From: CED AMCO REGS (CED sponsored)
To: CED MCB AMCO (CED sponsored)
Subject: FW: Analytical Testing Resource: Hemp Derived Cannabinoids in Your State
Date: Monday, September 15, 2025 1:24:59 PM
Attachments: P2_2024_ACIL_Product_Study_r.pdf
2023-1-Guide-to-Harmonizing.pdf

From: Mike Oscar - ACIL <moscar@acil.org>
Sent: Tuesday, July 29, 2025 11:27 AM
Subject: Analytical Testing Resource: Hemp Derived Cannabinoids in Your State

Good Afternoon: I'm reaching out to you today on behalf of the American Council of Independent Laboratories (ACIL). ACIL (est. 1937) is *the* trade organization representing independent, commercial laboratories across a variety of industries (e.g. environmental, food, dietary supplements, cannabis/hemp) to promote the adoption of best practices and protect public health.

We are aware that your agency has instituted or is considering instituting analytical requirements for products containing hemp derived cannabinoids within your state. We very much applaud these efforts as there are a variety of quality and safety concerns unique to these goods, and federal oversight is lacking. We would like to lend our support in the following ways:

1. Please find our 'Guide to Harmonizing Cannabis Laboratory Quality & Testing Practices' document attached to this email. This 45 page document was painstakingly developed over a number of years as a complement to the ISO 17025 standard typically required of testing laboratories performing cannabis or hemp compliance testing. The Guide has been shared with CANNRA and a number of members have referenced or adopted parts of the Guide within their own regulatory frameworks. We invite you to do the same.

2. We would be happy to review and advise on the feasibility of analytical requirements and how they compare to those of other established regulatory frameworks. We often see regulatory bodies propose requirements that, while well intentioned, are not practical or achievable in an economic way, so public health is not protected and enforceability is reduced.

3. We would be happy to share or present data on the quality and safety issues our member labs are finding in hemp products. Please find our recent 'Hemp Marketplace Study' attached, as a taste, though challenges in this industry tend to rapidly evolve, and we have more extensive and recent data to share.

We very much want to act as a resource to you, so if there are any other ways we can support your efforts, please let us know.

Take Care,

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ACIL Hemp Market Study

February 2024 - The 2018 U.S. Farm Bill authorized the production and sale of industrial hemp, defined as cannabis plant material confirmed to contain less than 0.3% d9-THC on a dry weight basis. The U.S. Department of Agriculture (USDA) regulates the cultivation and testing of industrial hemp, with provisions to allow states to adopt their own complementary frameworks. Testing laboratories are authorized by the USDA, Drug Enforcement Agency (DEA) or USDA-approved state programs to perform harvest testing to ensure compliant delta-9 THC levels in cannabis plant material.

Although the THC limit was only intended to be applied to industrial plant material, producers in recent years have interpreted a far more expansive definition, applying the standard to "hemp-derived" products containing THC (e.g. gummies, beverages, topicals). Because the USDA does not regulate manufactured goods and the Food & Drug Administration (FDA) has not shown any desire to get involved, these products are operating in a regulatory gray zone as a result. Many hemp product manufacturers do not perform any testing to demonstrate their compliance with the 0.3% delta-9 THC concentration, while others test irregularly, such as once per SKU, rather than every batch (as is typical in the cannabis industry).

ACIL member laboratories, all of whom are ISO 17025 and accredited within their resident states (CA, AZ, IL, NY, NJ, MA), collaborated in recent weeks to perform an off-the-shelf survey of the hemp market landscape. The study consisted of each laboratory purchasing hemp flower, prerolls, and vape pens of their own choice, either from smoke shops or online. The goals of the study were twofold: 1) To determine what percentage of products legitimately contained concentrations of delta-9 THC <0.3%, and 2) To compare the testing results performed by the ACIL laboratory and the original testing laboratory to determine the extent to which discrepancies may exist. The tabulated and anonymized results can be seen below. *The clear takeaway from this study is that the current landscape of intoxicating hemp product testing does not accurately reflect the legality of the products being sold by vendors nationwide.*

Issues identified in this study:

1) Although all hemp products indicate on the label that they are 'Farm Bill Compliant', many having a Certificate of Authenticity (COA) from laboratories reporting levels of delta-9 THC less than 0.3%, ***69%* of the products independently tested do not fulfill the <0.3% requirement for hemp** under the 2018 Farm Bill.
2) Many producers interpret the Farm Bill as only referring to delta-9 THC itself, excluding its acidic counterpart THCA. If the required USDA Total THC (a mathematical summation of d9-THC and the acid form decarboxylated THCA) is measured against the 0.3% THC requirement, ***81%* of products exceed legal standards**. This lack of compliance has two primary consequences:
    a) An even greater percentage of the products tested are illegal and shouldn't be considered industrial hemp or industrial hemp derived.

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b) Consumers are being defrauded and led to believe they are buying legal and/or nonintoxicating products when that is not the case.

3) Consumers are unwittingly consuming contaminated products. Seven of the 48 products tested (**15%**) had **failing levels of pesticides** (measured against action limits set by the regulated cannabis market of the states they were tested in) and sometimes up to **600x the action limits.**

4) Some products were mislabeled. For example, a product labeled 'THCA Flower Pre-roll' contained only *1.8%* THCA, while also containing *4.8%* delta-8 and *3.7%* delta-9 THC.

5) Some of the QR codes linked to the wrong COA or could not link the COA to the specific product/batch, as required in many states.

6) Most product COAs only display testing for cannabinoid content and did not have the full scope of testing that is required in the legal cannabis market.

7) Products also violate several other requirements that are standard in most legal cannabis markets:

   a) Lack of labeling of cannabinoid content,

   b) Lack of age gating (did not have to show ID when buying),

   c) Lack of batch control (batch numbers were not listed on labels which would make it impossible for a consumer to know if their product was applicable to a recall, or match it to a particular COA),

   d) Some product labels indicated they contained terpenes or flavor additives not derived from plants, which could not be determined to be safe since the ingredients were not specifically listed. Non-plant derived flavors or additives are not permitted in cannabis products in many legal markets.

Study Conclusion:

The results of the ACIL Hemp Market Study indicate that the current landscape of hemp products is not meeting the legal requirement of the Farm Bill nor the required USDA testing limits for intoxicating Total THC. The pesticide study data indicates the need to expand the testing of hemp products to ensure their safety. The ACIL Hemp Market Study only examined pesticide residues due to time and resource constraints, not microbial contamination, metals, mycotoxins, or residual solvents. All of these are required for state-regulated medical and adult use cannabis markets. Although the study only provides a snapshot of the hemp market as it currently operates, it does point to major problems with the legality, quality, and safety of hemp products sold. It also illustrates the need for legislators to provide a robust regulatory framework over the testing of hemp products that ensures honest and accurate reporting of intoxicants and contaminants by testing laboratories.

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ACIL Laboratory Testing Data (January 2024)

Prerolls:

Product Code	ACIL Testing Laboratory	Original COA Results			ACIL Study Results			Pesticides
		Delta-8 THC (%)	*Delta-9 THC (%)*	*THCA (%)*	*Delta-8 THC (%)*	*Delta-9 THC (%)*	*THCA (%)*	
P1	A	14.69	ND	ND	7.86	ND	ND	
P2	A	QR Code links to the wrong COA			ND	ND	1.03	Fail (under CA regulations for Chlorfenapyr (12300 ppb) and Pyridaben (137 ppb))
P3	A	ND	ND	47.7	ND	ND	4.91	Below LOD (14ppb) DDVP
P4	B	ND	0.21	23.14	4.29	3.71	1.77	
P5	B	ND	0.28	22	4.39	3.99	2.05	
P6	C	23.27	UI	0.42	3.32	1.09	0.29	
P7	C	23.27	UI	0.42	3.49	1.11	0.22	
P8	D	22.82	UI	0.05	9.89	1.11	0.06	
P9	E	14.69	ND	ND	9.3	ND	ND	
P10	E	14.73	ND	ND	8.42	ND	ND	
P11	F	6.358	ND	0.15	4.71	1.32	ND	
P12	F	no test results online			0.4	0.18	0.64	
P13	G	ND	0.16	28.17	ND	2.48	14.3	
P14	G	ND	0.26	26.51	ND	3.47	16.6	
P15	H	no test results online			ND	3.38	8.46	

Vapes:

Product Code	ACIL Testing Laboratory	Original COA Results			ACIL Study Results			Pesticides
		Delta-8 THC (%)	*Delta-9 THC (%)*	*THCA (%)*	*Delta-8 THC (%)*	*Delta-9 THC (%)*	*THCA (%)*	
V1	A	53.69	UI	ND	64.77	ND	ND	Below LOD (15ppb) Chlorpyrifos
V2	A	59.25	UI	ND	65.73	ND	ND	Below LOD (11ppb) Etoprophos
V3	A	81.13	UI	0.15	55.86	8.49	0.19	Fail (under CA regulations for Chlordane (39 ppb) and Chlorpyrifos (47 ppb))
V4	A	80.85	UI	0.29	56.93	5.84	0.21	Fail (under CA regulations for Chlorpyrifos (41 ppb))
V5	B	98.3	UI	ND	69.78	16.78	ND	
V6	B	88.8	UI	ND	69.54	16.67	ND	
V7	C	72.8	ND	ND	47.1	ND	ND	
V8	C	no test results online			49.5	6.03	ND	
V9	D	ND	ND	ND	4.64	12.7	0.09	Fail (under CA regulations for Ethoprophos <LOQ)
V10	D	ND	ND	ND	0.63	ND	0.01	
V11	E	89.46	ND	ND	47.59	ND	ND	
V12	E	87.1	ND	ND	52.97	ND	ND	
V13	F	66.75	ND	ND	41.05	16.49	ND	Fail (under IL regulations for Bifenthrin (70 ppb), Metalaxyl (115 ppb) and Trifloxystrobin (26 ppb))
V14	F	77.9	UI	0.22	54.04	14.23	0.23	
V15	G	91.64	UI	ND	83.8	10.9	ND	
V16	G	91.64	UI	ND	89.1	8.33	ND	
V17	H	no test results online			25.87	5.36	ND	Fail (under NY regulations for Bifenazate (3230 ppb) and Trifloxystrobin (68 ppb))
V18	H	no test results online			29.1	4.38	ND	Fail (under NY regulations for Trifloxystrobin (1500 ppb))

Flower:

Product Code	ACIL Testing Laboratory	Original COA Results			ACIL Study Results			Pesticides
		Delta-8 THC (%)	*Delta-9 THC (%)*	*THCA (%)*	*Delta-8 THC (%)*	*Delta-9 THC (%)*	*THCA (%)*	
F1	A	N/A	0.05	0.19	ND	0.26	0.18	
F2	B	ND	0.14	30.14	ND	0.48	29.93	
F3	B	ND	0.25	29.07	ND	0.6	23.72	
F4	C	no test results online			ND	1.96	24.4	
F5	C	no test results online			ND	0.83	16.6	
F6	D	no test results online			ND	1.21	0.59	
F7	D	no test results online			6.48	0.95	0.81	
F8	E	no test results online			2.06	ND	0.43	
F9	E	no test results online			3.89	ND	0.55	
F10	F	2.07	0.15	0.15	0.94	0.33	ND	
F11	F	no test results online			ND	2.25	18	
F13	G	ND	0.2	23.1	0.03	0.58	19.36	
F14	G	ND	0.25	24.34	0.04	1.41	15.2	

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From: Terry Grajczyk
To: CED MCB AMCO (CED sponsored)
Subject: ensuring safe Industrial Hemp and hemp products - from CHTA
Date: Thursday, October 2, 2025 2:03:31 PM
Attachments: 2025-10-01 CHTA Information for State Cannabis Regulators -Alaska.pdf

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Dear Sir or Madame,

The attached regulatory recommendations were developed to assist state agriculture, food, natural health and non-prescription drug, hemp, and cannabis regulators adapt regulatory frameworks that address safety but do not restrict industry growth.

The intention is to assist collaboration in developing regulations that safeguard consumers, food, feed, industrial fiber, and cannabinoid products. Further discussion is welcome by phoning 825-413-5749 or by email to standards@hemptrade.ca

Sincerely,
Ted Haney
Canadian Hemp Trade Alliance (CHTA)

attachment ...

ACIL

GUIDE TO HARMONIZING CANNABIS LABORATORY QUALITY AND TESTING PRACTICES

GUIDE TO HARMONIZING CANNABIS LABORATORY QUALITY AND TESTING PRACTICES

INTRODUCTION

Laboratories testing cannabis, cannabis-based products and hemp play an important role in ensuring public safety, improving product quality and consistency, as well as consumer satisfaction. Providing accurate and traceable quantitative and qualitative data, laboratories ensure that cannabis and hemp regulators and consumers are provided information to properly regulate and purchase cannabis or cannabis-based products regardless of the state in which they are purchased.

The Guide to Harmonizing Cannabis Laboratory Quality and Testing Practices was developed to recommend guidance for a consistent and science-based approach to regulatory processes by describing basic quality assurance requirements for the laboratories testing marijuana and/or hemp plant materials and their derivatives across the nation. The document was developed with the aid of industry experts and stakeholders including laboratories, accreditation bodies, and input from state regulatory bodies. The document is meant to be a living resource to support the growing cannabis and hemp industries and encourage a level playing field with regard to quality management systems, technical quality control, and method requirements for testing laboratories.

The recommendations and guidance in this document do not supersede accreditation requirements at the federal, state, or local levels. The guidance document is a collection of science-based best practices, which are common to other testing industries, as they apply to cannabis and hemp testing laboratories. The document was written to be harmonized with IS17025:2017 and includes interpretation of the standard with respect to cannabis testing. The compliance guidance is also derived from good laboratory practices (GLP) and good manufacturing practices (GMP). Though this document is guidance the following terms are used:

- “must” to represent a requirement which shall be applied as written
- “should” to represent a recommendation which can be modified when necessary

Each laboratory must evaluate, develop, and implement the appropriate safety, health and environmental standard operating procedures based on the local, state and federal regulatory requirements specific to the scope of work being performed within the laboratory. These items are outside the scope of this document. The security guidance provided in this document may not be sufficient to meet the regulatory guidance requirements under which the laboratory may be operating, however it is the responsibility of the individual laboratory to ensure it is meeting the federal, state, local security regulation requirements.

SCOPE

The Guide to Harmonizing Cannabis Laboratory and Quality Testing Practices provides recommendations for laboratories and regulators nationwide as the essential minimum elements of laboratory quality to make certain accurate, consistent, traceable, and defensible data are delivered which meet public safety and regulatory requirements. It should be noted that these are meant to be the minimum requirements. Users may choose to exceed these requirements at their discretion.

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The guide may be applied to all sizes of laboratories to ensure quality basics are met for the analyses performed by the laboratory. The guide is a reference which can be utilized by accrediting bodies, customers, or regulatory bodies to confirm quality assurance objectives are being met and are harmonized among all states in which cannabis and hemp testing programs have been implemented in support of their regulatory programs.

DEFINITIONS/TERMINOLOGY

Cannabis: A genus of flowering plants in the family Cannabaceae. This includes both "Hemp" and "Marijuana" as defined below. ILI definition

Cannabis-derived product: Product other than cannabis itself that contains or is derived from cannabis. ILI definition

Cannabis-derived compounds: Cannabis and cannabis-derived compounds that may be used in drug manufacturing include botanical raw materials, extracts, and highly purified substances of botanical origin. This guidance does not address development of fully synthetic versions of substances that occur in cannabis, sometimes known as cannabis-related compounds, which are regulated like other fully synthetic drugs.(1)

Cannabinoids: Distinctive class of compounds that are capable of interacting with the specific receptors of the endocannabinoid system in the human body. ILI definition

Corrective and Preventive Action (CAPA): A laboratory system implemented to collect information, analyze information, identify and investigate quality problems, and take appropriate and effective corrective and/or preventive actions to prevent their recurrence.(2)

Certified Reference Material (CRM): Reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate issued by an authoritative body that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.(3, 4)

Critical Supplies: A consumable, reference material, or service utilized by a laboratory that has a direct impact on the final reported result.(5)

Decision Rule: A rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement. (6)

Demonstration of Capability: A procedure to establish the ability of the analyst to perform analyses with acceptable accuracy and precision. (7)

Hemp: (a) For the purposes of 7 CFR part 990, and as defined in the 2018 Farm Bill, the term "hemp" means the plant species Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.(8)

The plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." 7 U.S.C. 1639o(1). Pursuant to the amended definition, cannabis plant material which contains 0.3 percent or less delta-9 tetrahydrocannabinol (THC) on a dry weight basis is not a controlled substance and does not require a DEA registration to grow.(9)

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Laboratory control sample (LCS) (however named, such as laboratory fortified blank, spiked blank, or QC check sample): A portion of appropriate clean matrix that is spiked with known quantities of target analytes and carried through the entire sample preparation process, and treated exactly as a sample, including exposure tall glassware, equipment, solvents, and reagents that are used with other samples. The LCS measures the accuracy of the methodology. The LCS may be prepared from the same source as the calibration standards, or from a second source. (10)

Laboratory Operation: Person, group of persons, or business entity that conducts analytical testing of cannabis and cannabis-derived products (This may include performance of work outside the permanent facility). (11)

Limited Access Area: An area in which cannabis or cannabis products are stored or held and is only accessible to a licensee and authorized persons.(12)

Limit of Detection (LOD): Is defined as the lowest concentration or mass of analyte in a test sample that can be distinguished from a true blank sample at a specified probability level.(13)

Limit of Quantitation (LOQ): Minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result.(14)

LIMS: Laboratory Information Management System that may be electronic, hardcopy, or some combination of electronic and hardcopy.(15)

Marijuana: 1. all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination." 21 U.S.C. § 802(16).(16)

Matrix: The components of a sample other than the analyte. (17)

Matrix-Specific Quality Control Sample: Real, thoroughly characterized in-house sample that is run once a day to track accuracy and precision; should record values in a control chart for monitoring. The sample can also be used for inter-instrument comparisons. Ideal variance (measured by %RSD) should be less than 5%. ACIL definition

Method Blank: A quality system matrix that is similar to the associated samples and is known to be free of the analytes of interest. (18)

Security Monitoring: Continuous and uninterrupted attention to potential alarm signals that could be transmitted from a security alarm system located at the laboratory premises for the purpose of summoning a law enforcement officer to the premises during alarm conditions. (19)

Nonconforming Work (Nonconformances): when any aspect of its laboratory activities or results of this work do not conform tits own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria) (20)

Reagent Blank: A sample without matrix, prepared identically to a field sample (i.e. same glassware, solvents, reagents, etc.). The purpose of a reagent blank is to identify any possible sources of contamination in the reagents, equipment, glassware or laboratory environment. ACIL definition

Phytocannabinoid: Cannabinoid chemical compounds found in the cannabis plant. (21)

Sequestered Microbial Sample: A representative subsample of the total sample batch which is incrementally sampled from within the sample batch and sequestered prior to homogenization then homogenized separately in a manner that does not affect the microbial load present in the sample prior to testing. ACIL definition

Standard Reference Material (SRM): A CRM issued by NIST that also meets additional NIST-specific certification criteria and is issued with a certificate or certificate of analysis that reports the results of its characterizations and provides information regarding the appropriate use(s) of the material (NIST SP 260-136). Note: An SRM is prepared and used for three main purposes: (1) to help develop accurate methods of analysis; (2) to calibrate measurement systems used to facilitate exchange of goods, institute quality control, determine performance characteristics, or measure a property at the state-of-the-art limit; and (3) to ensure the long-term adequacy and integrity of measurement quality assurance programs. The term "Standard Reference Material" is registered with the United States Patent and Trademark Office. (4)

Tamper-Evident Device: A device or procedure which makes unauthorized access to protected objects easily detectable (22)

References:

1. Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research Guidance for Industry Draft Guidance for Industry JULY 2020. US FDA
2. US Food & Drug Administration. Corrective and Preventive Actions (CAPA). 09/08/2014. link: https://www.fda.gov/corrective-and-preventive-actions-capa
3. CRM - IS17034:2016(E) General requirements for the competence of reference material producers, ISO, Geneva, Switzerland (2016)
4. SRM Definitions. NIST (National Institute of Standards and Technology), US Department of Commerce, Gaithersburg, MD. Created August 11, 2010, Updated June 2, 2022 website link: https://www.nist.gov/srm/srm-definitions
5. TNI (The NELAC Institute) Consumables Task Force Proposed definitions. 06/09/2020.
6. IS- 17025:2017 General requirements for the competence of testing and calibration laboratories, Terms and Definitions. Section 3.7
7. TNI EL-V1M2-2016-Rev2.1: Quality Systems General Requirements Section 3.1 Additional Terms and Definitions
8. Establishment of a Domestic Hemp Production Program. USDA Agricultural Marketing Service Final Rule. 86 FR 5596, CFR Title 7, Subtitle B, Chapter IX, Part 990, Subpart A. Doc No. 2021 00967, Jan 19,2021 under the Agriculture Improvement Act of 2018, Pub. L. 115-334, (the 2018 Farm Bill) was signed into law on October 31, 2019.
9. Federal Register /US Department of Justice. Drug Enforcement Administration. Diversion Control Division Docket No. DEA-392, Bulk Manufacturer of Controlled Substances Applications: Bulk Manufacturers of Marihuana. FR Vol 84, No. 166 Tuesday, August 27, 2019. pp 44921-44922.
10. Cannabis Laboratory Quality System Standard. August 2022. Section I Acronyms and Definitions. State of New York Office of Cannabis Management.
11. AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements and Pharmaceuticals. ALACC 2018. Terms and Definitions Section 3.19.
12. CA Department of Cannabis Control Medicinal and Adult-Use Commercial Cannabis Regulations California Code of Regulations Title 4 Division 19. Department of Cannabis Control. Chapter 1. All Licensees Article 1. Division Definitions and General Requirements §15000. Definitions. (ll), pg.3
13. AOAC OMA. Appendix M: Validation Procedures for Quantitative Food Allergen ELISA Methods: Community Guidance and Best Practices. Page 3
14. AOAC OMA. Appendix F: Guidelines for Standard Method Performance Requirements. Table A2, p7
15. AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements and Pharmaceuticals. ALACC 2018. Terms and Definitions Section 3.20.

16. The Controlled Substances Act of Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. [Title 21, Chapter 13, Subchapter 1, Part A, U.S.C. 802 Definitions (16)]

17. IUPAC. Compendium of Chemical Terminology, 2nd ed. (the "Gold Book"). Compiled by A. D. McNaught and A. Wilkinson. Blackwell Scientific Publications, Oxford (1997). Online version (2019-) created by S. J. Chalk. ISBN 0-9678550-9-8. https://doi.org/10.1351/goldbook.

18. TNI. EL-V1M2-2016-Rev2.1: Quality Systems General Requirements Section 1.7.2.1.c

19. Law Insider Definitions. https://www.lawinsider.com/dictionary/security-monitoring

20. IS- 17025:2017 General requirements for the competence of testing and calibration laboratories, Terms and Definitions. Section 7.10

21. Production and/or Use of Chemically Modified or Converted Industrial Hemp Cannabinoids. CDPHE Notice Letter. May 14, 2021.

22. Rule Number 64ER20-1, Certified Marijuana Testing Laboratory Rules, Definitions (68), State of Florida, January 22, 2020

Note: ACIL and ILI have defined some terms used in this document where another suitable definition could not be found in the public domain.

LABORATORY QUALITY MANAGEMENT SYSTEM

1. Organization and Scope of Work

The laboratory must be registered as a legal business operating within and compliant with federal, state, and local regulations.

The laboratory must define and document activities that occur within the laboratory and activities that are externally outsourced as part of adhering to this document and federal, state, and local regulations.

The laboratory must define its management structure and the responsibilities of its personnel in terms of customer support, analytical, and administrative operations.[a]

The laboratory management must have the responsibility and authority to establish, implement, and control documented procedures for laboratory activities to meet the needs and requirements of customers, regulators, and accreditation bodies.[a]

The laboratory must develop, control, and communicate the importance of standard operating procedures (SOPs) that must be followed for laboratory activities and improvement of processes.[a]

The laboratory must have a quality manual that documents and references quality-related procedures and SOPs. The contents of the quality manual must include the following to ensure that the quality, applicability, quality to meet regulatory and customer quality objectives:

- Policy and procedure references for the quality management system and laboratory operations
- Laboratory activities, goals, objectives, employee responsibility and accountability
- Ensure that employees know the importance of following SOPs, policies, and other related procedures.
- Ensure impartiality and confidentiality is incorporated into all employee training.

[a] Based on IS17025:2017(E) Section 5 Structural Requirements

2. Laboratory Personnel Requirements

The laboratory must define roles for personnel who have the responsibility and authority to carry out the following essential functions within the management system: [b]

- Manage laboratory activities to ensure compliance, reduce and manage occurrences of non-conformances, seek continual process improvement and effectiveness to the quality management system. [b]
- Ensure that implementation of the quality management system is effective and adheres to the requirements of its customers and federal, state, and local regulations. [b]

The laboratory must document and maintain the professional requirements for each position within the laboratory in terms of education, training, authorization to perform work, and effectiveness of training through documented demonstration of capability.

The laboratory must determine and implement a program to ensure the continued effectiveness of training through a process of continuing demonstration of capability.

The laboratory must document training specifically in the areas of safety, hazard, and emergency response. The laboratory must supply the appropriate information tallow employees to follow local, state, and federal regulatory requirements and understand their importance to the position of the employee.

[b] Based on IS17025:2017(E) Section 6.2 Personnel

3. Facility and Security

Facility and Laboratory Environment

The laboratory facility must have appropriate facilities, equipment, and environment to support and perform laboratory activities.

The environmental requirements for laboratory activities must be documented tallow for the laboratory to control, monitor, and record the environmental conditions, as applicable teach scope of testing. The goal of the requirements is to reduce or eliminate contamination, interferences, and/or adverse influences impacting laboratory activities. [c]

[c] Based on IS17025:2017(E) Section 6.3 Facilities and Environment

Laboratory Facilities Security

The laboratory must have the following security measures:

- Video surveillance
- Locks
- Biometric or key card access control for limited-access areas

The laboratory should have a security alarm system installed on perimeter entry points and perimeter windows to ensure premises are continuously monitored and secured.

The laboratory should have video surveillance coverage available at locations of key activities which may include but is not limited to:

- Sample receiving
- Sample storage
- Sample weighing
- Sample destruction

Video surveillance equipment must consist of, at a minimum, digital or network video recorders, video monitors, digital archiving devices, and a printer capable of delivering still photos.

The equipment should have a back-up battery, provide failure notification to designated laboratory staff, and be able to record in all lighting conditions.

Placement of camera(s) should allow for clear identification of any individuals and activities being performed.

Location and Maintenance of Surveillance Equipment

Surveillance recording equipment must be housed in a secured enclosure with access limited to authorized employees, agents of the regulatory authority and state or local law enforcement agencies.

Laboratory management should keep a current list of all authorized employees and service personnel who have access to the surveillance system.

A surveillance equipment maintenance activity log should be maintained and include all service activity including the identity of the individual(s) performing the service, the service date and time, and the reason for service.

Off-site monitoring and video recording storage should meet the requirements of this section.

All surveillance recordings should be kept for a minimum of 45 days.

Surveillance video recordings must not be destroyed if the laboratory management is aware of a pending criminal, civil, or administrative investigation or any other proceeding for which the recording may contain relevant information.

Recordings should be kept in a digital format easily accessed for viewing.

Recordings should be archived in a format that ensures authentication of the recording and guarantees that no alteration of the recorded image has taken place.

The laboratory should ensure that installation, maintenance, and monitoring services meet state requirements.

4. Outside Suppliers of Consumables and Services

External suppliers who are providing consumables or services affecting the quality of the result must be vetted and qualified to be a critical supplier. The laboratory must have procedures and retain records for the qualification of suppliers and, as appropriate, supplier personnel. [d]

The laboratory procedure for vetting vendors and suppliers must include actions to be taken when vendors and suppliers do not meet quality or service requirements (as pre-defined by the laboratory). [d]

The laboratory must have quality specifications for consumables and services that are communicated to the vendors and suppliers. The laboratory must retain records of quality requirements, orders and packing slips to ensure the correct supplies and services are ordered and delivered. [d]

The laboratory must ensure that the quality of critical supplies and services are met prior to using or approving orders for consumables or services. The approval must be performed by personnel who are technically qualified and recorded to ensure traceability to the original material.

Laboratories may subcontract preparation and/or analytical work if allowed under their regulatory requirements. The laboratory must have procedures and records to ensure that the subcontractor is accredited as appropriate to provide the services they are being subcontracted to perform.

All providers must have appropriate certifications and accreditations to the current standards:

- All calibration providers must be ISO/IEC 17025 accredited
- Where commercially available, only IS17034 CRMs or NIST SRMs will be used
- Where commercially available and when applicable to matrix and analyte(s), only 17043 Proficiency Test Providers will be used
- Distribution companies must, at a minimum, be IS9001 certified
- Accrediting bodies must be accredited tIS17011 and signatories to the ILAC Mutual Recognition Agreement (MRA)

[d] Based on IS17025:2017(E) Section 6.6 Externally provided products and services

5. Analytical Service Requests, Invitation for Bid (IFB) and Contracts

The laboratory must have procedures for the review of customer requests and contracts. The procedure must incorporate, at a minimum, the following items:

- The laboratory must understand the purpose of the request as defined and documented by the customer.
- The laboratory must have the capabilities and capacity to accommodate the request. [e]
- The laboratory methodology must be able to meet the data quality objectives, regulatory and quality control requirements needed by the customer.
- The laboratory must provide the customer notification as to when external or subcontract laboratories will be used and have documented approval from the customer. [e]

The laboratory must resolve all differences between the IFB and/or request and the contract with the customer and document the resolution agreed upon. The new contract must be reviewed once the revisions are completed, any changes to the contract must be approved by the customer.

The laboratory must inform the customer of their analytical method capabilities to ensure that the customer data quality objectives are being met. [e]

The laboratory must be cooperative and forthcoming in working with customers to achieve the best outcome for both the laboratory and the customer. The laboratory must have procedures to handle customer requests that may threaten or violate laboratory integrity and impartiality. [f]

All documentation surrounding the customer requests, IFBs, and contracts must be retained and must include but are not limited to: [g]

- Original requests, IFBs, and/or contract [g]
- All communications with the customer [g]
- All changes made to the request or contract [g]
- All approvals from the laboratory and the customer [g]

[e] Based on IS17025:2017(E) Section 7.1.1 Review of requests, tenders and contracts

[f] Based on IS17025:2017(E) Section 7.1.4 Review of requests, tenders and contracts

[g] Based on IS17025:2017(E) Section 7.1.8 Review of requests, tenders and contracts

6. Method Verification and Validation

Method verification and validation are two different activities. Method verification refers to the laboratory establishing their ability to meet the quality control and method specifications of a reference or validated method. A reference or validated method is one that has undergone a validation process by a regulatory body (e.g., state, federal) or a third-party consensus body (e.g., AOAC - *Official Method of Analysis* 2018.11 for cannabinoids in Cannabis plant materials, concentrates, and oils). The process of method verification is to verify that laboratory performance be able to meet the quality control requirements of the method including but is not limited to:

- Limit of detection and quantitation studies
- Initial calibration using a calibration curve and initial calibration verification using a second source material
- Continuing calibration verification, as defined by the method
- Laboratory control spikes or fortified blanks
- Analyst demonstration of competency
- Passing proficiency testing samples in the appropriate matrix, as commercially available.

Method validation refers to the determination that a preparation and analytical process has the ability to meet the sensitivity, selectivity, repeatability, and robustness of data quality objectives with a determined uncertainty. A laboratory developing its own method for use must provide and demonstrate that the process being developed meets predetermined quality control objectives for but not limited to the following aspects below.

- Sensitivity
- Selectivity
- Repeatability
- Reproducibility
- Robustness
- Accuracy
- Linearity
- LOD
- LOQ

Method validation procedures recommended for use are: ASTM D8282-19 Standard Practice for Laboratory Test Method Validation and Method Development, AOAC Guidelines for Single Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals, FDA Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products, or IUPAC Harmonized Guidelines for Single-Laboratory Validation of Methods of Analysis. These method validation documents have been specifically developed for the cannabis/hemp laboratories or have been in use by the food and botanical industry for many years.

7. Sample Management/Receipt

The laboratory must develop and implement a chain-of-custody process to ensure accurate documentation of the transport, handling, storage, and destruction of samples.

- The chain-of-custody process must require the use of a form containing the following information:
- Laboratory name, physical address, and license number (as required)
- Producer's name, physical address, and license number (as required)
- Where necessary, confirm producer is a legitimate business
- Unique sample identifier,
- Date and time of the sample collection, as available.
- Description and quantity of sample containers
- Amount of sample(s) (e.g. weight, volume)
- Identification of tests requested
- Identification of presence of tamper-evident device, as appropriate
- Printed and signed name(s) of the supplier(s) of sample, unless credentials are captured in the laboratory information management system (LIMS)
- Printed and signed name(s) of the sampler(s), unless credentials are captured in LIMS
- Printed and signed name(s) of the transporter, if different from sampler, unless credentials are captured in LIMS
- Printed and signed name(s) of the testing laboratory employee who received the sample, unless credentials are captured in LIMS
- The chain of custody process may be encompassed within a LIMS or state tracking system such as METRC.
- Description of samples and sample containers received.

Upon receipt in the laboratory, all samples must be compared to the chain-of-custody by a qualified member of the laboratory staff who was not involved with sampling or transportation of the items. All anomalies must be recorded and reported to management and the client upon the recognition of the disparity.

The receiving laboratory must separately document any differences between the quantity specified in the chain-of-custody and the quantities received. Such documentation must be made in any relevant business records and account for the discrepancy.

The laboratory must not accept a sample that is smaller than the standard minimum amount established in regulation or by the laboratory. If a sample is found to be smaller than its standard minimum amount for the analyses requested, the laboratory personnel are required to set it aside, notify the client, and remedy.

Each time the sample changes custody within the laboratory, the date, time, sample weight, and names and signatures of persons involved must be recorded.

Note: This could include but is not limited to when a sample is removed from storage for testing, placed back in storage, or destroyed or disposed.

The laboratory must maintain a record system that facilitates the reconciliation of the sample weight from receipt through destruction or disposal. The laboratory must be able to account for loss.

If any portion of a test or sampling is outsourced, a chain-of-custody meeting the requirements identified above must be implemented.

The chain-of-custody and sample tracking when samples are outsourced to contract laboratories must be done in accordance with state requirements.

8. Technical Records

Technical records must include all records such that a complete audit trail or historical recreation can be developed for the laboratory activities that were critical or determinative to the final reported result(s).

The technical records must include all of the identity(ies) of laboratory personnel who perform activities related to but not limited to, sample receipt, storage, preparation, analysis and disposal of samples. [h]

Observations, data, and calculations originally collected, gathered, or performed must be recorded at the time of their observance or calculation, and must include the identity of the analyst, date, must be legible, and retained per the laboratory's record retention procedure. [h]

If amendments to data, observations or calculations are required, then the following must be recorded, and the original data must be retained:

- The reason for the amendment,
- Identity of the person making the amendment, [h]
- Date of the amendment [h]
- The amendment must be retained per the laboratory's record retention procedure.

[h]Based on IS17025:2017(E) Section 7.5 Technical records

9. Uncertainty

The laboratory must have a procedure and records for the development of measurement uncertainty for the analyses being performed. The laboratory must determine the measurement uncertainty for each analysis performed.[i] The measurement uncertainty must be available for each analytical result should a customer or regulatory body request the information.

If the laboratory performs calibration for in-house equipment, it must provide the uncertainty for these calibrations. [j]

If the measurement uncertainty is explicitly stated in a standard test method in use by the laboratory and the laboratory does not make modifications, verifies they can meet the method's requirements, then the laboratory can assume the method's stated uncertainty.

[i]Based on IS17025:2017(E) Section 7.6.1 Evaluation of measurement uncertainty

[j]Based on IS17025:2017(E) Section 7.6.2 Evaluation of measurement uncertainty

10. Quality Control Data Analysis

The laboratory must have a procedure to track, monitor, and perform statistical data analysis on quality control data generated. The laboratory must perform trend analysis and can use the analysis to improve the quality of the laboratory. The laboratory quality control samples available for use are, but not limited to the below listed.

- Certified reference materials
- Third party quality control reference materials
- Analyte-free matrix blanks
- Laboratory control sample
- Replicate samples
- Proficiency test samples
- Interlaboratory round robin samples

The laboratory must participate in proficiency testing or interlaboratory comparison, as available and appropriate to the matrices the laboratory is analyzing.

11. Reporting Results

The laboratory must have a procedure for the generation and review of final reports prior to being issued to the customer.[k] The final results being reported must be reviewed by the laboratory prior to being released to the customer to ensure accuracy and completeness. The final issued report must be retained in accordance with the record retention procedure established by the laboratory. [l]

The final report must contain, but is not limited to, the following elements:

- Laboratory name, address, and contact information[m]
- Name and title of the individual releasing or issuing the report
- A unique identifier or revision number for the report[m]
- Unique sample name[m]
- Customer contact information [m]
- Methods used for the preparation and analysis of the samples[m]
- Preparation and analysis dates for each sample and analysis
- Report issue date
- Results with units as determined by the laboratory
- Description of the sample received
- Any deviations or changes made to the methods or agreements established for the analysis of the samples
- Any non-conformances accompanied by a statement describing how they affected the quality of the results
- Decision Rules, if statements of conformity are reported

The laboratory must record and make available the following information if requested:

- Sampling plan if the sampling was performed by the laboratory[m]
- The results of all Quality Assurance and Control samples associated with sample batches
- Measurement Uncertainty [m]
- Photograph of the sample(s)

Any amendments made to the final report must be noted and include, but not limited to the following:

- New revision identifier or report number[n]
- Reason for the amendment
- What portion of report was amended[n]
- Revision date. [n]

Both the amended and original report must be retained by the laboratory in accordance with the laboratory's record retention procedure.

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[k]Based on IS17025:2017(E) Section 7.8.1.1Reporting results

[l]Based on IS17025:2017(E) Section 7.8.1.2 Reporting results

[m]Based on IS17025:2017(E) Section 7.8.2.1 Common requirements for reports (test, calibration, or sampling)

[n]Based on IS17025:2017(E) Section 7.8.8 Amendments to reports

12. Customer Service/Feedback/Complaints

The laboratory should consider the data quality objectives of the customer when proposing which analytical services to offer for a particular scope of work. The laboratory should cooperate and work with customers to ensure customer needs are understood and documented. [o]

The laboratory must seek customer feedback annually related to the quality of their service performance, results package and products delivered to the customer.

The laboratory must have procedures and records to document the following steps concerning complaints: [o]

Acknowledge and document the complaint completely to ensure that the complaint is understood, [o]

The complaint is investigated for validity and accuracy to ensure that the complaint is addressed and resolved, [o]

Investigations must be overseen by management [o]

Investigations must be conducted by personnel other than those involved in initial test/processing

Review should, whenever possible, include empirical evidence/data to support the laboratory's conclusion(s)

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[o]Based on IS17025:2017(E) Section 7.9 Complaints

13. Nonconforming work

Nonconforming work is the occurrence of laboratory activities that do not conform to the quality management system, customer requirements, and/or regulatory requirements. The laboratory must have procedures and retain records for the investigation of nonconforming work. The laboratory must investigate the characteristics and inherent issues of the nonconforming work and determine scope of the nonconforming work.[p]

Nonconforming work must follow the laboratory's cause analysis, risk assessment, and corrective action processes.[p]

[p]Based on IS17025:2017(E) Section 7.10 Nonconforming work

14. Document and Record Control

The laboratory must have a system to control and track the revisions of SOPs, policies, procedures, and external documents.[q] The system must be able to provide a complete list or be housed in an electronic document management system (EDMS, or LIMS) for all SOPs, policies, procedures, and external documents.

The laboratory must have procedures to control revisions, editing, and approval of SOPs and policies for use in the laboratory.[q] The most current controlled version of laboratory SOPs and documents must be available tall staff at their workspace for use. Each document must be approved prior to use in the laboratory by the laboratory management and/or quality personnel to ensure completeness, compliance, and technical correctness.[r]

The laboratory must have procedure(s) that are consistent with legal commitments, regulatory and client requirements. Records must include::

- Designation of authorized users for LIMS
- Retention
- Archival
- Disposition of records
- Storage
- Protection of documents and data including data archives. Back-up/retrieval and cloud-based data retention services.

The laboratory must have procedures to ensure that technical records are complete including all laboratory records and data allowing for an historical reconstruction of the data contained in the final report. This includes, but is not limited to the following:

- All raw data, bench sheets and sample receiving documentation
- Preparation and analysis information
- Instrumentation outputs
- Transfer files for LIMS input
- Data review checklists
- Quality assurance reviews
- Customer service completeness review
- Final report delivered to the customer
- Documentation of all reagents and reference materials indicating traceability, stability use and disposal
- Instrument maintenance, on-going and corrective.

[q]Based on IS17025:2017(E) Section 8.2 Management system documentation

[r]Based on IS17025:2017(E) Section 8.3 Control of management system documents

15. Corrective Action/Risk Analysis (CAP) Process[s]

The laboratory must have a written process describing how to address and record nonconforming work. Once nonconforming work is identified, the laboratory must take the following steps taddress the nonconforming work by applying a cause and risk analysis, and implementing corrective actions. The corrective action once implemented must be monitored or reviewed to ensure their efficacy.

- Address and correct the nonconforming work to control or initially correct the process,
- Evaluate to eliminate the nonconforming work through a review and analysis of data,
- Must have a procedure to perform and document a risk analysis for the nonconforming work
- Determine the cause or causes, as there is rarely a single cause
- Design and implement the corrective action, implement actions to eliminate the underlying cause or causes, and to prevent its recurrence.
- Review the corrective action to ensure its effectiveness on a periodic basis to be defined by the laboratory based on risk and severity. The laboratory must evaluate whether the nonconforming work and its corrective action warrants a change to the quality management system.

[s]Based on IS17025:2017(E) Section 8.7 Corrective actions

16. Internal Audits

Internal audits must be performed by the laboratory on a schedule to cover all laboratory activities on a laboratory determined periodic basis. [t] The laboratory should utilize both horizontal and vertical audit approaches across technical and management areas. The laboratory must retain records of internal audits including, not limited to; checklists, SOP, data review, and CAPA results. [t]

[t]Based on IS17025:2017(E) Section 8.8 Internal audits

17. Management Reviews[u]

Management Reviews are a tool tallow the laboratory to review laboratory activities, assess the effectiveness of the quality management system, CAPA, and external influences upon the laboratory activities. The management review must occur annually including, but not limited to the following areas of review:

- Internal and outside factors that are impactful to the laboratory business
- Changes to the scope, definition, and amount of incoming work
- Ensure Management goals are being met
- Policies and SOPs are relevant and appropriate
- Action items from previous management review meetings have been addressed
- Results from internal and external audits
- Status of CAPAs
- Feedback from customers and employees
- Status of complaints and trending
- Effectiveness of improvements and corrective actions
- Resource allocation (personnel, equipment, consumables, etc.)
- Need for changes to the quality management system

[u]Based on IS17025:2017(E) Section 8.9 Management review

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18. Analytical Technical Requirements for Chemical Analysis

For chemical analysis, the daily batch requirements for quality control must be able to demonstrate that the laboratory is able to produce data of known and documented quality that is fit for purpose for the end user or customer of the laboratory. These goals are documented in the analytical process through the calibration, batch quality control samples, and establishment and monitoring of laboratory generated control limits.

Prior to analysis of samples in a batch, calibration curves must be established for all target analytes; the calibrations must meet the criteria noted in the appendices. The lowest and highest points within a calibration curve represent the working range for the instrument. Accuracy is verified by performing an initial calibration verification (ICV) using a standard derived from a second source.

Where applicable, once calibration curves have been established and verified, a blank is analyzed to ensure that the instrument is free of contamination from the initial calibration or other sources. A continuing calibration verification (CCV) is performed as outlined in the individual analytical appendices to verify that the accuracy of the initial calibration is sustained. If a CCV fails, another CCV can be run immediately. If the second CCV fails, then the laboratory must perform corrective action which may include another initial calibration and instrument maintenance.

APPENDICES

19. Appendix A: Cannabinoid Analysis

Cannabinoids are found in (or structurally related to compounds found in) the plant Cannabis sativa L. Prior to the 2018 Farm Bill, cannabinoids as a class were largely considered to be illegal on a federal level; the Farm Bill authorized the production and sale of hemp, which was defined as "the plant Cannabis sativa L. and any part of that plant… with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."[a] Individual states have further passed laws and developed regulations authorizing the sale of cannabinoids, including delta-9 tetrahydrocannabinol at concentrations higher than 0.3%.

The commonality between all cannabinoid types is their role in and interaction with the endocannabinoid system, more specifically the CB1 and CB2 receptors. Although these cannabinoid receptors can interact with several different classes of compounds, most state and federal regulations largely are limited to phytocannabinoids, which are cannabinoids produced directly by the Cannabis sativa L. plant. As a result, phytocannabinoids are therefore the focus of this appendix, but it should be noted that chemically modified cannabinoids have become increasingly relevant in the current regulatory environment, and will be discussed in more detail in a future whitepaper.

[a] H.R.2 - Agricultural Improvement Act of 2018.

Analytes:

Required Cannabinoid Analytes (chosen for their ubiquity in cannabis plant material and manufactured products)		
Compound	**Abbreviation**	**CAS Number**
Tetrahydrocannabinolic acid (A)	THCA-A	23978-85-0
Delta 9 – Tetrahydrocannabinol	Δ9-THC	1972-08-3
Delta 8 – Tetrahydrocannabinol	Δ8-THC	5957-75-5
Cannabinol	CBN	521-35-7
Cannabigerolic acid	CBGA	25555-57-1
Cannabigerol	CBG	25654-31-3
Cannabidiolic acid	CBDA	1244-58-2
Cannabidiol	CBD	13956-29-1
Additional Analytes (may be required by individual regulators)		
Compound	**Abbreviation**	**CAS Number**
(6aR,9R)-Delta 10 – Tetrahydrocannabinol	(6aR,9R)-Δ10-THC	95543-62-7
(6aR,9S)-Delta 10 – Tetrahydrocannabinol	(6aR,9S)-Δ10-THC	95588-87-7
(9R)-Delta 6a,10a – Tetrahydrocannabinol	(9R)-Δ(6a,10a)-THC	95720-01-7
(9S)-Delta 6a,10a – Tetrahydrocannabinol	(9S)-Δ(6a,10a)-THC	95720-02-8
Tetrahydrocannabivarinic acid	THCVA	39986-26-0
Tetrahydrocannabivarin	THCV	31262-37-0
Cannabichromenic acid	CBCA	185505-15-1
Cannabichromene	CBC	20675-51-8
Cannabichromevarin	CBCV	41408-19-9
Cannabinolic acid	CBNA	2808-39-1
Cannabidivarinic acid	CBDVA	24274-48-4
Cannabidivarin	CBDV	13956-29-1
Cannabicyclolic acid	CBLA	40524-99-0
Cannabicyclol	CBL	21366-63-2
Cannabicitran	CBT	31508-71-1
Any additional Cannabinoids, if labeled in a cannabis good		

Appendix A, Table 1: Required and Additional Cannabinoids

Calculation to determine Total Potential Cannabinoids in a sample:

- Total potential [cannabinoid] concentration (mg/g) = ([cannabinoid] acidic form concentration (mg/g) × 0.877) + [cannabinoid] concentration (mg/g) + ...)
  - where [Cannabinoid] = Any isomers of that specific cannabinoid (in the instance for THC, where there may be multiple isomers present)

Hemp Cannabinoid Analysis Protocol

- Per federal regulations hemp is defined to have a Total delta-9 THC concentration of < 0.3%. If the Total THC is greater than 0.3% then the material is considered marijuana, and is subject to additional legal restrictions and considerations for the lab in terms of handling and disposal.

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Technology/Equipment/Supplies

- Instrumentation recommended: LC-Diode Array Detection, LC-MS
- Methodologies recommended:
  - AOAC Official Method 2018.10 Cannabinoids in Cannabis sativa Dried Flowers and Oils Liquid Chromatography with UV Detection (First Action 2018)
  - AOAC Official Method 2018.11 Quantitation of Cannabinoids in Cannabis Dried Plant Materials, Concentrates, and Oils Liquid Chromatography–Diode Array Detection Technique with Optional Mass Spectrometric Detection (First Action 2018, Revised First Action 2020)
  - If the testing lab wishes to utilize or develop their own method for cannabinoid analysis, preferred analyte recoveries for different matrices can be found in the following SMPRs:
    - AOAC SMPR® 2019.003 Standard Method Performance Requirements (SMPRs®) for Quantitation of Cannabinoids in Plant Materials of Hemp (Low THC Varieties Cannabis sp.)
    - AOAC SMPR® 2017.001 Standard Method Performance Requirements(SMPRs) for Quantitation of Cannabinoids in Cannabis Concentrates
    - AOAC SMPR® 2017.019 Standard Method Performance Requirements (SMPRs®) for Quantitation of Cannabinoids in Edible Chocolate

Batch QC Requirements

- Prior to initiating a batch:
  - Initial Calibration Standards
  - Initial Calibration Verification (ICV) – must perform, at minimum, 2 ICV checks (high, low) at different levels in the calibration curve
- *If above ICVs pass, batches can be run following the sequence below
- Typical Batch QC/ Frequency/ Criteria:
- Batch size: 20 samples
  - Method Blank
  - CCV
  - LCS
  - Duplicate Sample(s) (can be a customer sample in the first set of 10)
  - Samples 1-10
  - CCV every 10 samples
  - Samples 11-20
  - CCV – closing

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Additional QC Recommendations

- Matrix-Specific Quality Control Sample – real, thoroughly characterized in-house sample that is run once a day to track accuracy and precision; should record values in a control chart for monitoring. The sample can also be used for inter-instrument comparisons. Ideal variance (measured by %RSD) should be less than 5%.

Batch Acceptance Criteria

(Note: Some LQC samples include both a "Warning" or "Failure" acceptance criteria. In general, the "Warning" criteria is still enough to deem the batch acceptable for reporting data but suggests a re-calibration or other corrective action prior to running the next batch. Acceptance criteria are more stringent than other analyses, both due to the lower variability provided by the detector type, as well as the expectations of the industry).

Laboratory Quality Control Sample	Frequency	Acceptance Criteria	Corrective Action
Method Blank	One per batch	Not to exceed LOQ	Perform a root cause analysis to determine the source of contamination. Re-prepare Method Blank and reanalyze entire analytical batch.
Laboratory Control Sample (LCS)	One per batch	Recoveries: Warning: 90-110% Failure: 95-115%	Failure: Re-prep LCS and reanalyze. If LCS fails again, determine if failure is a result of sample contamination or matrix effects, or due to improperly calibrated instruments. Remedy issue and reanalyze entire analytical batch.
Matrix Spike/Matrix Spike Duplicate Or Sample/ Sample Duplicate	One set per batch	RPD ≤ 30% for all analytes with concentrations ≥ LOQ	Reanalyze sample and associated matrix spike sample once.
Initial Calibration verification (ICV)	High-, Mid-, Low-points of the calibration curve with second source CRM	Recoveries: High: 95-105% Mid: 90-110% Low: 85-118%	If the recovery for any analyte is outside of the acceptance criteria, recalibrate the instrument. Perform a root cause analysis.
Continued Calibration Verification (CCV)	One per every 10 samples. All analytes in each CCV must meet the criteria.	Recoveries: Warning: 90-110% Failure: 95-115%	Reanalyze all samples that preceded the last CCV that met the acceptance criteria. If CCV samples continue to fail, then recalibrate the instrument.

[a]Adapted from the AOAC SMPR 2019.003 performance requirements for Low-THC hemp samples

Appendix A, Table 2: Batch QC Criteria for Cannabinoid Analysis

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Calibration Criteria

- Basic calibration scheme
  - Recommend two separate calibration curves, separating acid/non-acid standards; acid standards will degrade more readily in protic solvents, and most non-acid standards come dissolved in a protic solvent (methanol).
    - Acid standards – should dilute with non-protic solvents only, example: acetonitrile
    - Non-acid standards – can dilute with either protic- or non-protic solvents, examples: acetonitrile, methanol
  - Dilution factors should be determined gravimetrically; accurate results for samples depend on an accurate calibration curve. Determining dilution factors for standards in g/g allows for higher accuracy and traceability.
  - Minimum number of calibration levels: 5 Levels with linear regression.
  - Calibration points concentrations are laboratory derived
  - Types of calibration:
    - Average Response Factor
    - Linear regression
    - Weighted linear regression (up t1/x)
    - Calibration criteria: $R^2 \geq 0.995$ and RSE < 25%
  - LOQ for analytes tested must be the lowest calibration level within the range of the calibration curve. If testing hemp samples, LOQ for d9-THC must be greater than 0.3% for all matrix types and preparations.

20. Appendix B: Microbial Analysis

Microbial contamination represents an important acute public health concern for cannabis, cannabis derived products and edible products containing cannabis. The testing for microbial contaminants is essential for ensuring public health and safety. The action limits and the organisms listed below are representative of a comprehensive testing program to ensure safer products. Due to the large and expanding acceptable performance tested methods that are acceptable for microbial detection in cannabis, a dedicated methods section was not included in this section. It is instead our recommendation to follow the methods listed on the performance tested methods that your lab utilizes. Any chosen deviations from those methods would be recommended to determine if a verification or validation is needed (see section 17 to help with the determination) and make sure that the appropriateness of the changes are in line with the lab's regulating bodies.

Analytes:

Recommended Minimum Achievable Limits (CFU/g)			
Microbes Tested	**Flower/ Inhalable Compound Concentrate Products**	**Cannabis-Infused Products**	**Cannabis Extract non-solvent & non-CO2**
Total Yeast and Mold	≤100,000	N/A inhalants only	≤1,000
Total Coliform Count	≤1,000	≤100	≤100
Total Aerobic	≤10^5	≤10^5	≤10^5
Bile-Tolerant Gram-Negative Bacteria	≤1,000	≤1,000	≤1,000
Shiga toxin-producing *E. coli* (STEC)	Not detected in 1 gram	Not detected in 1 gram	Not detected in 1 gram
Pathogenic *Salmonella* spp.	Not detected in 1 gram	Not detected in 1 gram	Not detected in 1 gram
Aspergillus flavus, fumigatus, niger & terreus	Not detected in 1 gram (Speciation not required but capability is recommended)	N/A inhalants only	Not detected in 1 gram (Speciation not required but capability is recommended)

Appendix B, Table 1: Recommended Action Limits for Microbial Contamination

Technology/Equipment/Supplies

- Instrumentation recommended: Plating/Petrifilm/Simplate, Plate Reader, Incubator, Thermocycler (Salmonella, STEC, Aspergillus)

Preparation

- Preparation Notes
  - Due to large variations in potential total batch sizes, specifically among cannabis growers, PCR sample weight requirements will be determined by percentage of the total sampled amount.
  - Proper incremental sampling is required in order to accurately analyze microbial loads. To ensure this is done a Sequestered Microbial Sample should be taken.
  - The sequestered microbial sample should fully represent the sample as a whole.
  - Sequestered microbial samples should be homogenized separately from the rest of the sample and using methods that will not impact the microbial load prior to testing. Cryogenic grinding or heat introduction may kill target microbes leading to potential false-negative results, leading to possible harm to the general public.
  - Most AOAC methods for PCR use 10-25g of sample for testing, however due to overall sample batch size this may create undue financial burden when a smaller sample weight may still adequately represent the whole of the batch. Results must include the sample weight used in the analysis (e.g. Negative in 5 g)
  - Verification of any methods using less than the validated amount will be required.
  - Following homogenization of the sequestered microbial sample, at least 10% of the total sample received, by weight, should be used as the PCR prep weight not exceeding 25g or subceeding 1g.
  - Plating will require 1.0 grams of sample
  - A phosphate buffer will be required for plating and an enrichment broth will be needed for PCR i.e. Tryptic Soy Broth or Potato Dextrose Broth

- If PCR is the detection method, it will require an enrichment and incubation of the sample, followed by DNA extraction, prior to running the PCR.
- For PCR detection methods it is recommended to have a "kill step" such as DNAse treatment prior to cell analysis to ensure that only viable DNA is amplified to prevent potential false positives.
- Plating will require dilution gradients for plating that accounts for action limits and accurate counting. Ideally a passing plate should have no more than 100 colonies growing on it.
    - For standard plating using traditional pour plate with agar, total plate count is recommended for plates to have 25-250 or 30-300 colonies to be considered a "countable" range. For total Yeast + Mold, the countable range is considered 10-150 colonies per plate.
    - For alternate methods such as Simplate and Petrifilm granted Performance Tested Method (PTM) status under AOAC for enumerations of yeasts and mold in dried cannabis flower, the countable range recommendations are as follows:
        - Simplate has a range of 10-7,380 for a single dilution
        - Petrifilm total plate count recommends 300 colonies or less
        - Petrifilm Yeast and Mold recommends a maximum 150 colonies
    - PCR batch size is determined by the plate capacity. Most standard thermocyclers have 96 wells, though other cyclers range from 36 t384 wells.
    - A batch or test run is defined as an uninterrupted series of analyses, generally 20 -30 samples including appropriate QC controls. The time limit between filtration of samples cannot exceed 30 mins with an overall batch time of 4 hrs.

Batch QC Requirements

- Plating
    - There should be an exposed plate tact as an environmental negative control to account for environmental contamination during the preparation period.
    - 1 Duplicate sample per batch RSD ≤30%
    - 1 Positive reference target organism spike of live microorganism per batch
    - 1 negative buffer blank per batch
- PCR
    - 1 duplicate sample per batch
    - 1 Positive reference target organism spike of live microorganism per prior to enrichment step per batch
    - 1 negative control blank broth prior to enrichment
    - Internal standards used for all samples to ensure proper amplification is performed by the thermocycler

Batch QC Acceptance Criteria

- Any failing positive or negative control QC will result in a complete batch retest
- If the duplicates fail but all other QC passes, then the sample can be reprepared by the original technician if that prep accurately passes one of the thresholds on one of the original samples the batch can be accepted and the original sample that matched the reprep is accepted
- For PCR if the Internal standard fails to amplify for a specific sample that sample must be prepared again and run in a different batch.

Calibration Criteria

- Basic calibration scheme
  - Plating does not require any calibration
  - Most thermocyclers are calibrated yearly following manufacturer's specification

21. Appendix C: Heavy Metals Analysis

The presence of toxic heavy metals is widespread in the environment. Some of the health issues associated with heavy metals are kidney disease, neuropathy, anemia, cancer, and developmental toxicity.1 Cannabis plants have an exceptional ability to bioaccumulate heavy metals from soil and thus, the impetus for testing cannabis products is even greater. The following appendix provides guidance for testing of heavy metals in cannabis and cannabis-containing matrices.

Analytes

Required elements for all cannabis and cannabis containing products:

Required Heavy Metal Analytes		
Element	**CAS #**	**Routine Achievable LOQ (ng/g)**
Arsenic	7440-38-2	50
Cadmium	7439-92-1	50
Lead	7440-43-9	125
Mercury	7439-97-6	60
Additional Analytes (may be required by individual regulators)		
Element	CAS #	
Antimony	7440-36-0	
Barium	7440-39-3	
Nickel	7440-02-0	
Total Chromium	7440-47-3	
Copper	7440-50-8	
Silver	7440-22-4	
Selenium	7782-49-2	
Zinc	7440-66-6	

Appendix C, Table 1: Analytes for heavy metal analysis

Technology/Equipment/Supplies

- Analytical Instrumentation Recommended: ICP-MS equipped with collision / reaction cell technology. Note: ICP-OES may be suitable in theory, however, the scarcity of literature precedence in the context of cannabis or food matrices precludes recommendation. Generally, ICP-MS is a much more sensitive technique. Mainstream ICP-OES instruments may not be capable of achieving reliable measurement of sub-ppm analyte concentrations, particularly in cannabis matrices.
- Sample preparation instrumentation recommended: Microwave Digestion System capable of reaching 210□.

Methodologies recommended:

- *AOAC Official Method 2021.03 Heavy Metals in a Variety of Cannabis and Cannabis-Derived Products Inductively Coupled Plasma–Mass Spectrometry (First Action 2021)*
- If the testing lab wishes to utilize or develop their own method for heavy metals analysis, preferred analyte recoveries can be found in the following SMPR:
  - *AOAC SMPR® 2020.001 Standard Method Performance Requirements (SMPRs®) for Determination of Heavy Metals in a Variety of Cannabis and Cannabis-Derived Products*

Sample Preparation

- Sample Mass:
  - Minimum 0.5 g
- Digestion Technique (closed vessel system):
  - 0.5 g homogenized sample
  - Acids for digestion:
    - Nitric Acid (HNO_3): Concentrated (Ultrapure or equivalent)
    - Hydrochloric Acid (HCl): Concentrated (Ultrapure or equivalent)
      - Note: HCl used for Hg stabilization
  - Diluent for Sample Preparation:
    - 1% - 5% (v/v) HNO_3 / 0.5% (v/v) HCl solution in DI Water (Resistance > 18 MΩ•cm)
  - Rinse Blank:
    - 1% - 5% (v/v) HNO_3 / 0.5% HCl in DI Water (Resistance > 18 MΩ•cm)
- Additional notes on sample preparation and digestion:
  - Closed-vessel microwave digestion vs. hot plate digestion at ambient pressure:
    - Closed-vessel microwave digestion:
      - Preferred digestion method (easiest and most practical). A closed-vessel digestion system significantly reduces loss of nitric acid. Increased vessel pressure increases the nitric acid boiling point; therefore, higher digestion temperatures can be reached. Higher temperatures (up to 210 °C) are often needed for complete digestion of complex matrices. Time required for digestion is approximately 1 hour, depending on the microwave method.

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- Hot plate digestion (not recommended):
  - The boiling point of nitric acid at ambient pressure is ~181 °C. Often, plant materials and concentrates require temperatures > 181 °C for full digestion. The digestion process may take several hours (i.e., 3-5 hours). During this time, the operator must replenish the nitric acid that boils out of the mixture. The possibility of contamination is greater with an open container. Additionally, mercury can potentially evaporate out of the solution.

- Predigestion recommended for extracts, distillates, isolates, etc. A 15-minute predigestion to initiate the breakdown of hydrocarbons. Use caution when digesting samples containing alcohol (e.g. cannabis ethanol extracts) as they will rapidly increase in volume and can produce a violent reaction.
- Glass vials - may contain lead. Acid wash recommended before use.
- Closed vessels - be vigilant of ruptured caps; may hinder reaching higher digestion temperatures.
- Hydrogen peroxide (H_2O_2) - using a small volume of hydrogen peroxide may be useful for achieving full digestion of difficult matrices (e.g. concentrates), however it is typically not necessary in most cases. Addition of H2O2 leads to regeneration of nitric acid, and thus helps in sustaining the digestion process. Note: it dilutes the acid strength; denatures into water at high temperatures (~ 150 °C).

Batch QC Requirements :

- Calibration:
  - Initial Calibration Standards
  - Initial Calibration Verification (ICV) - either an alternate lot or alternate product containing the same analytes, or an alternate manufacturer. If the ICV passes (according to guidelines in Table 1), continue the batch sequence described below.
- Batch size: ≤ 20 samples
  - Reagent Blank
  - Continuing Calibration Verification (CCV)
  - Method Blank
  - Laboratory Control Sample (LCS)
  - Matrix Spike (not mandatory; informative)
  - Duplicate of the LCS or duplicate of matrix spike (for precision)
  - Samples 1-10
  - CCV every 10 samples
  - Samples 11-20
  - CCV – closing

Batch QC Acceptance Criteria

Laboratory Control Sample	Frequency	Acceptance Criteria	Corrective Action
Method Blank	One per digestion batch to ensure no contaminants in vessels	Not to exceed LOQ	Failure: Reanalyze sample; if the sample fail again, perform a root cause analysis to determine the source of contamination, reprep and reanalyze the entire analytical batch. .
Laboratory Control Sample (LCS)	One per batch	Recoveries: Warning: 90-110% Failure: 80-115%	Failure: Re-prep and reanalyze entire analytical batch, or if necessary, re-run initial cal curve
Matrix Spike	One per batch Refer to AOAC SMPR 2021.001, run a blank matrix, prior to spiking	No accuracy requirement (informative)	N/A
Laboratory Control Sample Duplicate or Matrix Spike Duplicate	One or the other; purpose is to assess batch precision.	RPD < 30%	Failure: Reanalyze samples; if the RPD is still > 30%, reprep and reanalyze all samples in the analytical batch.
Initial Calibration verification (ICV)	Mid-point on the calibration curve with second source standard; to be run immediately after the calibration curve.	% Recovery must be between 80-115%a:	Failure: Reanalyze ICV one time. If it fails again, determine source of failure, re-prep and reanalyze ICV and/or calibration curve, if necessary.
Continued Calibration Verification (CCV)	Each set of 10 or portion of 10 samples must be bracketed by CCVs. Each CCV must meet the criteria. Minimum of three CCVs per batch of 20 (or two per batch of 10).	% Recovery must be between 80-115%[a]:	Failure: Reanalyze all samples that are either followed by or preceded by failing CCVs. Two consecutive CCV failures should be followed by troubleshooting and re-running the initial cal curve and all samples in the analytical sequence

[a]Refer to AOAC SMPR® 2020.001

Appendix C, Table 2: Batch Acceptance Criteria for Heavy Metal Analysis

Calibration Criteria

- Basic Calibration Scheme
  - Number of Calibration Levels: minimum 5
    - Prepared weekly or as needed to maintain QCs
  - Calibration Concentrations:
    - Determined by laboratory based on concentration of analytes typically found in samples
    - Calibration Blank: 1 - 5% HNO3 / 0.5% HCl in DI Water (Resistivity > 18 MΩ⍰cm)

- Prepare blank solutions the same day as analysis
- Regression: Linear or weighted linear (1/x)
- R2 ≥ 0.995; RSE < 25%
- LOQ for analytes tested must be either the lowest calibration level within the range of the calibration curve or at a concentration that achieves a S/N > 10 within the calibration curve.

- NOTE: It is suggested/required in some states that a CRM/SRM be included as a sample for validation.

Calculations

Note: These can be automatically performed in most software platforms

- Concentration (ppb, ng/g) = S × DF × (*M*/*m*)
  - S: concentration of analyte in analytical solution (ng/g)
  - *M*: mass (g) of analytical solution
  - *m*: mass of analytical portion (g)
  - DF: dilution factor (=1 if analytical solution is not diluted)
- Spike Recovery (%) = $[(C_{x+s}-C_x) / (C_sM_s/M_x)] \times 100$
  - C_{x+s}: concentration determined in spiked sample (ng/g)
  - C_x: concentration determined in unspiked sample (ng/g)
  - C_s: concentration of spiking solution (ng/g)
  - M_s: mass of spiking solution added tan analytical portion (g)
  - M_x: mass of analytical portion (g)
- Interference Corrections:

  Isobaric interferences can interfere with the analyte signal. Interference from polyatomic and doubly-charged isobaric species can be sufficiently mitigated (although not always fully) by operating in KED mode (Kinetic Energy Discrimination) using He gas in a collision cell. Elemental isobaric interferences and residual polyatomic or doubly charged isobaric interferences can be mathematically corrected for using interference correction equations that are well-known in literature.[2,3]

  - Interference correction equation for ^{111}Cd: Corrects for residual MoO interference
    - Mc(111) = M(111) - M(108) × 1.18 + M(106) × 0.712
  - Interference correction equation for ^{115}In: Corrects for ^{115}Sn interference
    - Mc(115) = M(115) - M(118) × 0.0149
  - Interference correction equation for ^{75}As:
    - Correcting for $^{150}Sm^{2+}$ and $^{150}Nd^{2+}$
      - Mc(75) = M(75) - M(72.5) × 0.6747 - M(73.5) × 0.4923

- Correcting for $^{75}ArCl^{+}$ and ^{77}Se
  - $Mc(75) = M(75) - M(77) \times 3.13 + M(82) \times 2.73$
- Pb Isotopes: Summation of main Pb isotopes at m/z 206, 207 & 208
  - $Mc(208) = M(206) + M(207) + M(208)$

Reporting

- Ultimately, analyte concentrations should be converted / reported in µg/g or ng/g of sample

References

1. Jaishankar, M.; Tseten, T.; Anbalagan, N.; Mathew, B. B.; Beeregowda, K. N.; "Toxicity, mechanism and health effects of some heavy metals," **2014**, 7, 60-72.
2. May, T. W.; Wiedmeyer, R. H. "A Table of Polyatomic Interferences in ICP-MS"; *Atomic Spectroscopy*, **1998**, 19, 150-155.
3. "Inductively Coupled Plasma - Mass Spectroscopy," EPA Method 6020A.

22. Appendix D: Pesticides and Mycotoxin Analysis

The following appendix provides guidance for analysis of pesticides and mycotoxins in cannabis and cannabis-derived products. The pesticide analytes to be considered are listed in Table 1; the list was adapted from the document AOAC SMPR 2018.011. The recommended target LOQs described in the AOAC document were deemed to be impractically low in the context of non-hemp cannabis plant material, therefore, target LOQs were revised based on a survey of achievable LOQs collected from several testing laboratories. Pesticide analysis can be divided between LC-MS/MS and GC-MS/MS methods. The mycotoxin analytes to be considered are listed in Table 2. Typically, LC-MS/MS is the preferred method for mycotoxin analysis. Often, pesticides and mycotoxins can be analyzed using the same analytical method, therefore, the guidance is combined in this appendix.

Analytes

Compound	CAS #	Routine Achievable LOQ (ug/g)
Abamectin	71751-41-2	0.1
Acephate	30560-19-1	0.06
Acequinocyl	57960-19-7	0.1
Acetamiprid	135410-20-7	0.06
Aldicarb	116-06-3	0.075
Allethrin	584-79-2	0.2
Ancymidol	12771-68-5	0.05
Azadirachtin	108168-76-9	1.0
Azoxystrobin	131860-33-8	0.06
Benzovindiflupyr	1072957-71-1	0.05
Bifenazate	149877-41-8	0.06

Compound	CAS #	Routine Achievable LOQ (ug/g)
Bifenthrin	82657-04-3	0.1
Boscalid	188425-85-6	0.06
Buprofezin	69327-76-0	0.05
Captan	133-06-2	0.6
Carbaryl	63-25-2	0.1
Carbofuran	1563-66-2	0.06
Chlorantraniliprole	500008-45-7	0.1
Chlordane	57-74-9	0.075
Chlorfenapyr	122453-73-0	0.0875
Chlormequat chloride	999-81-5	0.1
Chlorpyrifos	2921-88-2	0.06
Clofentezine	74115-24-5	0.06
Clothianidin	21088-92-5	0.05
Coumaphos	56-72-4	0.06
Cyantraniliprole	736994-63-1	0.02
Cyfluthrin	68359-37-5	0.3
Cypermethrin	52315-07-8	0.3
Cyprodinil	121552-61-2	0.05
Daminozide	1596-84-5	0.1
Deltamethrin	52918-63-5	0.3
Diazinon	333-41-5	0.06
Dichlorvos	62-73-7	0.075
Dimethoate	60-51-5	0.06
Dimethomorph	110488-70-5	1.0
Dinotefuran	165252-70-0	0.05
Dodemorph	1593-77-7	0.05
Endosulfan 1 (alpha)	959-98-8	0.05
Endosulfan II (beta)	33213-65-9	0.15
Endosulfan sulfate	1031-07-8	0.075

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Compound	CAS #	Routine Achievable LOQ (ug/g)
Ethephon	16672-87-0	1.0
Ethoprophos	13194-48-4	0.06
Etofenprox	80844-07-1	0.06
Etoxazole	153233-91-1	0.06
Etridiazole (Terrazole)	2593-15-9	0.03
Fenhexamid	126833-17-8	0.1
Fenoxycarb	79127-80-3	0.06
Fenpyroximate (mix of isomers)	111812-58-9	0.06
Fensulfothion	115-90-2	0.02
Fenthion	55-38-9	0.02
Fenvalerate (Sanmarton)	51630-58-1	0.1
Fipronil	120068-37-3	0.06
Flonicamid	158062-67-0	0.06
Fludioxonil	131341-86-1	0.06
Fluopyram	658066-35-4	0.02
Flurprimidol	56425-91-3	0.01
hexythiazox	78587-05-0	0.06
Imazalil	35554-44-0	0.06
Imidacloprid	138261-41-3	0.06
Iprodione	36734-19-7	0.5
Kinoprene	37882-31-8	0.5
Kresoxim-methyl	143390-89-0	0.06
Malathion	121-75-5	0.06
Metalaxyl	57837-19-1	0.1
Methiocarb	2032-65-7	0.06
Methomyl	16752-77-5	0.2
Methoprene	40596-69-8	2.0
Methyl Parathion	298-00-0	0.06
Mevinphos	7786-34-7	0.06

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Compound	CAS #	Routine Achievable LOQ (ug/g)
MGK-264	113-8-4	0.1
Myclobutanil	88671-89-0	0.06
Naled (Systhane)(Dibrom)	300-76-5	0.075
Novaluron	116714-46-6	0.05
Oxamyl	23135-22-0	0.25
Paclobutrazol	76738-62-0	0.06
Pentachloronitrobenzene (Quintozene)	82-68-8	0.1
Permethrin (mix of isomers)	52645-53-1	0.3
Phenothrin (d-phenothrin)	26002-80-2	0.05
Phosmet (Imidan)	732-11-6	0.06
Phosmet (oxon)	3735-33-9	0.1
Piperonyl butoxide	51-03-6	0.5
Pirimicarb	23103-98-2	0.02
Prallethrin (mix of isomers)	23031-36-9	0.1
Propiconazole (tilt)	60207-90-1	0.06
Propoxur (Baygon)	114-26-1	0.06
Pyraclostrobin	175013-18-0	0.02
Pyrethrin (mix of isomers)	8003-34-7	0.3
Pyridaben	96489-71-3	0.06
Resmethrin	10453-86-8	0.1
Spinetoram	187166-40-1	0.06
Spinosad (mixture of A and D)	168316-95-8	0.06
Spirodiclofen	148477-71-8	0.1
Spiromesifen	283594-90-1	0.1
Spirotetramat	203313-25-1	0.06
Spiroxamine	118134-30-8	0.06
Tebuconazole	107534-96-3	0.06
Tebufenozide	112410-23-8	0.02
Teflubenzuron	83121-18-0	0.05

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Compound	CAS #	Routine Achievable LOQ (ug/g)
Tetrachlorvinphos	961-11-5	0.02
Tetramethrin	7696-12-0	0.1
Thiacloprid	111988-49-9	0.06
Thiamethoxam	153719-23-4	0.25
Thiophanate-methyl	23564-05-8	0.05
Trifloxystrobin	141517-21-7	0.06

adopted from AOAC SMPR 2018.011

Appendix D, Table 1: Pesticide Analytes to be Considered

Analyte	CAS #	Routine Achievable LOQ (ug/g)
Aflatoxin B1	1162-65-8	0.005
Aflatoxin B2	7220-81-7	0.005
Aflatoxin G1	1165-39-5	0.005
Aflatoxin G2	7241-98-7	0.005
Ochratoxin A	303-47-9	0.02

Appendix D, Table 2: Mycotoxin Analytes to be Considered

- Concentration ranges for each analyte
  - Range of concentrations that produces a linear calibration curve
  - Pesticide and mycotoxin concentrations typically found in samples that the laboratory has received should be considered when defining the upper limit of the calibration curve.

Technology/Equipment/Supplies

- Instrumentation recommended:
  - Both LC-MS/MS and GC-MS/MS instruments at a minimum.
- Instrument peripherals recommended:
  - Columns: biphenyl, polar C18, or comparable.
  - MS sources for LC-MS/MS: Electrospray Ionization (ESI) or Atmospheric Pressure Chemical Ionization (APCI)

Preparation

- Preparation Notes
  - Sample amount: no less than 0.5 gram, provided that the sample is homogenized thoroughly (particularly biomass, edibles).
  - Solvents/Reagents
    - LC-MS grade solvent (refer to standardized methods)
    - Strongly suggest use of internal standards (isotopically labeled), particularly for analytes that are prone to degradation or issues with extraction from matrix.
    - Appropriate additives, if needed, promote stabilizing analytes that are prone to degradation.
  - Preparation technique
    - Homogenization
      - Blending using a food processor or similar apparatus
      - Stirring (extracts, oils, tinctures, etc.)
      - Cryogrinding
    - Extractions Types
      - Solid-liquid extraction
      - QuEChERS
      - SPE
  - Final extract
    - Final Volume - dilution volume determined by individual labs
    - Final Reagents - determined by individual labs

Batch QC Requirements

- Calibration:
  - Initial Calibration Standards
  - Initial Calibration Verification (ICV) - if the ICV passes (according to guidelines in Table 3), continue the batch sequence described below.
- Batch size: ≤ 20 samples
  - Continuing Calibration Verification (CCV)
  - Reagent Blank
  - Method Blank
  - Laboratory Control Sample (LCS; Spiked Method Blank)

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- MS/MSD (for precision and informative)
  - sample duplicate if MS/MSD are not available
- Samples 1-10
- CCV every 10 samples
- Samples 11-20
- CCV-closing

- Batch acceptance criteria is described in Table 3.

- Additional Considerations:
  - It is recommended that each analyte/internal standard peak includes at least one qualifying ion to confirm identity.
  - *Analytes with multiple isomers:* Several analytes in Table 1 are composed of multiple isomers or derivatives that are represented by a single CAS number (e.g. chlordane, spinosad, pyrethrins, etc.). Often there is no information available about concentrations of individual components on the certificate of analysis. For example, a technical grade mixture of chlordane may contain >100 derivatives that make up the 1000 ug/mL certified concentration. Most compounds with multiple isomers can be categorized into two groups: 1) If individual concentrations of each isomer or derivative are clearly listed on the certificate of analysis, they should be integrated, calibrated, and quantified as separate peaks and then summed to produce the reportable concentration. 2) If isomer/derivative peaks are overlapping or very close together (i.e., within the same scan window) in the chromatographic profile, they should be integrated, calibrated, and quantified together as one peak. In the case of complex mixtures of isomers (e.g. chlordane), it is not feasible to try to quantify and sum all isomers in the mixture. Instead, the recommended course of action is to quantify at least two of the most prominent isomers/derivatives using the certified concentration and then average the measurements to represent the total analyte concentration. For example, alpha- and gamma-chlordane, the two most prominent isomers in technical grade chlordane, can be individually quantified and then averaged to represent the concentration of the >100 derivatives present in the mixture.

Batch QC Acceptance Criteria

Laboratory Quality Control Sample	Frequency and Level	Acceptance Criteria	Corrective Action
Method Blank (Definition: a pre-tested matrix that is free of analytes, prepared in the same way as a typical sample).	1 per batch	Not to exceed LOQ	**Failure:** Perform a root cause analysis to determine the source of contamination. If the reagent(s) is not contaminated, reanalyze entire analytical batch. If reagent(s) is contaminated, re-prepare samples with uncontaminated reagent(s) and reanalyze entire analytical batch.
Laboratory Control Sample (LCS) (Definition: a pre-tested matrix that is free of analytes - same as method blank - spiked with a known concentration of all analytes, and prepared in exactly the same way as a typical sample)	2 LCS per batch. One low level LCS (at or near action limit) to determine if sensitivity is maintained in batch; one mid-level LCS.	Recovery 70% t130%	**Failure:** Re-analyze the LCS. If the LCS fails again, re-prepare samples and reanalyze or re-run initial cal curve.
Matrix Spike/Matrix Spike Duplicate (a sample within the batch spiked with a known level of analytes)	2 per batch (1 MS, 1 MSD) Spike should be mid-level	- relative percent difference (RPD) must be <30% - no accuracy requirement (for informational purposes, such as the evaluation of matrix effects)	**Failure:** Reanalyze sample and associated matrix spike sample once. If RPD is still not acceptable, re-prepare samples and reanalyze
Initial Calibration verification (ICV) - a second source CRM	- Midpoint of the calibration curve - One ICV run directly after calibration curve	Recovery 70% t130%	**Failure:** Reanalyze the ICV once, if it fails again, re-prepare ICV. If the re-prepared ICV fails, re-prepare and/or re-run calibration curve as necessary.
Continued Calibration Verification (CCV)	Each set of 10 or portion of 10 samples must be bracketed by CCVs. Each CCV must meet the criteria. **Minimum of three CCVs per batch of 20 (or two per batch of 10)**	Recovery 70% t130%	**Failure:** Reanalyze all samples that are either followed by or preceded by failing CCVs. Two consecutive CCV failures should be followed by troubleshooting and re-running the initial cal curve and all samples in the analytical sequence

Appendix D, Table 1: QC Acceptance Criteria for Pesticide Batches

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Calibration Criteria

- Basic calibration scheme
  - Number of calibration levels: minimum six-point calibration for quadratic curves, minimum five-point calibration for linear curves.
  - Type of calibration - Linear, weighted linear, or quadratic regression
  - Calibration concentrations - LOQ determined as 50% of the action limit; upper range should be dictated by typical concentrations seen in samples by lab.
  - Calibration criteria - RSE < 30%. R2 value for curves minimum 0.99.
  - Calibration frequency - instrument should be calibrated as often as necessary; dependent on the results of the ICV, CCV, and/or QC samples. If significant drift is detected, then consider recalibration.
- ICV
  - Should be run immediately after the instrument calibration
  - Criteria 70-130 % recovery

23. Appendix E: Moisture Content Analysis

Moisture content and water activity are two analytical procedures to measure the amount of water in a sample. In cannabis and hemp labs, the two procedures are performed for distinct and different reasons. Moisture content is commonly used to determine a dry weight correction factor, while water activity is useful mainly in determining the ability of microorganisms to grow on the sample.

Moisture Content is the measure of the quantity of water present in a sample, expressed as a percentage by weight of the total sample. The historical importance of the measurement of moisture content in the cannabis and hemp spaces is to provide a correction factor for the amount of water in the plant material as a way to normalize the measurement of other cannabinoids, particularly delta-9 tetrahydrocannabinol (d9-THC). Raw hemp material typically contains 70-80% water by weight when removed from the field and is then dried to under approximately 15% moisture prior to performing analysis.

The 2018 Farm Bill defines hemp as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." In response, the USDA has established guidelines for the analytical testing of hemp that require the concentration of delta-9 tetrahydrocannabinol to be determined and reported on a dry weight basis. The final reported result is corrected for moisture to report on the dry weight basis.

Moisture is measured either through gravimetric means (either Loss on Drying, which involves cycles of heating and weighing a sample to measure the loss of water, or a Moisture Analyzer, which is a balance with a built-in heater that applies heat directly to the sample to vaporize water and measures the change in mass) or through chemical means using Karl Fischer, the determination of free water by measuring the oxidation reaction of iodine and sulfur dioxide in the presence of water.

Technology/Equipment/Supplies

- Instrumentation recommended:
  - Oven - for Loss on Drying
  - Moisture Analyzer
  - Karl Fischer Titrator
- Instrumentation must be qualified and calibrated prior to use

Moisture Methodologies/References recommended:

- AOAC 930.15 Moisture in Animal Feed
- AOAC 966.02 Loss on Drying (Moisture) in Tobacco
- USP <731> Loss on Drying
- USP <921> Water Determination
- The method of analysis for moisture, regardless of technique, must be validated to ensure the accuracy and precision of the results. The impact on the final reported results should also be evaluated, such that the moisture result does not negatively influence the dry weight result.

Batch QC Requirements

(Where applicable, in some cases based on instrumentation used a particular QC requirement may not apply) See Tables 1 through Table 3 for instrument specific batch QC Requirements.

- Recommended max batch size 20 samples

Additional QC Requirements:

The laboratory should periodically participate in a PT program.

Batch QC Acceptance Criteria

Laboratory Control Sample	Method	Frequency	Acceptance Criteria	Corrective Action
Laboratory Control Sample (LCS)	Spike a sample with water to determine recovery (e.g. Cellulose)	Once per batch	90-110 % Recovery	Verify the calibration of the balance. Out of specification investigation.
Duplicate Sample	NA	One set of duplicates per batch	< 10 % Relative Percent Difference	Homogenize sample again sample and reanalyze.
Continued Calibration Verification (CCV)	Verify the Balance using a Calibrated Weight Set	Daily	< 0.1 % difference from assigned mass	If balance calibration is invalidated remove equipment from service, and calibrate using an IScertified provider.

Appendix E, Table 1: QC Acceptance Criteria for the Loss on Drying/Moisture Analyzer Technique

Laboratory Control Sample	Method	Frequency	Acceptance Criteria	Corrective Action
Instrument Standardization/ Titer Determination	Perform based on manufacturers recommendation or defined procedure.	Daily	NA	Variability in determined titer values could be indicative of poor analytical technique or instrument performance. Perform root cause analysis to determine source of error.
Method Blank	Determine impact of potential environmental moisture by titrating empty vessel using the same solvents used under test.	Once per batch	< LOQ	Perform a root cause analysis to determine the source of contamination
Duplicate Sample	NA	One set of duplicates per batch	< 10 % Relative Percent Difference	Homogenize sample again sample and reanalyze.
Continued Calibration Verification (CCV)	Perform a water standard check.	Every 10 samples	Within the stated criteria of the water standard used.	Perform a root cause analysis to determine the assignable cause (e.g. room humidity or sample homogeneity). Rerun standard, after consecutive failures reanalyze samples since last passing CCV.

Appendix E, Table 2: QC Acceptance Criteria for the Karl Fischer Technique

24. Appendix F: Residual Solvents Analysis

Solvents are volatile chemicals that are often used in the extraction of cannabinoids and in the processing of cannabis products. Residual solvents may remain if proper techniques are not used to remove them completely. Residual solvents analysis deals with the identification and quantitation of these remaining compounds in finished and unfinished cannabis products.

Residual Solvents & Processing Chemicals Analytes:

Individual states and regulatory bodies have significant differences in the analyte lists and action limits for residual solvents and processing chemicals. Tables 1-3 below present a comprehensive list of analytes from USP <467> (developed for pharmaceutical products); along with recommended action limits (most action limits from USP <467>, unless indicated otherwise). Analytes that are commonly used in cannabis and hemp are selected in bold, and should be considered as a minimum list of analytes to include as required analytes to screen for.

It is important to recognize USP<467> was developed using GC-FID as the analytical technique for the analysis of pharmaceutical raw material ingredients and not for plant material. The USP <467> method also requires a secondary column confirmation since an FID is a non-specific detector.

Since cannabis plant material and derived products are considered complex matrices, using an FID for detection most likely will not be sufficient to reach the concentration limits in the tables below. For these reasons, GC-MS detection is recommended to achieve the additional sensitivity and specificity required to meet these limits for cannabis plant and product matrices and also eliminates the need for a secondary column confirmation of results.

Note: The analytes provided in Tables 1-3 include routine achievable LOQs provided from laboratories participating in the development of this document; analytes in these tables that are not tested by any participating laboratory were left without LOQ recommendations.

Solvent	CAS Number	USP Health Concentration Limit (ppm)[a]	Routine Achievable LOQs (ppm)	Concern
Benzene	71-43-2	2	0.6	Carcinogen
Carbon Tetrachloride	56-23-5	4	-	Toxic and environmental hazard
1,2-Dichloroethane	107-06-2	5	1	Toxic
1,1-Dichloroethene	75-35-4	8	4	Toxic
Ethylene Oxide	75-21-8	1	2.5	Carcinogen, neurological impairment
1,1,1-Trichloroethane	71-55-6	1500[b]	-	Environmental hazard

[a] From USP 467 Interim Revision Announcement (unless otherwise indicated) .
[b] OSHA Standard 29 CFR 1910.1047
Appendix F, Table 1: Residual Solvents Class 1 - Solvents to be Avoided

Solvent	CAS Number	USP Health Conc Limit (ppm)[a]	Routine Achievable LOQs (ppm)	Solvent	CAS Number	USP Health Conc Limit (ppm)[a]	Routine Achievable LOQs (ppm)
Acetonitrile	75-05-8	410	200	2-Methoxyethanol	109-86-4	50	-
Chlorobenzene	108-90-7	360	-	Methylbutylketone	591-78-6	50	-
Chloroform	67-66-3	60	1	Methylcyclohexane	108-87-2	1180	-
Cumene	98-82-8	70	-	Methylene chloride	75-09-2	600	62.5
Cyclohexane	110-82-7	3880	-	Methylisobutylketone	108-10-1	4500	-
1,2-Dichloroethene	156-59-2	1870	-	N-Methylpyrrolidone	872-50-4	530	-
1,2-Dimethoxyethane	110-71-4	100	-	Nitromethane	75-52-5	50	-
N,N-Dimethylacetamide	127-19-5	1090	-	Pyridine	110-86-1	200	-
N,N-Dimethylformamide	68-12-2	880	-	Sulfolane	126-33-0	160	-

Solvent	CAS Number	USP Health Conc Limit (ppm)[a]	Routine Achievable LOQs (ppm)	Solvent	CAS Number	USP Health Conc Limit (ppm)[a]	Routine Achievable LOQs (ppm)
1,4-Dioxane	123-91-1	380	-	Tetrahydrofuran	109-99-9	720	-
2-Ethoxyethanol	110-80-5	160	-	Tetralin	119-64-2	100	-
Ethylene glycol	107-21-1	620	-	Toluene	108-88-3	890	200
Formamide	75-12-7	220	-	Trichloroethylene	79-01-6	80	0.5
Hexane[b]	110-54-3	290	200	Xylene	1330-20-7	2170	200
Methanol	67-56-1	3000	500	Ethylbenzene[c,d]	100-41-4	100	7

[a] From USP 467 Interim Revision Announcement (unless otherwise indicated). [b] Sum of isomers.
[c] May be combined with xylenes. [d] OSHA Standard 1910.1000

Appendix F, Table 2: Residual Solvents Class 2 - Solvents to be Limited

Solvent	CAS Number	USP Health Conc Limit (ppm)[a]	Routine Achievable LOQ	Solvent	CAS Number	USP Health Conc Limit (ppm)[a]	Routine Achievable LOQ
Acetic acid	64-19-7	5000	-	Heptane	142-82-5	5000	700
Acetone	67-64-1	5000	700	Isobutyl acetate	110-19-0	5000	-
Anisole	100-66-3	5000	-	Isopropyl acetate	108-21-4	5000	-
1-Butanol	71-36-3	5000	-	Methyl acetate	79-20-9	5000	-
2-Butanol	78-92-2	5000	-	3-methyl-1-butanol	123-51-3	5000	-
Butyl acetate	123-86-4	5000	-	Methylethylketone	78-93-3	5000	-
tert-Butylmethyl ether	1634-04-4	5000	-	2-Methyl-1-propanol	78-83-1	5000	-
Dimethyl sulfoxide	67-68-5	5000	-	Pentane[b]	109-66-0	5000	200
Ethanol	64-17-5	5000	700	1-Pentanol	71-41-0	5000	-
Ethyl acetate	141-78-6	5000	200	1-Propanol	71-23-8	5000	-
Ethyl ether	60-29-7	5000	700	2-Propanol	67-63-0	5000	700
Ethyl formate	109-94-4	5000	-	Propyl acetate	109-60-4	5000	-
Formic acid	64-18-6	5000	-	Triethylamine	121-44-8	5000	-
Propane[c,d]	74-98-6	5000	500	Butane[b,d]	106-97-8	5000	200

[a] From USP 467 Interim Revision Announcement (unless otherwise indicated). [b] Sum of isomers.
[c] OSHA Standard 1910.1000. [d] NIOSH REL (recommended exposure limits).

Appendix F, Table 3: Residual Solvents Class 3 - Solvents with Low Toxic Potential

For information regarding membership, contact Richard Bright
Tel: 202-887-5872 | Email: rbright@acil.org | www.acil.org

Technology/Equipment/Supplies

- Instrumentation recommended:
  - Headspace GC-MS (preferred - headspace autosampling leads to lower matrix interferences, MS more definitively identifies the compounds of interest)
  - Liquid Injection GC-MS
- Equipment recommended:
  - Mininert valves - valves that allow for sampling of standards with a gastight syringe, yet create an airtight seal to avoid evaporation of volatile solvents
  - Vials that fit Mininert caps - should match closely with target volumes for standards, to minimize headspace in standard vial
  - Headspace vials - 10 mL: can help with sensitivity, 20 mL: may help avoid evaporation after addition of solution to vial
- Methodologies recommended:
  - **USP 467 Residual Solvents**
- If the testing lab wishes to utilize or develop their own method for Residual solvent analysis, that method must be validated in each matrix type (concentrate, flower, tincture, edible, topical, etc) that will be tested in the laboratory to ensure the accuracy and precision of the results.

Additional Laboratory Considerations:

- The extraction/dilution solvent chosen for preparation of any standards or samples must follow two rules:
  - All analytes must be soluble in the extraction solvent
  - The extraction solvent must not be included on the analyte list itself. Common solvents for residual solvent analysis are N,N-dimethylacetamide (DMA or DMAc), dimethylsulfoxide (DMSO), triacetin, and trimethylbenzene
- The laboratory should be set up to avoid contamination by other solvents used in the preparation of laboratory samples. Examples can include:
  - Storing and using laboratory solvents in a fume hood
  - Preparing residual solvent samples in a separate fume hood or separate area of the building
- Background levels of contamination from laboratory solvents must be well-controlled and well below the action limit for each solvent. The determination of the LOD/LOQ for each analyte must take the background levels of the analyte into consideration; if the LODs are set below the background levels for each analyte, the laboratory may be reporting results for those analytes that are not representative of the sample. This can be achieved by following the protocol described in EPA 40 CFR 136 Appendix B, which involves a statistical analysis of variance using at least 7 samples spiked with analytes at levels near an estimated detection limit.

Batch QC Requirements

- Prior to starting an analytical batch:
  - Initial Calibration Standards
  - Initial Calibration Verification (ICV) – *If ICV passes, BEGIN BATCH SEQUENCE below

Typical Batch QC/ Frequency/ Criteria:

- Batch size: 20 samples
  - Instrument Blank (aka Reagent Blank)
  - Method Blank
  - CCV
  - LCS (Spiked Method Blank)
  - Duplicate Sample(s)
  - Samples 1-10
  - CCV every 10 samples
  - Samples 11-20
  - CCV – closing

Batch QC Acceptance Criteria

Laboratory Control Sample	Frequency	Acceptance Criteria	Corrective Action
Method Blank	One per batch	Not to exceed LOQ	**Failure:** Perform a root cause analysis to determine the source of contamination and remove/remedy it. *Common sources of contamination: 1) mobile phase waste from LC analysis. 2) solvents used in preparation of other analyses, 3) other samples with high levels of solvent 4) carryover from previous injection* Reanalyze a new Method/Reagent Blank with entire analytical batch. If solvent for Reagent Blank is contaminated, re-prep and reanalyze entire analytical batch using a different solvent source.
Laboratory Control Sample (LCS)	One per batch.	Recoveries: 70-130% (analytes with BP<0°C - propane, butane, isobutane - should be exempted from recovery requirements provided the analytes pass in the CCV)	**Failure:** Re-prep LCS and reanalyze. If LCS fails again, determine if failure is a result of sample contamination or matrix effects, or due to improperly calibrated instruments. Remedy issue and reanalyze entire analytical batch.
Laboratory Replicate Sample	One per batch	< 20 % RPD for all analytes with concentrations >LOQ	Reanalyze the sample and associated matrix spike sample once to verify the matrix impact. **Failure:** Re-prep samples and reanalyze

Laboratory Control Sample	Frequency	Acceptance Criteria	Corrective Action
Initial Calibration verification (ICV)	Mid-point of the calibration curve with second source CRM	Recoveries: 70-130%	If the recovery for any analyte is outside of the acceptance criteria, recalibrate the instrument. Perform a root cause analysis.
Continued Calibration Verification (CCV)	One per every 10 samples. All analytes in each CCV must meet the criteria.	Recoveries: 80-120% (exempting analytes listed below) **70-130% for the following: -analytes with BP<0°C -methanol -acetonitrile -acetone -isopropyl alcohol -ethanol	Reanalyze all samples that preceded the last CCV that met the acceptance criteria. If CCV samples continue to fail, then recalibrate the instrument. ** These are common laboratory solvents found in cannabis laboratories for extractions for other analyses. The acceptance criteria are reflective of the potential low-level contamination.

Appendix F, Table 4: Batch QC Acceptance Criteria for Residual Solvents analysis

Calibration Criteria

- Basic calibration scheme
  - Gravimetric dilution – determine dilution factors for standards in g/g
  - Minimum number of calibration levels: 5 Levels
  - Calibration concentrations:
    - Laboratory shall determine appropriate concentrations for calibration standard levels given their relevant lists of analytes and the mixes available to them.
    - Laboratory must ensure that for the standard sample preparation, the concentration in solution that corresponds to the action limit for each analyte lies within the concentration range of the calibration curve. (e.g. for a 0.25 g sample, is the pass/fail concentration of an analyte within the range of your calibration curve?)
    - If possible, the concentration corresponding to the action limit should lie at a midpoint of the calibration curve.
  - Types of calibration and acceptance criteria:
    - Average Response Factor
    - Linear or quadratic regression
    - Weighted linear regression (up t1/x)
    - Calibration criteria: R2 ≥ 0.995 and RSE < 25%

25. Appendix G: Terpene Analysis

Terpenes are a class of compounds that are found occurring in nature, they are iterations on the same basic backbone, an isoprene unit $(C_5H_8)_n$. There are over 30,000 unique terpenes that have been found to exist. These special compounds lend plants their flavor or odor properties. Terpenes are further classified by the number of carbons: monoterpenes (C10),

sesquiterpenes (C15), diterpenes (C20), etc. Some common terpenes found in cannabis and other plants are limonene, the smell of citrus, pinene, the smell of pine needles, and beta-myrcene, present in mangoes.

Cannabis terpenes provide unique properties and potential interactions with cannabinoids that can influence the perception of effects. They also help biologists keep track of cultivars and phenotypes, using chemovar profiling by measuring the concentration of terpenes in a specific variety of cannabis. Knowledge surrounding terpenes is ever growing, and cannabis terpenes have brought some of these molecules and their properties into public discourse.

Analytes

Required Terpene Analytes[a] (chosen for their ubiquity in cannabis plant material and manufactured products)	
Compound	CAS Number
beta-Myrcene	123-35-3
beta-Caryophyllene	87-44-5
alpha-Pinene	80-56-8
beta-Pinene	18172-67-3
alpha-Humulene	6753-98-6
alpha-Bisabolol	515-69-5
Limonene	138-86-3
Linalool	78-70-6
Terpinolene	586-62-9
Caryophyllene oxide	1139-30-6
Additional Analytes	
	CAS Number
Delta-3-carene	13466-78-9
Camphene	79-92-5
p-cymene	99-87-6
Guaiol	489-86-1
Geraniol	106-24-1
Alpha-terpinene	99-86-5
Gamma-terpinene	99-85-4
Alpha & Beta Terpineol	98-55-5 (alpha), 138-87-4 (beta)
Cis- & Trans- nerolidol	3790-78-1 (cis), 40716-66-3 (trans)
Eucalyptol	470-82-6
Ocimene (variety of isomers, beta-Ocimene dominant)	3779-61-1 (E-beta), 13877-91-3 (Z-beta)
Borneol	464-43-7
alpha and beta Farnesene	502-61-4 (alpha), 18794-84-8 (beta)
Any additional terpenes, if labeled in a cannabis good	

[a]Adapted from Nevada cannabis regulation 11.055; most common terpenes found in cannabis

Appendix G, Table 1: Analyte list for terpene analysis
(list is not comprehensive, there are additional analytes found in cannabis not listed here)

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Concentration Considerations

- Range of concentrations that produce a linear calibration curve
- Routine Achievable LOQs: Generally ~ 10 ppm in sample
- Upper limit of the calibration curve should be defined by the concentrations of terpenes typically found in samples the laboratory is receiving.

Technology/Equipment/Supplies

- Instrumentation recommended: GC-MS, GC-MS-Headspace
- Instrument peripherals recommendations (Columns: 5-MS, 5-sil, rxi624 or equivalent)

Preparation

- Preparation Notes (direct inject, extraction headspace)
  - Sample Mass:
    - At least 0.5 grams
  - Solvents
    - Methanol
    - Ethanol
    - Isopropanol
  - Final extract
    - Final Volume: 10-30 mL

Batch QC Requirements

- Batch size: 20 samples maximum
- Batch QC/ Frequency/ Criteria
  - CCV - Prior to analysis, and one every ten samples thereafter
  - Reagent Blank - ⍰ LOQ - one per batch
  - Method Blank - one per batch
  - LCS - one per batch
  - Sample Duplicate - one duplicate sample per batch

Batch QC Acceptance Criteria

Laboratory Control Sample	Frequency	Acceptance Criteria	Corrective Action
Method Blank/ Reagent Blank	Once each per batch	Non-detect for all analytes	Perform a root cause analysis to determine the source of contamination and remove it. Re-prep and reanalyze the entire analytical batch.
Laboratory Control Sample (LCS)	Once per batch.	Recovery 70% t130%	Re-prep LCS and reanalyze. If LCS fails again, determine if failure is a result of sample contamination or matrix effects, or due to improperly calibrated instruments. Remedy issue and reanalyze entire analytical batch.
Duplicate Sample	One per batch	RPD less than or equal t30 % between the duplicates.	Reanalyze sample and associated duplicate once. If the duplicates fail the precision criteria, determine if the error was instrumental or human. If human error, re-prep samples and reanalyze. If instrument error, remedy issue and re-analyze entire analytical batch.
Matrix Spike	Any new matrices not validated	Recovery 70% t130%	
Initial Calibration verification (ICV)	Directly after calibration.	Recovery 70% t130%	If the recovery for any analyte is outside of the acceptance criteria, recalibrate the instrument. Perform a root cause analysis.
Continued Calibration Verification (CCV)	Prior to analysis, and every 10 samples thereafter.	Recovery 70% t130%	Reanalyze all samples that preceded the last CCV that met the acceptance criteria. If CCV samples continue to fail, then recalibrate the instrument.

Appendix G, Table 2: Batch QC acceptance criteria for terpene analysis

Calibration Criteria

- Basic calibration scheme
  - Number of calibration levels: 5
  - Calibration concentrations
    - Range of concentrations that produce a linear calibration curve
    - Desired lowest LOQ ~ 10 ppm in sample
    - Upper limit of the calibration curve should be defined by the concentrations of terpenes typically found in samples the laboratory is receiving.
  - Type of calibration
    - Direct inject: Linear
    - Headspace: Linear or quadratic

- Calibration criteria: r^2 > 0.98 (linear), r^2 > 0.99 (quadratic). Perform a least squares error analysis to verify goodness of fit.
- Calibration frequency: analyze and trend & track CCV results to determine the validity of your calibration

- ICV: should be run immediately after calibration, and should be midpoint of the curve
- CCV: should be run prior to analysis, and one every ten samples thereafter

26. Appendix H: Water Activity Analysis

Water activity are two analytical procedures to measure the amount of water in a sample. In cannabis and hemp labs, the two procedures are performed for distinct and different reasons. Water activity is useful mainly in determining the ability of microorganisms to grow on the sample.

Technology/Equipment/Supplies

- Instrumentation recommended:
  - Water activity meter using a chilled mirror dew point analysis
  - Other water activity meter technologies

Generally aw< 0.65 is desired for inhalable products and < 0.85 for edible products.

Water Activity Methodologies Recommended:

- *USP <922> Water Activity*
- *ASTM D8196-20: Standard Practice for Determination of Water Activity in Cannabis Flower*
- *AOAC 978.18-1978 Water activity of canned vegetables*
- *USP <1112> Application of Water Activity Determination to Nonsterile Pharmaceutical Products*

Batch QC Requirements

- Max batch size 20 samples
- CCV or LCS (depending on the system suitability)
  - Frequency: at the start of batch, and every ten samples thereafter
- Duplicate samples
  - Frequency: once per batch
- Reference **Appendix H, Table 1** for Quality Control Sample Acceptance criteria requirements

Additional QC Recommendations

- Participate in a PT program at least annually.
- Measure and monitor environmental conditions such as the relative humidity and temperature. Establish acceptable criteria suitable for environmental conditions where you perform the water activity analysis, consider how these variables may be affecting your water activity measurements. If your environmental conditions are found to affect the measurements considerably then identify the contributing factors and adjust the environmental conditions until they return to acceptable ranges.

Batch QC Acceptance Criteria

Quality Control Sample	Water Analysis Method	Frequency	Acceptance Criteria	Corrective Action
Continued Calibration Verification (CCV)	Water Activity Standards	Two CCVs, bracketing the action limits	95-105 % Recovery	Perform a root cause analysis to attempt to identify the source of the failure. Remediate and run CCV again. If CCV fails a second time, service instrument.
Laboratory Control Sample (LCS)	Run a gauze sample that is saturated with one of the Water Activity Standards (comes as a kit)	One per batch at a midpoint concentration, unless a duplicate sample cannot be run, then add a second LCS.	95-105 % Recovery	Perform a root cause analysis to attempt to identify the source of the failure. Remediate and run the LCS again.
Duplicate Sample	Run one duplicate per batch.	One per batch	< 5 % Relative Percent Difference	Homogenize sample again and reanalyze.

Appendix H, Table 1: Batch QC Acceptance Criteria for water activity analysis

- Water activity meters typically come calibrated from the factory
    - The % recovery of a CCV sample can give you information about the continued validity of your calibration. If the instrument is found to be out of calibration, then either perform a calibration procedure as detailed in the manual or take the instrument out of service and send it to a manufacturer for calibration.

REVISION HISTORY

Revision Level	Description
Original Release	Original release.

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CHTA ACCC
Canadian Hemp Trade Alliance
Alliance Commerciale Canadienne du Chanvre

October 1, 2025

Bailey Stuart
Chair
Alcohol & Marijuana Control Office
550 W 7th AVE, STE 1600
Anchorage, Alaska 99501
USA

Delivered by Email
(bailey.stuart@alaska.gov)

Dear Chair Stuart:

RE: Ensuring Safe Industrial Hemp Products

A safe and effective regulatory framework that protects the health and wellbeing of production employees, consumers, livestock, international customers, and the environment is important to the success of the American industrial hemp (hemp) industry. North America is an integrated marketplace, and a consistent, responsible regulatory approach is key for those producing products and to customers.

The following regulatory recommendations were developed to assist state agriculture, food, natural health and non-prescription drug, hemp, and cannabis regulators create consistent regulatory structures for industrial hemp that address safety, but do not restrict industry growth and consumer access.

The Canadian Hemp Trade Alliance (CHTA) provides the attached information from an industry that has focused on hempseed-derived food, feed, and fiber products over the past 27 years. CHTA works closely with global research agencies, and hemp food processing companies to provide wholesome and nutritious products for human and animal consumption.

CHTA strongly encourages all state regulators to exempt industrial hempseed (hemp seed or grain), stalks and branches, roots, and all food, feed, fibre, natural health, and non-prescription drug products derived from these plant tissues from regulations targeting high-THC cannabis (marijuana) and products containing concentrated, isolated, or semi-synthetic phytocannabinoids extracted from Cannabis sativa L. (high-THC cannabis and industrial hemp) plant. CHTA endorses regulation of phytocannabinoid extraction from industrial hemp and high-THC cannabis (i.e. marijuana) flowers as high-THC Cannabis (marijuana).

We invite further collaboration and request that you circulate the following material to related agencies. Further queries or comments are welcomed by contacting the CHTA Hemp Standards Committee (Tel: 825-413-5749 Email: standards@hemptrade.ca).

Yours truly,

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CHTA ACCC
Canadian Hemp Trade Alliance
Alliance Commerciale Canadienne du Chanvre

October 1, 2025

Ensuring Safe Industrial Hemp Products

Introduction

It is important that industrial hemp (hemp) plants in Canada and the USA are subject to regulation of a maximum ∆-9 tetrahydrocannabinol (THC) level in the flowers and upper leaf of the inflorescence (flowering tops). The flowers and leaves of the Cannabis sativa L. plant inflorescence (upper flowering top) produce natural phytochemicals which, when concentrated for medical or adult use purposes, are very different from industrial hemp. Thus a distinction between the three industrial sectors – medical cannabis (disease reduction and therapeutics), adult use cannabis (intoxication and recreation), and industrial hemp (food, feed, and fiber) – has enabled many jurisdictions to develop each sector with justifiably separate risk-informed regulations. Such a regulatory framework can enable industry growth and provide access to many nutritive and health products for humans and animals. It is also important that any regulatory framework guards against fraud and unsafe or illegal products being diverted to the food, feed, and phytochemical extraction sectors.

Agricultural hemp has been bred for centuries to contain extremely low levels of THC in the flower and upper leaf. Residual amounts of THC can be distributed to the outer shell of the hempseed, however remain at trace levels and are managed by food processors and fit-for-purpose regulations. Plant breeders manage multi-generational seed lines to develop certified cultivars that ensure regulatory alignment meeting ∆-9 THC thresholds in its flowering tops.

Products containing concentrated or isolated phytocannabinoids, or semi-synthetic or synthetic cannabinoids are not industrial hemp and may be regulated as and co-processed with high-THC cannabis flower products. Thus, the move to differentiate hemp foods and feeds from medical or recreational cannabis products is important.

1. **Regulations – Industrial Hemp Farming**

   Hemp has contributed to a growing agriculture and agri-food sector through farm incomes, sustainability, value added products, human nutrition, and jobs. Most of the hemp produced in Canada and the USA is an outdoor broadacre[19] pollinated agricultural crop that is a viable option within crop rotations due to its contribution to plant pest and weed control, soil health, water quality, and growing demand for food, feed, and industrial fiber products. Outdoor broadacre hemp production can also play a role in climate change mitigation due to its durable, recyclable industrial fiber from the plant's stalks and its use in displacing synthetics in manufactured products.

   A minority of hemp (feminized or unpollinated) is an outdoor or indoor horticultural crop. This system produces plants exclusively for inflorescence harvest and phytochemical extraction. No seed is produced when using feminized seed or non-pollinated production systems.

   While THC (primarily THC-A) is a natural constituent of the hemp plant's flowers, it is not produced in hempseed. Flowers, leaves, and straw (plant stalk) are separated from the

[19] Broadacre is a term used to describe farms or industries engaged in the production of grains, oilseeds and other crops, or the grazing of livestock for meat or wool, on a large scale (i.e., using extensive parcels of land) Source: Agricultural Policies in OECD Countries: Monitoring and Evaluation 2000: Glossary of Agricultural Policy Terms, OECD

hempseed when broadacre hemp is harvested. Trace levels of THC are therefore present when processing hempseed due to incidental contact with flower material during harvest. THC and other cannabinoids are present on hempseed, hemp roots, hemp stalks, and hemp flowers (outside of the inflorescence) at very low trace levels that are not commercially recoverable.

Regulatory Recommendations for Industrial Hemp Farming:

a. Licensing of hemp farmers (cultivators) is not recommended. Hemp farming should be regulated as any other agriculture or horticulture sector (e.g. corn, soybeans, wheat, grapes, and hops). Moving regulatory oversight of hemp production to agriculture authorities – without the requirement for unique licensing – has been supported by the United Nations Conference on Trade and Development (UNCTAD.)[20]

> *Countries wishing to promote an industrial hemp sector need to consider the reform of existing regulations, to facilitate the exploitation of all parts of the plant. The removal of legislative barriers to industrial hemp cultivation may increase production by farmers. For example, the common practice of having entities related to the control of narcotic drugs issue licences for growing industrial hemp should be reconsidered. A larger scale of production is necessary to reduce the long-term average production costs faced by farmers, as even primary processing operations, such as decortication or seed drying and cleaning, require machinery, the cost of which remains prohibitive for small-scale producers*.

If multi-year licensing of hemp cultivators (farmers) is to be considered, such licensing may cover the following activities: buying hempseed for sowing; growing hemp plants; and selling hemp products (i.e. whole hemp plants, hempseed/grain, hemp stalks and branches, hemp roots, and hemp flowers and leaves). Multi-purpose production (e.g. grain-flower, fiber-flower, or grain-fiber-flower) may occur in any cultivation unit;

b. Criminal background checks are not required for hemp farmers, hempseed processors, and other hempseed handlers (e.g. transporters, cleaners, sellers, and brokers) in jurisdictions that require elevated licensing requirements for phytocannabinoid extraction from hemp flowers that are separate and distinct from all hemp licensing or regulation;

c. Representative sampling and random testing for total available ∆-9 THC (∆-9-THC + THC-A x 0.877).[21] levels in flowers and leaves of the inflorescence (flowering tops) at physiological maturity (regardless of use) is required where hemp is grown to produce hempseed for sowing (e.g. Breeder, Select, Foundation, Registered, Certified, and non-certified). Testing is generally completed with hempseed breeders and farmers growing hempseed for sowing;

d. THC pre-harvest testing of commercially-grown hemp plants is not required in jurisdictions where farmers are required to exclusively sow recognized industrial hemp hempseed varieties/cultivars that are certified by globally-recognized seed certification programs (CSGA, AOSCA, or other OECD Seed Scheme compliant organizations) for the production of: hempseed/grain, stalks and branches, roots, or flowers and leaves; and, have been proven to produce hemp plants with THC levels in the flowers and leaves of the inflorescence at physiological maturity (regardless of use) that are not

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[20] United Nations Conference on Trade and Development, 2023, Industrial hemp: An old crop in a modern era, Policy Brief No. 110.

[21] Adjusting the level of acidic precursor THC-A by 0.877 accounts for the absorbable amount remaining after decarboxylation. Decarboxylation requires the significant application of heat. Decarboxylation does not occur in food/feed processing.

higher that the maximum regulated THC levels established by authorities having jurisdiction; and,

e. Mandatory pre-harvest THC testing of commercial hemp production is required in jurisdictions that do not require the use of certified hempseed for sowing as described in section 1.d. above. Where hempseed for sowing from certified and compliant industrial hemp varieties/cultivars is not regulated, USDA performance-based representative sampling with recognized methodology and standardized protocols is to be implemented by the USDA or state authorities having jurisdiction.

Hemp plants in Canada and the USA are currently regulated to a maximum total available ∆-9 tetrahydrocannabinol (THC) level of not more than 0.3% in the flowers and leaves of the inflorescence. Consideration should be given to moving this level to not more than 1% total available ∆-9 THC, based on the proven safety of hemp at that threshold level produced and processed in other regions of the world (See Appendix, Table 1).

2. **Regulations – Hempseed Food, Livestock Feed, and Pet Food Products**

a. **Hempseed-Derived Food**

Food products derived from hempseed are a valuable source of protein, energy, digestible fiber, and a wide array of minerals and vitamins for human nutrition. In addition, when hempseed is mechanically crushed, its oil contains an optimal balance of omega 3-6-9 fatty acids.

Hempseed and its derivatives contain only low natural constituent cannabinoid levels. Intoxicating, toxic, or therapeutic cannabinoid levels can only be found in food products that have been supplemented or adulterated with concentrated, isolated, semi-synthetic, or synthetic cannabinoids. Specific regulatory requirements for phytocannabinoid extraction are required and presented in Section 3 below.

Hempseed-derived ingredients were subject to an extensive USDA Generally Recognized as Safe (GRAS) review in 2018. THC was the only phytocannabinoid identified in an upper threshold and reviewers indicated consumption of hempseed-derived ingredients is not capable of intoxicating consumers. This level was submitted due to an upper limit in Canada of 10 ppm, which has since then been eliminated due to existing controls in plant breeding, licensing of farmers and food processor input controls.

CHTA has developed a set of regulatory recommendations related to hempseed-derived foods, based on peer-reviewed global research and work completed by the Federation of International Hemp Organizations (FIHO).

<u>Regulatory Recommendations for Hempseed-Derived Food</u>:

i. Food and food ingredients containing hemp ingredients may not contain concentrated or isolated phytocannabinoids, or semi-synthetic or synthetic cannabinoids. Any food product containing concentrated or isolated phytocannabinoids, or semi-synthetic or synthetic cannabinoids is not hemp;

ii. No maximum total available ∆-9-THC (∆-9 THC + 0.877 x THC-A) limits are required for hempseed-derived food ingredients if certified hemp cultivars proven to produce plants with total available ∆-9-THC less than the regulated maximum concentration at physiological maturity are exclusively used;

iii. No maximum total available ∆-9-THC limits are required for foods or food ingredients derived from hemp roots, hemp stalks and branches, or hemp leaves outside of the inflorescence;

iv. No maximum total available ∆-9-THC limits in foods containing hemp ingredients are required if included hemp-derived ingredients meet the provisions in subsections 2.a.i-iii above;

v. No upper threshold limit for total available CBD (CBD + 0.877 x CBD-A) in hemp food ingredients or foods containing hemp is required, as research indicates natural residual constituent CBD levels in hempseed, hemp roots, hemp stalks and branches, or hemp leaves outside of the inflorescence do not represent risks to human health or wellbeing;

vi. A maximum total available ∆-9-THC limit of 20 ppm is required for hempseed-derived foods or food ingredients if certified hemp cultivars proven to produce plants with total available ∆-9-THC less than the regulated maximum concentration at physiological maturity are not exclusively used;

vii. As the natural constituent levels of total available ∆-9-THC, CBD, and other phytocannabinoids are well below concentrations of concern for human health and wellbeing, no cannabinoid warning statements, cannabinoid content, or warning symbols are required on hemp food product packaging sold in wholesale or consumer markets; and,

viii. As random testing for total available ∆-9-THC will identify adulterated product and requirements to identify all ingredients on food packaging exists, a limit on serving size or age restriction for food products derived from hempseed, hulled/dehulled hempseed, hemp protein, hempseed oil, hemp roots, hemp stalks and branches hemp leaves outside of the inflorescence, and their derivatives is not required.

Food processors produce additional byproducts that may be valuable as ingredients in animal supplements and feed. Hempseed-derived products are low-risk as they contain very low concentrations of natural constituent (i.e. residual) cannabinoids, and provide valued nutritional benefits for livestock and pets. Repurposing hempseed-derived products – rather than diverting them as food waste to landfills – support food processors' economic and environmental position. Thus, recommendations 2b. and 2c. are provided below to utilize product that would otherwise be waste. These products will assist food processor's product flow and represent a significant source of additional revenue which will be important for long-term growth and sustainability.

b. **Hempseed-Derived Livestock Feed Ingredients**

Since hempseed-derived livestock feed ingredients are not subject to high processing temperatures for a significant period of time, over 90% of the THC and CBD naturally present in livestock feed ingredients is in the precursor THC-A form – thus not readily absorbed in livestock tissues (e.g. meat, milk, and eggs) intended as food.

Hempseed grown from certified and compliant industrial hemp varieties/cultivars produces consistently low levels of ∆-9 THC in the flowering tops. This translates to extremely low/trace levels on the outer hempseed shell – which poses no processing, employee or animal safety concerns for hempseed-derived products.

<u>Regulatory Recommendations for Hempseed-Derived Livestock Feed Products</u>:

i. Hemp feed ingredients and mixed feeds containing hemp ingredients may not contain concentrated or isolated phytocannabinoids, or semi-synthetic or synthetic cannabinoids. Any product containing concentrated or isolated phytocannabinoids, or semi-synthetic or synthetic cannabinoids is not hemp;

ii. No maximum total available ∆-9-THC (∆-9 THC + 0.877 x THC-A) limits are required for hempseed-derived livestock feed ingredients if certified hemp cultivars proven to

produce plants with total available ∆-9-THC less than the regulated maximum concentration at physiological maturity are exclusively used;

iii. No maximum total available ∆-9-THC limits are required for livestock feed ingredients derived from hemp roots, hemp stalks and branches, or hemp leaves outside of the inflorescence;

iv. No maximum total available ∆-9-THC limits in livestock feeds containing hemp ingredients are required if included hemp-derived ingredients meet the provisions in subsections 2.b.i-iii above;

v. A maximum total available ∆-9-THC limit of 100 ppm is required for hempseed-derived livestock feed ingredients if certified hemp cultivars proven to produce plants with total available ∆-9-THC less than the regulated maximum concentration at physiological maturity are not exclusively used;

vi. A maximum total available ∆-9-THC limit of 100 ppm is required for whole-plant hemp livestock feed ingredients consisting of whole hemp plants (grazing) or ground/shredded whole hemp plants;

vii. No upper threshold limit for total available CBD (CBD + 0.877 x CBD-A) is required, as research indicates natural residual constituent CBD levels in hempseed, hemp roots, hemp stalks and branches, or hemp leaves outside of the inflorescence do not represent risks to human or animal health or wellbeing;

viii. Demonstration of hemp-derived feed ingredient efficacy (i.e. weight gain, palatability, and tolerance at various inclusion rates) may be provided by the application of animal nutrition science and, where necessary, literature reviews of credible livestock feeding trials completed in any jurisdiction;

ix. Demonstration of food safety (i.e. cannabinoid concentration, and nutritional profile) of meat, milk, and eggs derived from livestock fed hemp feed ingredients may be provided by literature reviews of credible livestock feeding trials completed in any jurisdiction;

x. As the natural constituent levels of total available ∆-9-THC, CBD, and other phytocannabinoids are well below concentrations of concern for animal health and wellbeing, no cannabinoid warning statements, cannabinoid content, or warning symbols are required on hemp livestock feed ingredient product packaging sold in wholesale or consumer markets;

xi. As random testing for total available ∆-9-THC will identify adulterated product and requirements to identify all ingredients on livestock feed packaging exists, a limit on feed inclusion rates for feed products derived from hempseed, hulled/dehulled hempseed, hemp protein, hempseed oil, hemp roots, hemp stalks and branches hemp leaves outside of the inflorescence, and their derivatives is not required; and,

xii. Further regulatory provisions for feed ingredients derived from whole hempseed, dehulled/hulled hempseed, hempseed oil, hemp protein, hempseed hulls, hempseed meal (protein cake), hempseed screenings, and hempseed fines without added cannabinoids are not required.

c. **Hempseed-Derived Non-Food-Animal Feed Ingredients**

Since hempseed-derived pet food ingredients are not subject to high processing temperatures for a significant time period, over 90% of the THC naturally present in pet food ingredients is in the precursor THC-A form – thus not readily absorbed.

Hempseed grown from certified and compliant industrial hemp varieties/cultivars produces consistently low levels of ∆-9 THC in the flowering tops. This translates to

extremely low/trace levels on the outer hempseed shell – which poses no processing, employee or animal safety concerns for hempseed-derived products

Regulatory Recommendations for Non-Food Animal Hemp Feed Products:

i. Non-Food Animal feed ingredients derived from hempseed including mixed feeds and nutritional supplements containing hemp ingredients may not contain concentrated or isolated phytocannabinoids, or semi-synthetic or synthetic cannabinoids. Any product containing concentrated or isolated phytocannabinoids, or semi-synthetic or synthetic cannabinoids is not hemp;

ii. No maximum total available ∆-9-THC (∆-9 THC + 0.877 x THC-A) limits are required for non-food animal feed ingredients derived from hemp if certified hemp cultivars proven to produce plants with total available ∆-9-THC no more than the regulated maximum concentration at physiological maturity are exclusively used;

iii. No maximum total available ∆-9-THC limits are required for non-food animal feed ingredients derived from hemp roots, hemp stalks and branches, or hemp leaves outside of the inflorescence;

iv. No maximum total available ∆-9-THC limits in hempseed derived non-food animal feeds are required if included ingredients meet the provisions in subsections 2.c.i-iii above;

v. A maximum total available ∆-9-THC limit of 100 ppm is required for hempseed-derived non-food animal feed ingredients if certified hemp cultivars proven to produce plants with total available ∆-9-THC less than the regulated maximum concentration at physiological maturity are not exclusively used;

vi. A maximum total available ∆-9-THC limit of 100 ppm is required for non-food animal food/feed ingredients consisting of whole hemp plants (grazing) or ground/shredded whole hemp plants;

vii. No upper threshold limit for total available CBD (CBD + 0.877 x CBD-A) is required, as research indicates natural residual constituent CBD levels in hempseed, hemp roots, hemp stalks and branches, or hemp leaves outside of the inflorescence do not represent risks to human or animal health or wellbeing;

viii. Demonstration of hempseed-derived feed ingredient efficacy (i.e. nutritional profile and feeding rates) may be provided by the application of animal nutrition science and, where necessary, literature reviews of credible feeding trials completed in any jurisdiction;

ix. As the natural constituent levels of total available ∆-9-THC, CBD, and other phytocannabinoids are well below concentrations of concern for animal health and wellbeing, no cannabinoid warning statements, cannabinoid content, or warning symbols are required on hemp feed ingredient product packaging sold for non-food animals in wholesale or consumer markets;

x. As random testing for total available ∆-9-THC will identify adulterated product and requirements to identify all ingredients on feed packaging for non-food animals exists, further limits on hempseed-derived products, hemp roots, leaves outside of the inflorescence or hemp stalks are not required. See section 4 for targeted cannabinoid products intended for pets or companion animals; and,

xi. Further regulatory provisions for feed ingredients for non-food animals derived from whole hempseed, dehulled/hulled hempseed, hempseed oil, hemp protein, hempseed hulls, hempseed meal (protein cake), hempseed screenings, and hempseed fines without added cannabinoids are not required.

3. **Regulations – Hemp Flowers and Leaves of the Inflorescence**

Hemp flowers are contained in the inflorescence (flowering tops) of the hemp plant. Hemp flowers and leaves of the inflorescence, whether fresh or dried, contain higher concentrations of cannabinoids than other hemp plant tissues. Maximum total available ∆-9-THC concentration limits in the flowers and leaves of the inflorescence are established by authorities having jurisdiction, and are currently set at 0.3% (3,000 ppm) by national regulators in both Canada (Health Canada) and the USA (United States Department of Agriculture).

The majority of horticultural hemp grown for cannabinoid extraction is not pollenated. This allows the plant to increase resin production by focusing its energy on the trichome glands in flowers and leaves contained within the inflorescence. Unpollinated hemp plants do not produce hempseed.

Regulatory Recommendations for Hemp Flowers and Leaves of the Inflorescence:

a. Hemp flowers and leaves of the inflorescence, when separated from the hemp plant and not having cannabinoids extracted, may be considered for sale in the consumer market as natural health product and non-prescription drug ingredients. Such products shall not contain concentrated, isolated, semi-synthetic, or synthetic cannabinoids. Disease reduction or therapeutic claims must be verified through credible peer-reviewed research;

b. Hemp flowers and leaves of the inflorescence, when separated from the hemp plant and not having cannabinoids extracted, may be considered for sale in the consumer market as an infusion product (tea). Such products shall not contain concentrated, isolated, semi-synthetic, or synthetic cannabinoids;

c. Hemp flowers and leaves of the inflorescence, when separated from the hemp plant and not having cannabinoids extracted, and prepared for inhalation are no longer a hemp product. Such products must be regulated uniquely in a manner aligned with tobacco products, and natural health and non-prescription drug products; and,

d. Hemp flowers and leaves of the inflorescence, when separated from the hemp plant and not having cannabinoids extracted, are not recommended as a livestock feed ingredient or a feed/ ingredient for non-food animals until further safety research is available.

4. **Regulations – Phytocannabinoid Extraction and Phytochemical Processing**

Phytocannabinoids may be extracted, concentrated, isolated, or chemically altered (semi-synthesized) though post farmgate manufacturing processes. Extracted, concentrated, and isolated phytocannabinoids are not hemp products[22] and may represent risks not associated with the hemp plant or processed hempseed products. Semi-synthesized and synthesized cannabinoids may include cannabinoid isomers that are intoxicating and/or contaminants that are harmful to humans or animals.

Food and livestock feed ingredients derived from hemp roots, hemp stalks, or hempseed can be rendered unsafe if supplemented with or adulterated by concentrated or isolated phytocannabinoids, chemically altered phytocannabinoids, or synthesized cannabinoids. Products containing concentrated or isolated phytocannabinoids, or semi-synthetic or synthetic cannabinoids are not hemp – and should be regulated separately as medical or adult use/recreational cannabis, natural health products, non-prescription drugs. Those

[22] Hemp plant components from primary production may be hemp products, but if additives or processing changes occur, they are not known as hemp in most countries. This assists management of fraudulent or illegal product in post-farm manufacturing.

sectors have unique value chains, regulatory systems, and customers that are separate and distinct from industrial hemp.

Notwithstanding the above, the World Health Organization's Expert Committee on Drug Dependence (ECDD) determined that the safe threshold for ∆-9-THC in unregulated tinctures is 1,500 ppm (1.5%). As the ECDD noted that member states may have difficulty measuring ∆-9-THC concentrations less than 2,000 ppm (2.0%), they recommended that:

> *A footnote be added to Schedule I of the 1961 Single Convention on Narcotic Drugs to read: "Preparations containing predominantly cannabidiol and not more than 0.2 per cent [2,000 ppm] of delta-9-tetrahydrocannabinol are not under international control*.[23]

Regulatory Recommendations for Cannabinoid Extraction and Phytochemical Processing:

a. Separate and unique regulatory actions are required to appropriately address intoxication, addiction, habituation, therapeutic potential, toxicity, and contamination risks associated with the extraction, concentration, isolation, and chemical alteration of hemp-flower-derived phytocannabinoids;

b. Such regulation should include risk-based approaches that consider consumer age, cannabinoid concentration, and daily dose limits to address safety concerns for natural health and non-prescription drugs (e.g. supplements), inhalation products (e.g. dried flowers and vapes), topical products (transdermal and emollients), oral products (supplemented foods and beverages), sublingual products, and other dosage mechanisms;

c. Research licenses should be made available to study concentrated and isolated phytocannabinoids and semi-synthesized and synthesized cannabinoids that may provide beneficial factors to positively and safely influence health outcomes in humans and animals;

d. Regulatory exemptions for "Low-THC cannabis" products that do not contain semi-synthetic or synthetic cannabinoids may be considered to allow sale of safe food products containing extracted (concentrated or isolated) phytocannabinoids in the consumer market. Based on the ECDD finding that the minimum intoxicating ∆-9-THC dose is 1.5 mg, the following maximum ∆-9-THC concentrations of eligible low-THC tinctures, supplemented foods, and supplemented beverages are recommended:

    i. Tinctures – 750 ppm – 2 servings x 1 ml/serving = 2 ml consumption x 750 µg/mg (750 ppm) THC = 1,500 µg THC = 1.5 mg THC consumed;

    ii. Supplemented Foods – 15 ppm – 2 servings x 50 grams/serving = 100 grams consumption x 15 µg/mg = 1,500 µg THC = 1.5 mg THC consumed;

    iii. Supplemented Beverages – 2 ppm – 2 servings x 350 ml/serving = 700 ml consumption = 700 mg consumption x 2 µg/mg (2 ppm) THC = 1,400 µg THC = 1.4 mg THC consumed;

    iv. Companion dogs – CBD administered at between 0.2-2mg/kg orally twice daily.[24] If administering to assist managing osteoarthritis, pet owners should consult a veterinarian for use instructions prior to administering CBD; and,

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[23] WHO Expert Committee on Drug Dependence, 2019, Forty-first report WHO Technical Report Series, No. 1018, Section 7.5 Cannabidiol preparations (pp. 53-54), ISBN 978-92-4-121027-0 (68 pages)

[24] Health Canada, 2022, Review of cannabidiol: Report of the Science Advisory Committee on Health Products Containing Cannabis, Recommendation G, ISBN 978-0-660-43616-6

v. Further advisement on targeted use of phytocannabinoids to companion animals to become available as objective, peer-reviewed research becomes available; and,

e. The distribution and sale of safe products containing non-phytocannabinoid compounds (e.g. terpenes, flavonoids, sterols, fatty acids, polysaccharides, and polyphenols) in the consumer market without specific industrial hemp or high-THC (marijuana) licensing or regulation. These compounds are found and produced from a wide range of agriculture and horticulture crops. Existing food, supplements, and non-prescription drug regulations – as applied to products produced from other plants – exist and should be used to regulate non-phytocannabinoid products extracted from industrial hemp or high-THC cannabis flowers.

5. **Regulations – Post-Extraction Cannabinoid Biomass**

Hemp flowers and leaves of the inflorescence can be processed to extract phytocannabinoids, terpenes, flavonoids, phenolics, and other bio-active compounds. Regardless of the solvent extraction (e.g. alcohol, hexane, critical CO2, and water) or solventless extraction (e.g. ultrasonic, microwave, hydrodynamic cavitation, heat, and microwave) technology used, the post-extraction biomass represents a valuable livestock and pet feed ingredient.

Regulatory Recommendations for Post-Extraction Cannabinoid Biomass

a. Where a solvent extraction technology is used, solvent residues must be no higher than allowable solvent residues in other livestock feed ingredients (e.g. avocado meal, canola meal, coconut meal, corn meal, cottonseed meal, olive meal, peanut meal, safflower meal, soybean meal, or sunflower meal);

b. A maximum total available ∆-9-THC (∆-9 THC + 0.877 x THC-A) limit of 100 ppm is required for post-extraction cannabinoid biomass livestock feed ingredients and non-food animal feed ingredients (excluding dogs and cats); and,

c. No upper threshold limit for total available CBD (CBD + 0.877 x CBD-A) is required for post-extraction cannabinoid biomass livestock feed ingredients and non-food animal food/feed ingredients.

APPENDIX

References

1. USDA *Generally Recognized as Safe (GRAS)* reviews of dehulled hempseed , hempseed protein, and hempseed oil in 2018. These reviews confirmed food safety for hempseed products:
   a. Agency Response Letter GRAS Notice No. GRN 000765
   b. Agency Response Letter GRAS Notice No. GRN 000771
   c. Agency Response Letter GRAS Notice No. GRN 000778
2. AOSCA, Association of Official Seed Certifying Agencies is a trade organization with standards on production, identification, distribution and promotion of certified classes of seed and other crop propagation materials. Founded in 1919 it is based in Moline, Illinois USA with member agencies across the world (www.aosca.org).
3. CSGA, Canadian Seed Growers Association is an industry association that delivers an inclusive and transparent national seed crop certification. It's standards system advances collaboration and innovation while upholding quality, trust, and excellence in seed production for the benefit of Canadian agriculture (https://seedgrowers.ca/).
4. OECD, Organization for Economic Co-operation and Development, is an intergovernmental organization with standards for agricultural seed quality. Many commonwealth and European countries base seed certification on OECD standards, similar to AOSCA standards with equivalent outcomes. Founded in 1948 it is headquartered in Paris France with major offices in Berlin, Mexico City, Tokyo and Washington DC https://www.oecd.org/agriculture/seeds/).
5. World Health Organization's Expert Committee on Drug Dependence (ECDD) expert reviews:
   a. ECDD – 34th Session Report 942 – Dronabinol Critical Review (2.1.1) Recommendation to Schedule III
   b. ECDD – 39th Session Report 1009 – Cannabidiol (5.15) and Pre-Review Update (6) (2017-11)
      i. ECDD – 39th Session - Cannabidiol (CBD) Pre-Review Report - Agenda Item 5.2 (2017-11).
   c. WHO ECDD 40th Session Report 1013 - Cannabidiol (6), Cannabis and cannabis resin (7), and Extracts and tinctures of cannabis (8). Section 6 – Cannabidiol (pp 13-17) (2018-06).
      i. ECDD – 40th Session - Critical Review – Cannabinol (CBD) Report (2018-06).
   d. ECDD – 41st Session Report 1018, Cannabis and cannabis-related substances (Section 7), ISBN 978-92-4-121027-0
      i. ECDD – WHO ECDD 41st Session – Critical Review – Extracts and Tinctures of Cannabis (2018-11)
      ii. ECDD – 41st Session – Critical Review – Cannabis and cannabis resin (2018-11)
      iii. ECDD 41st Session – Critical Review – Delta-9-tetrahydrocannabinol (2018-11)
      iv. WHO ECDD 41st Session – Critical Review – Isomers of THC

Table 1: **Global THC and CBD Threshold Levels in Hemp Food Products**				
	Maximum Δ-9 THC Limit			Maximum CBD Limit
Jurisdiction	Hemp Plant Definition	Hempseed for Food	Hempseed Oil for Food	Hempseed for Food
Switzerland	1.0%	10 ppm	20 ppm	No maximum threshold
Australia	1.0%	5 ppm	10 ppm	75 ppm
New Zealand	1.0%	5 ppm; 0.2 ppm(beverages)	10 ppm	75 ppm
European Union	0.3%	3 ppm +50% variance	7.5 ppm + 50% variance	No maximum threshold
Canada	0.3% (0.5% compliance)	No maximum threshold	No maximum threshold	No maximum threshold
United States	0.3 % (0.5% compliance)	10 ppm (GRAS)	10 ppm (GRAS)	No maximum threshold
Hemp Plant Definition: Total available Δ-9 THC (Δ-9 THC + 0.877 x THC-A) in flowering tops				

Table 2: **Hempseed product standards – THC and CBD Upper Thresholds**				
Agency	Comments	THC in hemp food products	THC in hempseed oil	CBD in hemp food products
ASTM Standards International D8440 [1]	Consensus Standard	Total Δ-9 THC of 20 ppm	Total Δ-9 THC of 20 ppm	No maximum threshold
USA GRAS 2018 Notices GRN 771, GRN 778, GRN 765	Significant assessment of potential human toxicity	Total Δ-9 THC of 10 ppm (dehulled hempseed, hempseed protein)	Total Δ-9 THC of 10 ppm	No maximum threshold
Food Chemicals Codex , USA [2]	Consensus standard / monograph	Total Δ-9 THC of 10 ppm	Total Δ-9 THC of 10 ppm	Total CBD of not more than 75 ppm. Purpose: identify non- adulterated product
Source: standard setting bodies, and national regulatory agencies				

Notes:

1. D8440 Specification for Food Safety and Quality of Hempseed Protein Products Intended for Human Consumption (2022) available at www.astm.org The standard identifies thresholds for food safety and quality in hempseed and its byproducts. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA USA

2. Food Chemicals Codex (USA) 2021 food identity monographs for hempseed oil and hempseed protein are available at https://www.foodchemicalscodex.org/ US Pharmacopeia,12601 Twinbrook Parkway, Rockville, MD USA

From:	Sherman Hom
To:	CED AMCO REGS (CED sponsored)
Subject:	Public Comment to the Alaska Marijuana Control Board concerning microbial contamination testing
Date:	Wednesday, November 12, 2025 10:54:45 AM
Attachments:	Recommendation Letter to AK - Marijuana Control Board on Micro testing rules (1).pdf Sherman Hom Cannabis Experience_10-26-25.pdf

Chair Bailey Stuart
I would like to take this opportunity to acknowledge your, the other commissioners, and the Board's staff efforts to continuously improve the regulatory framework of Alaska's cannabis program.

I have attached our recommendations for modifying microbial contamination regulations to ensure safe products for your state's patients and consumers.

I have also attached a brief document summarizing my 14+ years experience in the cannabis testing and cannabis testing regulations space, which was mostly with the New Jersey Department of Health Division of Public Health and Environmental Laboratories.

If you, any of the other commissioners, or any scientific staff have any questions, please contact me.

I thank you for your time and consideration.
Respectfully
Dr. Sherman Hom

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Sherman Hom, PhD
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.....
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November 12, 2025

Chair Bailey Stuart
Alaska Marijuana Control Board

Chair Stuart
As industry leaders in cannabis and pathogen genomics, we have spent decades working with quantitative polymerase chain reaction (qPCR) and culture-based methods for the detection of microorganisms. We are experts in the field with over 40 patents related to PCR and DNA sequencing based methods for detecting microorganisms. Kevin McKernan, Chief Scientific Officer at Medicinal Genomics Corporation (MGC) managed the Research and Development team for the Human Genome Project at the Whitehead Institute of MIT. He has over 64,540 citations related to his work in this field. Our scientists recommend microbial testing specifications that will ensure that medical cannabis plant material and manufactured products are safe for patients. Due to concerns for public health, the Alaska Marijuana Control Board (AMCB) should draft the cannabis testing regulations, which include those to detect microbial contaminants that reflect ongoing efforts at AOAC International, ASTM International, the United States Pharmacopeia (USP), the Centers of Disease Control and Prevention (CDC), and the United States Food and Drug Administration (FDA) that are consistent with our findings at MGC.

The presence of microorganisms is common on plants, such as cannabis. One must be able to differentiate between harmless and/or beneficial microbes (bacteria, yeasts, and fungi) ubiquitous in nature and those that are human pathogens that have contaminated the cannabis plant material and/or manufactured products. Examples of pathogens that have caused human illness and even death affiliated with cannabis use are *Salmonella* species, Shiga toxin producing *E. coli* (STEC), *Aspergillus flavus, A. fumigatus*, *A. niger*, and *A. terreus* [1-29].

Current required tests for microbial contamination in states that have medical cannabis programs vary among the states. Some states require different combinations of total count tests, such as Total Viable Aerobic Bacteria (TVAB), Total Yeast & Mold (TYM), [Total] Bile-Tolerant Gram-Negative Bacteria (BTGN), and Total Coliforms (TC); as well as the six human pathogens listed above with various action levels for each test and each cannabis product type. On the other hand, other states, such as California, Montana, and Vermont only require tests for detecting the human pathogens *Salmonella* spp., STEC, *A. flavus*, *A. fumigatus*, *A. niger*, and *A. terreus* for inhalable products.
NOTE: Total count tests have action levels as colony forming units (cfu/g), which is the number of colonies that grow on the surface of an agar medium plate. Specific pathogen tests have an action level of "<1 cfu/10 grams".

The 3 AAC 306 REGULATIONS FOR THE MARIJUANA CONTROL BOARD [30], Section 306.645. Laboratory testing of marijuana and marijuana products (b)(2) microbial testing for the listed substances on the listed marijuana and marijuana products is required as follows:

Substance	**Acceptable Limits Per Gram**	**Product to be Tested**
--*Shiga*-toxin producing *Escherichia coli* (STEC)-bacteria	Less than 1 colony forming unit (CFU/g)	Marijuana; retail marijuana products; water-and food-based concentrates
Salmonella species-bacteria	Less than 1 colony forming unit (CFU/g)	
Substance	**Acceptable Limits Per Gram**	**Product to be Tested**
Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger-fungus	Less than 1 colony forming unit (CFU/g)	Marijuana; retail marijuana products; water-and food-based concentrates

Our first recommendation is requiring testing to detect the fourth *Aspergillus* human pathogen - *Aspergillus terreus* that has been associated with cannabis use for marijuana, retail marijuana products, and water- & food-based concentrates (listed in the table above). All of the previously mentioned products could be administered through the inhalation route via combustion of a blunt, a vape pen, or a nebulizer, such as a volcano. The United States Pharmacopeia (USP) stated that "Many states with legalized cannabis markets now require that all cannabis goods intended for consumption by inhalation be tested for the four pathogenic *Aspergillus* species (*A. flavus, A. fumigatus, A. niger,* and *A. terreus*). When inhaled, all four of these species are known to cause a variety of immune lung disorders, ranging from asthma, allergic bronchopulmonary aspergillosis, and hypersensitivity pneumonitis to invasive and life-threatening systemic fungal infections in immunocompromised hosts." [31]

The number of states and territories that require microbial testing rules for inhaled cannabis products (flower, pre-rolls, vape pens, *etc*) was 25 in 2019 [32] and 43 in 2025 [33]. A comparative analysis of the required microbial testing rules for all jurisdictions with legal cannabis programs in 2019 and in 2025 showed that the percentage of states and territory that require the detection of the pathogens listed above has increased during this 6 year period (see the following table).

Microorganism (2019)	# (%)	Microorganism (2025)	# (%)	% Increase over 5 years
Salmonella species	22 (85%)	*Salmonella* species	41 (95%)	**10%**
STEC	4 (15%)	STEC	21 (49%)	**34%**
4 *Aspergillus* species	8 (30%)	4 *Aspergillus* species	24 (56%)	**26%**

Since other states and territories are in the process of either modifying or adopting their initial microbial testing rules and new states & territories will legalize cannabis in the future, we predict that the percentage of jurisdictions requiring the detection of microbial pathogens for inhaled products will continue to increase.

Therefore, the following modifications should be made to the above table:

For microbiological testing of marijuana, retail marijuana products, and water- & food-based concentrates

	Standard
Shiga toxin producing strains of *Escherichia coli* and *Salmonella* species	<1 CFU/10 grams
Aspergillus flavus	<1 CFU/10 grams
Aspergillus fumigatus	<1 CFU/10 grams
Aspergillus niger	<1 CFU/10 grams
Aspergillus terreus	<1 CFU/10 grams

NOTE: The action levels for all tests listed in the table above should be "<1 CFU/10 grams" to allow for a sample size recommendation that follows.

For MICROBIOLOGICAL TESTING OF INFUSED EDIBLES

	Standard
Shiga toxin producing strains of *Escherichia coli*	<1 CFU/10 grams
Salmonella species	<1 CFU/10 grams
Listeria monocytogenes	<1 CFU/10 grams

3. For MICROBIOLOGICAL TESTING OF INFUSED NON-EDIBLES

	Standard
Candida albicans	<1 CFU/10 grams
Pseudomonas aeruginosa	<1 CFU/10 grams
Streptococcus aureus	<1 CFU/10 grams

Our second recommendation concerns the allowable methods to detect these recommended 10 human pathogens for the different sample types, which should be molecular detection. In light of advancements in laboratory technology and the critical need for accurate and timely pathogen detection, MGC recommends that the AMCB allow molecular testing methods, such as qPCR and other DNA-based assays, as validated technologies for specific cannabis pathogen testing.

Molecular methods offer significant advantages over traditional agar plating, which includes greater specificity & sensitivity for detecting the human pathogenic species of *Aspergillus, Salmonella*, and Shiga-toxin producing *E. coli* (STEC), *Candida, Pseudomonas, and Staphylococcus*. These methods can provide results in hours rather than days, enhancing safety by enabling faster decision-making in product release, and reducing the risk of contaminated products reaching consumers. The adoption of molecular methods will align Alaska's cannabis

testing regulations with those in other highly regulated industries, such as food and pharmaceuticals, which already leverage these tools to ensure product safety. By allowing for molecular testing, Alaska can strengthen its public health protections, support innovation in its testing labs, and streamline the regulatory compliance process for cannabis producers and testing facilities.

Most importantly, there are multiple AOAC certified Performance Tested Methods (PTMs) using cannabis as a sample type that are being used by licensed cannabis labs throughout the world. These PTMs were developed by the AOAC Cannabis Analytical Science Program (CASP), which is a forum where the science of cannabis analysis can be discussed and cannabis standards and methods developed. To date, AOAC has released three (3) Standard Method Performance Requirements (SMPRs) for the six human pathogens that we have recommended for testing (see #1-3 below).

1. Detection of *Aspergillus* in Cannabis and Cannabis Products
   https://www.aoac.org/wp-content/uploads/2019/10/SMPR-2019_001.pdf
2. Detection of *Salmonella* species in Cannabis and Cannabis Products
   https://www.aoac.org/wp-content/uploads/2020/07/SMPR-2020_002.pdf
3. Detection of Shiga toxin-producing *Escherichia coli* in Cannabis and Cannabis Products
   https://www.aoac.org/wp-content/uploads/2021/02/SMPR-2020_012.pdf
   NOTE: A SMPR for Detection of *Listeria monocytogenes* in Cannabis Edible Products will be approved in 2025.

Medicinal Genomics is a member of **AOAC's CASP Microbial Contaminants Working Group**. The goal and objectives of this working group are to:

- Develop Standard Method Performance Requirements (SMPR) for cannabis and hemp
- Extend a Call for Methods for each of the completed SMPRs
- Empanel an Expert Review Panel to review candidate methods
- Deliver consensus-based validated Performance Test Methods (PTMs) & Final Action Official Methods for the cannabis industry

Medicinal Genomics has a single AOAC Certified **qPCR** PTM for the detection of the 4 pathogenic *Aspergillus* species in one test and has a single AOAC Certified **qPCR** PTM for the detection of *Salmonella* spp. & STEC in one test. The sample types for the 4 *Aspergillus* species test are flower, infused products, oils & concentrates, and hemp. Moreover, the sample types for the Sal/STEC test are flowers, oils, chocolates, and hemp. Each of these two **multiplex qPCR assays** were validated by an independent 3rd party cannabis testing laboratory using the various cannabis sample

There are several **major disadvantages** of using plating methods to detect specific bacterial and fungal pathogens:

- Cannabinoids, which can represent up to 30% of a cannabis flower's weight, have been shown to have antibiotic activity. Antibiotics inhibit the growth of bacteria. *Salmonella* & STEC bacteria are very sensitive to antibiotics, which may lead to a false negative result using a plating system *vs.* a positive result using a qPCR method. [36-37]
- The USP stated "Detection of pathogenic *Aspergillus* species using culture based methods is very difficult, requiring a highly trained and experienced mycologist to correctly identify these pathogens by colony appearance and morphology, as there are many nonpathogenic species of *Aspergillus* that may be indistinguishable from those that are pathogenic [31].
- Agar plating methods cannot detect bacterial and fungal endophytes [38-39] that live a part or all of their life cycle **inside** a plant. Examples of endophytes are the *Aspergillus* pathogens. Methods to break open the plant cells to access these endophytes for plating methods also lyses these bacterial and mold cells (killing these cells in the process). Therefore, these endophytes will never form colonies, which will lead to a false negative result using a plating system *vs.* a positive result using a qPCR method.
- Selective media for mold plating methods, such as Dichloran Rose-Bengal Chloramphenicol (DRBC) reduces mold growth; especially *Aspergillus* by 5-fold. This may lead to a false negative result for this human pathogen. In other words, although DRBC medium is typically used to reduce bacteria; it comes at the cost of missing 5 fold more yeast and molds than Potato Dextrose Agar (PDA) + Chloramphenicol or molecular methods. These observations were derived from study results of the AOAC emergency response validation [40].

Therefore, a rule must be adopted that reads:
An AOAC Certified Performance Tested Method (PTM) that has an enrichment step with a minimum of sixteen hours (16 hrs) of incubation.

Our third recommendation is to increase the sample testing size. As cannabis prices fall, a 10-gram test amount may become necessary to address sampling challenges. Since the maximum batch size for taking samples for subsequent compliance and/or retention testing is 10 lbs. If a lab tests a 1 gram from a 10-pound batch (1 gram from 4,536 grams), this test sample size increases the risk of sample bias. Contaminants like bacteria or fungi in a sample are often not evenly distributed throughout a batch test sample. In a 1-gram sample for testing, there's a higher likelihood that no pathogen is present in the small portion tested, even if it exists elsewhere in the batch. Therefore, MGC suggests larger sample testing size (10 or 25 grams) to enhance one's probability of capturing a more representative portion of the entire batch, reducing the chance of missing contaminated areas.

Our fourth recommendation is:
Implement Species-Specific Testing in Phases: Transitioning to species-specific pathogen testing should follow a phased approach to ensure accuracy, minimize disruption to the cannabis industry, and allow sufficient time for assay development and validation by method developers. These pathogen recommendations are grounded in clinical literature that highlights the potential harm posed by certain cannabis-associated microbes. Prevalence data has been sourced from Simon Fraser University (British Columbia, Canada) and Kannapedia.net, which catalog over 2,200 microbiomes of bacterial, fungal, and viral DNA found on cannabis tissues across the U.S. This data has identified and prioritized the most relevant pathogens for cannabis safety, which supports the need for a targeted testing approach.

This phased strategy will enable Alaska to adopt pathogen testing protocols that are more clinically relevant, focused on consumer safety, and aligned with best practices from other states. Species-specific testing truly protects consumers by differentiating between thousands of non-harmful fungi and molds that pose no risk. California and 23 other US jurisdictions have already adopted this modern approach, which mirrors the protocols used in hospitals to rapidly diagnose multiple pathogens using extensive PCR-based platforms for gastrointestinal and respiratory diseases. By adopting this methodology, Alaska can ensure a more accurate and safety-focused testing regime

Phase 2 - Future Considerations - The following pathogens have been found on cannabis and known to cause clinical harm.

1. *Fusarium falciforme* - Kannapedia.net (https://kannapedia.net/) and References [41-46]; Fusariosis, Skin Infections, Pulmonary Infections, Disseminated Infections, mycotoxins - References [41-42. 47-52]
2. *Fusarium proliferatum* - Kannapedia.net, References [41-46]; Fusariosis, Keratomycosis, Sinusitis, Onychomycosis, Pulmonary Infections, Systemic Infections - References [41-42. 47-52]
3. *Fusarium solani* - Kannapedia.net, References [41-46, 53]; Keratitis, sinusitis, endophthalmitis, onychomycosis, cutaneous infections, mycetoma and arthritis, organ membrane disruption - References [41-42. 47-52]
4. *Fusarium oxysporum* - Kannapedia.net, References [41-46, 53]; Keratitis & onychomycosis in both immunocompetent and immunocompromised - References [41-42. 47-52]
5. *Mucor circinelloides* - Reference [53]; Pulmonary, Cutaneous, Rhinocerebral, Gastrointestinal & Disseminated Mucormycosis - References [54-55]
6. *Mucor racemosus* - References [53]; Pulmonary, Cutaneous, Rhinocerebral, Gastrointestinal & Disseminated Mucormycosis References 54-55]

7. *Penicillium citrinum* - Kannapedi.net, References [41, 50-51, 53]; Hypersensitivity Pneumonitis, mycotoxins, Severe Asthma with fungal sensitization, Occupational Lung disease, mycotoxins, particularly citrinin. Citrinin is a nephrotoxic compound, meaning it can damage the kidneys when ingested. Reference [41-42, 46, 52, 54, 56]
8. *Penicillium expansum* - Kannapedia.net, References [41, 51, 53]; Mycotoxins, particularly patulin, which is harmful if ingested. Patulin is known to cause a variety of adverse health effects, including nausea, gastrointestinal disturbances, and immune suppression. References [41-42, 52, 54]
9. *Penicillium marneffei* - Kannapedia.net, References [40, 50]; Skin lesions, fungemia, pulmonary lesions, anemia. Typically impacts individuals with HIV, hematological malignancies, and immunosuppressive agents. It is the only species in the Penicillium genus known to cause systemic infections in humans - References [41-42, 52, 54, 56]
10. *Candida albicans* - Kannapedia.net; Oropharyngeal candidiasis (oral thrush): Common in those with HIV/AIDS, Vulvovaginal candidiasis (vaginal thrush), Candidemia/disseminated infections, Pneumonia, Meningitis, paronychia, onychomycosis, endocarditis, eye infection, and intertriginous candidiasis - Reference [57]

I thank you for your time and consideration. If you have any questions, please feel free to contact me.

Respectfully,

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Dr. Sherman Hom - Cannabis Industry Experience

In 2012 at the New Jersey Department of Health, Division of Public Health and Environmental Laboratories, Dr. Hom was the Project Manager that led a team of expert analytical chemists that started the first Cannabis Testing Laboratory in support of the State's Medical Cannabis Program. The team validated methods for the quantitation of eight (8) cannabinoids using HPLC UV-DAD, various heavy metals using ICP-MS, and various aflatoxins & ochratoxin A using affinity chromatography & HPLC MS.

From 2019 to 2021, Sherman was the Project Manager of a team that started the Cannabis Microbial Testing Lab and validated qPCR methods to detect shiga toxin producing *E. coli* (STEC), *Salmonella* spp., and the four human pathogenic species of *Aspergillus* (*A. flavus, A. fumigatus, A. niger,* and A. *terreus*).

From 2017 to 2021, he led a team that created the first continuously updated Medical Cannabis Testing Regulations by State. Comparative analyses were performed to make general observations and identify gaps & trends in the testing rules. For example in 2019, a literature search identified 25 chemical pesticides that were detected in a cannabis marketed product. Of these 25 pesticides, nine pesticides were not required to be tested by any state, while the other sixteen pesticides were required to be tested by various fractions of the states. Moreover in 2019, sixteen (16) of 27 states (59%) had a unique set of microbial testing regulations.

Since May 2021, Dr. Hom has been the Director of Regulatory Affairs at Medicinal Genomics Corporation (MGC), which markets genetics-based cannabis tests and breeding technologies. His primary responsibility is to make recommendations concerning microbial contamination testing and other related testing regulations to US state, Washington D.C., US territory, tribal nations within US borders, and country regulatory and legislative officials that are tasked with either drafting and/or modifying cannabis, hemp, and psychedelic mushroom regulations and bills to ensure safe products for patients and consumers. Approximately 75% of the US jurisdictions have partially or fully adopted MGC's cannabis microbial contamination testing regulations based on scientific principles.

Another major task is to continuously update MGC's Cannabis Microbial Testing Regulations by US State, Washington D.C., Territory, and tribal nations. (https://www.medicinalgenomics.com/cannabis-microbial-testing-regulations-by-state/). Comparative analyses of the microbial testing rules for the cannabis product types (plant material, concentrates, edibles, and infused-products non-edible) by state have been performed to provide information concerning general observations, identify gaps, and trends over the previous 7 years.

A third task is the creation of cannabis standards. Sherman supports the AOAC's Cannabis Analytical Science Program (CASP), the National Cannabis Laboratory Council, ASTM International D37.03 Cannabis Committee's Laboratory Subcommittee and the Association of Food and Drug Officials Cannabis, Hemp, and Natural Medicine's Committee.

Dr. Hom is the microbial contamination testing subject matter expert for the One Plant Policy Team that is drafting a whitepaper for cannabis policy standardization for the United States and other interested countries.

Lastly, Sherman has proposed next steps in providing the genomic data from cannabis flower microbiome research study to support a panel of national, regional, state, or country subject matter experts in various fields to engage in a dialogue to propose a consensus set(s) of cannabis microbial contaminant testing rules. The technology to obtain this genomic data has been developed by the MGC R&D team.

He has a B.A. in Biology from the University of California at San Diego, a Ph.D. in Microbiology from University of California at Davis, and was a Postdoctoral Fellow in Molecular Microbiology at the Department of Biology, The John Hopkins University (Baltimore, MD).

From: Trevor Haynes
To: CED MCB AMCO (CED sponsored)
Subject: AMIA Public Comment
Date: Friday, November 21, 2025 9:49:17 AM
Attachments: AMIA Written Comment to MCB Nov 2025.pdf

Please find AMIA's written comments for the Marijuana Mailbox attached to this email.

Thank you!

Trevor Haynes
General Manager, GOOD Cannabis
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www.alaskamia.org

11/21/2025

Dear Members of the Marijuana Control Board,

Thank you for the continued work you do to oversee and safeguard Alaska's regulated cannabis industry. The Alaska Marijuana Industry Association (AMIA) respectfully submits the following comments in support of actions that will strengthen regulatory stability and ensure that both the marijuana and hemp industries can continue to operate safely, transparently, and successfully.

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1. Temporary Pause on the Issuance of New Marijuana Licenses

AMIA urges the Marijuana Control Board to support a temporary pause of approximately **6 to 12 months** on the issuance of new marijuana licenses.

A pause is needed to allow the Alcohol and Marijuana Control Office (AMCO) sufficient capacity to fulfill its responsibilities to current licensees. AMCO is managing a substantial workload, including:

- Processing license renewals on time
- Conducting regular and consistent site visits
- Providing responsive communication and guidance to licensees
- Supporting multiple working groups and industry–agency collaborations
- Implementing the Governor's executive order requiring significant regulatory reduction
- Coordinating enforcement operations and maintaining public safety

Given these wide-ranging responsibilities, a temporary pause on issuing new licenses will allow the agency to focus on stabilizing its core functions. Strengthening AMCO's operational capacity is essential before expanding the number of businesses that depend on it.

AMIA believes this proactive approach will benefit both regulatory integrity and long-term industry health.

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2. Advisory on Intoxicating Hemp and Clarification of Alaska Law

AMIA also requests that the Board direct AMCO to issue a formal advisory addressing growing concerns surrounding **intoxicating hemp products**.

The advisory should:

- Clarify Alaska's zero-THC hemp policy
- Remind hemp and marijuana licensees and consumers what is and is not legal under state law

- Provide clear, accessible education on the current regulatory framework
- Communicate recent federal developments, including proposed Farm Bill updates that would remove federal pathways for intoxicating cannabinoids within the legal definition of hemp

Clear guidance is increasingly important as consumer confusion grows and federal rules continue to evolve. A statewide advisory would support responsible commerce, protect public safety, and ensure consistent expectations across industries.

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3. Support for Alaska's Hemp Industry

AMIA also wants to emphasize our ongoing support for Alaska's hemp industry. Many marijuana licensees are also hemp licensees, and our sectors share aligned goals related to agriculture, small business development, manufacturing, and consumer protection.

We support the hemp industry broadly and want to see it flourish. Our request for a hemp advisory is not intended to restrict hemp commerce; rather, it is intended to bring clarity and regulatory certainty during a time of significant national change.

Clear, consistent education and enforcement of state law benefits both hemp operators and marijuana licensees and helps ensure a fair and safe marketplace for all.

Conclusion

A temporary pause on new marijuana licenses, combined with a clear advisory on intoxicating hemp, will strengthen Alaska's regulatory framework, support AMCO in managing its extensive responsibilities, and protect both the marijuana and hemp industries during a period of transition.

AMIA respectfully urges the Marijuana Control Board to take these actions at an upcoming meeting in order to support a strong, stable, and transparent cannabis landscape in Alaska.

We would also like to extend our sincere thanks to the members of the Marijuana Control Board and the staff of the Alcohol and Marijuana Control Office for their continued dedication, professionalism, and commitment to maintaining a safe and responsible regulatory system.

Thank you for your consideration,

Alaska Marijuana Industry Association Board of Directors