Act 65

MARIJUANA-INFUSED PRODUCT TESTING: REPORT

Preamble:

The General Assembly recognized the importance of independent testing of marijuana-infused products sold by dispensaries to determine proper labeling of products in compliance with 18 V.S.A. § 4474e. Therefore, the Agency of Agriculture, Food & Markets (VAAFM) and the Department of Public Safety (DPS), in consultation with registered dispensaries, shall report their recommendations to the Joint Legislative Justice Oversight Committee and the General Assembly no later than October 15, 2017 on the following:

(1) Who should be responsible for testing marijuana-infused products;
(2) The approved methods and frequency of testing;
(3) Estimated costs associated with such testing and how these costs should be funded;
(4) If testing will be done through an independent testing entity, the process by which the State will certify such entities and oversee such testing; and
(5) How to implement a weights and measures program for medical marijuana dispensaries.

Act 65 charges VAAFM and DPS in consultation with registered dispensaries to provide recommendations for establishing a sampling and testing for marijuana-infused products. This report is intended to provided recommendations related to testing and labeling. It includes suggestions for examining cannabinoid potency and contaminates in usable marijuana and marijuana-infused products.

Who should be responsible for testing marijuana-infused products

Under the current constraints prohibiting interstate movement of marijuana and marijuana-infused products, without appropriate US Drug Enforcement Administration (DEA) licensure, must remain in Vermont. There should be two parties responsible for testing the dispensary and the State. Dispensaries would be responsible for testing inputs and products to ensure quality, purity, and dosing utilizing services currently authorized under the regulatory framework.

Dispensaries producing marijuana-infused products should test their products and inputs for potency and appropriate labeling.

The State laboratory identified for testing, marijuana and marijuana-infused products, is the Vermont Agriculture and Environmental Laboratory (VAEL), a component of the Agency of Agriculture, Food & Markets (AAFM). Minimally, VAEL should be equipped, staffed, and prepared to perform routine cannabinoid potency testing on marijuana-infused products to ensure consumer protection. The VAEL should be prepared to perform potency, adulterant, and contaminant testing on cannabis raw material and cannabis-infused products. Furthermore, the VAEL has the ability to evaluate the in-house procedures utilized by the dispensaries to ensure adequate method performance.

As written, Act 65 (2017) recognizes the importance of testing to determine proper labeling, identifying the amount of tetrahydrocannabinol (THC) in each single dose marijuana-infused edible or potable product, but other states, including Massachusetts and Maine, include testing for contaminants, such as:

- pesticides,
- solvents,
- heavy metals,
- mycotoxins, and
- bacterial and fungal contamination.

The approved methods and frequency of testing

DPS in consultation with VAAFM will establish sampling protocols that specify random selection methods of marijuana and marijuana-infused products. There are models within VAAFM that provide guidelines for testing frequency. The State would implement protocols for testing potency, adulterants, and contaminants to ensure label guarantees, qualities, and purity based on a random sampling scheme, complaints, and inspection protocols.

Cannabinoid potency

Analytical testing for cannabinoid potency testing will need to be developed by VAEL. Verifiable and defensible methods are not anticipated to be a challenge, as methods currently exist and are in use by other states. Testing methods, at minimum, will require dual confirmation. Currently VAEL proposes utilization of a High-Performance Liquid Chromatography (HPLC) as a baseline. Given that cannabinoids are present in percentage range concentrations, more sensitive means would not be required. Terpenes and sesquiterpenes, compounds that contribute to the therapeutic, flavor, and aromatic profile of cannabis, are best assessed using gas chromatographic (GC). Product potency testing would be performed by VAEL on behalf of the dispensaries and/or DPS to confirm the accuracy of the label requirements to be established. Continuing compliance testing should be performed for all usable marijuana and marijuana-infused products sold by each dispensary, at a minimum, on an annual basis for cannabinoid potency.

Contaminants/Adulterants

Depending on the material being tested and the nature of the constituent/contaminant being tested for, analytical methods require a variety of instruments and methods. Table 1 provides an overview of these. Note that there may be other methods and technologies available or more appropriate at the time of testing.

TABLE 1. List of contaminants and instruments

Contaminant	Instrument
Pesticides	LC/MS and GC/MS
Solvents	HPLC
Heavy Metals	ICP/MS
Microbial Testing	Culture methods, PCR, ELISA
Mycotoxins	LC/MS, GC/MS

ELISA, enzyme-linked immunosorbent assay; GC, gas chromatography; ICP, inductively coupled plasma; LC, liquid chromatography; MS, mass spectrometry; HPLC, high-performance liquid chromatography; PCR, polymerase chain reaction

Other states require that testing be done at various stages of product production, starting with a broad range of contaminant testing on usable marijuana and more focused testing on marijuana-infused products. This approach tailors the testing regimen to follow the potential sources of contamination. Testing would be performed by VAEL for residues or other contaminants above defined tolerances.

Estimated costs associated with such testing and how these costs should be funded

TABLE 2. Testing fees

Cannabinoid testing: HPLC (THC, THCA, CBD, CBDA, CBN, and sample collection)	$150/sample (same as Hemp pilot program fee)
Cannabinoid testing: HPLC (THC, THCA, CBD, CBDA, CBN, excluding sample collection)	$60-$80/sample (based on current private sector costs)
Contaminant/adulteration testing	$20-$150/sample
Pesticides/Mycotoxins: GC/MS and LC/MS	$100-$200/sample
Microbiological/Microbial: Culture, PCR, ELISA	$15-$100/sample
VAEL evaluation of dispensary in-house procedures	No fee

Pursuant to the Rules Regulating Cannabis for Symptom Relief, sections 6.9.5 and 8.7, dispensaries are responsible for the cost of laboratory testing required by the Department.

Funding source options include:

• General Fund:

$120,000 would provide initial startup and acquisition of necessary resources (lab technician, equipment, etc.).

• Fee for service, borne by dispensaries at time of analysis: *(Dispensaries Opposed)*

If the fee is to cover the costs associated with the program in its entirety the cost could be excessively high on a per-sample basis and would increase the fees contained in Table 2. Supplemental funding from other sources would be required for initial startup. The fee-for-service charge could potentially cover VAEL's ongoing cost for analysis.

• Marijuana Registry Special Fund: *(DPS Opposed)*

The FY2018 Governor's General Fund Rescission Plan to resolve the General Fund shortfall resulted in a one-time sweep of prior year carry-over. As a result, Marijuana Registry Special Fund would be unable to cover initial costs associated with a testing program.

• Other available sources:

A proficiency certification program and split sample analyses fees could help support the costs of establishing a usable marijuana and marijuana-infused product testing program. This program could as be expanded to include a hemp laboratory certification program.

If testing will be done through an independent testing entity, the process by which the State will certify such entities and oversee such testing

To accommodate a state accreditation process legislative authority would need to be provided to the State. The entities the State would certify and oversee related to testing are dispensaries, hemp entities, and private laboratories. The State will need to define parameters and serve as an accrediting authority for any analytical cannabinoid and contaminant testing.

- Accreditation requirements would include the following (similar to NELAC, ISO, or GMP):
  - Use of standard operating procedures (SOPs) based on internationally accepted laboratory methods;
  - Development of a Quality Management Program with a Quality Systems Manual that addresses the management and technical requirements outlined in ISO 17025 (Second Edition, 2005) and/or NELAP standards (2009);
  - Participation in an annual proficiency testing program and analyst proficiency;
  - Maintenance of safety and chemical hygiene training and operation of a hazardous waste management program that meets OSHA and EPA requirements.

- Specific standards and parameters developed by VAEL, including demonstration of proficiency, paperwork, and on-site audits to ensure compliance. Additionally, annual renewal of accreditation submitted to the State would be required.

How to implement a weights and measures program for medical marijuana dispensaries

As specified by Tile 9 Chapter 73, the Secretary of VAAFM retains the authority to regulate all weights and measures (W&M) within the State, including certifying and inspecting devices used for weighing and measuring for direct sale scales and verifying the weight of pre-packaged products.

The current W&M program deals primarily with commodities sold in retail stores, such as produce, meat, seafood, etc. Marijuana and marijuana-infused products pose an added requirement to the current W&M program. As of the date this report was submitted, the W&M program does not possess scales to accurately weigh light high-value products, such as dried herbs, certain tobacco products, and pharmaceuticals. Additionally, the W&M program does not possess the appropriate calibration standards needed to test these scales. Therefore, the W&M program will need to obtain equipment to appropriately measure these products.

The following is required to implement a W&M program for the dispensaries:

- Purchase and calibrate a Class II weight kit appropriate for these scales;
- Maintain documentation and traceability on weights;
- Training for W&M inspectors on the testing of Class II scales, including handling of the test weights; for example, these weights require special handling from current field standards;
- Inspection of scales used by dispensaries to ensure devices are adequate and accurate;
- Annual inspection and certification of dispensary direct sale scales, and;
- Create and maintain a database with information relevant to dispensary locations.

Estimated costs to implement:

Class II Weight Kit with calibration report:	$3,000.00
Inspector training:	$2,500.00
Research and implementation:	$2,500.00
Total	***$8,000.00***

Conclusion

In summation, this report provides a proposed framework for the implementation and development of medical marijuana sampling and testing to ensure proper labeling of marijuana and marijuana-infused products based on existing technologies, information from other states, and a collaborative effort with DPS, VAAFM, and currently registered dispensaries. It is important to note collectively the contributors of this report strongly recommend sampling and testing include marijuana and not be limited to marijuana-infused products.

Two methods have been recommended for validating laboratory operations conducted by the registered dispensaries and independent testing by the State. Certainly, there may be considerations not included, but overall, the VAEL should be equipped to provide analytical services for consumer assurance and regulatory enforcement purposes, and evaluation of the registered dispensaries in-house procedures. The VAEL is currently working to develop an independent analytical capacity anticipating the need for third-party laboratories as the marketplace develops.

The State would approach this in two phases. The first phase would entail VAEL developing the capabilities to audit and evaluate the current registered dispensary laboratories. The second phase would be the VAEL testing marijuana and marijuana-infused products for compliance, label guarantees, and consumer safety. Implementation of the weights and measures program would include certifying and inspecting scales utilized by the registered dispensaries, verifying the weight of pre-packaged products, and labeling requirements contained in 9 V.S.A. Chapter 73.

Total costs are estimated and will require adjustment. Funding will also need to be determined and several sources may be needed to cover initial and ongoing costs. While not exhaustive or all inclusive, this report will provide a framework for discussion and designing a testing program for marijuana and marijuana-infused products. Hopefully, this report will also serve as a template for an expanded testing for all cannabis (hemp and marijuana) and cannabis-infused products sold, manufactured, offered for sale, and/or consumed in Vermont whether produced by the medicinal, recreational or agricultural markets.