## **Potency/Moisture/Water Activity Workgroup**

### **Completed Work to Date**

The workgroup had several meetings discussing moisture. The workgroup found that it did not have enough information on the requirements to select a method. The private labs reported that they were doing a loss on drying test. Each lab had its own version of the test. No one was performing the Karl-Fisher test. The workgroup did not know why the test was being performed. The workgroup found no scientific reason to favor one test over another. The workgroup needed more policy and/or data user requirements in order to determine what test would be best.

The workgroup had two meetings discussing Water Activity. The workgroup found that labs were using a specialized instrument for this test. The workgroup did not have time to construct a specific SOP. Instead it developed a set of proposals that the workgroup believed the ICT should use when evaluating water activity procedures. They include the use of specialized instruments, following the instrument manual, and required QC samples. The motion with the specific proposals is below. The proposals would provide data that auditors could use to validate the accuracy of the testing.

### **Defined Challenges, Gaps and Actions Needed**

1) Challenge 1 - Moisture

The ICT will need to select a moisture test. The workgroup recommends that the ICT obtain policy guidance prior to selecting a method. This may include asking if the test should be performed at all, if the expensive and time-consuming Karl-Fisher is needed or if the current loss on drying methods are sufficient and if so which one should be used.

2) Challenge 2- Water Activity

The ICT may wish to evaluate each instrument used for Water Activity separately and create specific procedures for each one based on the proposals approved by the task force.

### **Background**

Moisture is commonly approximated by a loss on drying test. Loss on drying will detect free moisture, some volatile compounds, and some bound moisture depending on the conditions of the test. This is fine for many uses but not all. Different industries or use cases use different versions of the test. Water Activity is useful and well defined in determining the potential of microbial or fungal growth and is used by FDA to set food risk standards. Karl-Fisher can determine total water present in all forms and distinct from other volatile compounds but it is expensive and time consuming to run. No one is doing it on cannabis and it is not generally

used on other commodities. The workgroup could only speculate on why both tests were required and what type of moisture test was needed by the data user.

## **Appendix a – Motions Passed**

December 7, 2021.

(Motion includes proposals below.)

The ICT must finalize and establish methodology for testing water activity or provide a performance based approach. The ICT should leverage off of the proposals by the CSTF as follows for establishing an approved method/procedure. The proposals were developed based on current industry application and were specific to AQUALAB and Rotronic moisture analyzers.

### **Proposal One:**

Use an instrument specifically designed to perform the water activity test. An AQUALAB or Rotronic moisture analyzer or equivalent.

### **Proposal Two:**

Follow the instructions in the instruments manual. The instructions generally include, type of cups the instrument accepts, warm up time, and other requirements specific to the analyzers. All QA requirements found in the manual should be followed.

### **Proposal Three:**

The instrument should be standardized (calibrated) with four levels of standards that cover at least 0.4 to 0.75 but may include a larger range.

The calibration should be checked with a standard from a different manufacture than the standards used to make the calibration.

### **Proposal Four:**

Each batch, at least once a day, the instrument calibration should be verified with two check standards, one at a high level and one at a low level. In addition, one sample should be run in duplicate.

The check standards and the duplicate must match within 0.01 of each other. The instrument may be recalibrated or maintenance may be performed (such as cleaning the cup, refilling check standard or other maintained recommended by the equipment manufacturer). The instrument must be checked again if maintenance is performed prior to sample testing. If the check fails, the instrument must be recalibrated.