clean label PROJECT®

Clean. Pure. Science.

Code of Practice:

THC-Free

Version 3: November 2020

CERTIFIED THC FREE clean label PROJECT®

The Clean Label Project is a national non-profit with the mission to bring truth and transparency to consumer product labeling. Using actual retail sampling and testing, we establish evidence-based benchmarks to identify the America's best products using data and science as opposed to marketing.

Together, we are changing the definition of food and consumer product safety in America.

This Code of Practice: Clean Label Project THC-Free Certification is subject to revision. Go to www.cleanlabelproject.org to confirm the current version.

Questions, clarification, interpretations, and suggested revisions regarding this Code of Practice: Clean Label Project THC-Free Certification may be provided in writing to:

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Objectives and Disclaimers

This Code of Practice: THC-Free provides criteria for the evaluation and marketing of manufacturers seeking compliance and certification for their products to the Clean Label Project Code of Practice: THC-Free. The implied compliance, evaluations, and the contents contained within are limited exclusively to meeting the minimum requirements for the Clean Label Project Code of Practice: THC-Free. It is the responsibility of the Operator to comply with all applicable state, national, and international laws such as, but not limited to, California Prop 65, FDA food labeling laws, FDA food safety laws, FDA pesticide tolerance level requirements, Country of Origin labeling, Tobacco, Tax, and Trade Bureau Laws, and USDA National Organic Program requirements, as applicable. It is also the responsibility of the Operator to comply with any applicable voluntary third-party private schemes such as, but not limited to Organic, Fair Trade, and Global Food Safety Initiative benchmarked standards.

In no way does compliance to this Code of Practice: THC-Free imply compliance to any other state or federal regulation or private standard. The Clean Label Project does not assume, displace, or undertake to discharge any obligations or responsibilities of the manufacturer or any other party, including but not limited to those responsibilities and obligations arising from the other certifications or standards referenced within this Code of Practice: THC-Free. Under no circumstances shall Clean Label Project or any of its affiliates be liable for direct, indirect, incidental, consequential, special, punitive or any other use of this Code of Practice: THC-Free. This Code of Practice: THC-Free may be revised from time to time.

Code of Practice: THC-Free

I. Purpose

CBD stands for cannabidiol. It is the second most prevalent of the active ingredients of cannabis (marijuana). While CBD is one of hundreds of components of marijuana, by itself it does not cause a "high." The "high" is created by another well-known cannabinoid, tetrahydrocannabinol (THC)[1]. This compound is known for its psychoactive effects when consumed with cannabis, or marijuana. With the recent passing of the 2018 Farm Bill[2], CBD-infused products have seen a surge in popularity. With CBD being linked to potential benefits like aiding with anxiety and pain relief, it is no surprise that the CBD industry has been experiencing significant growth. Reports show the potential for the CBD industry to reach $20 billion by 2024[3].

While the industry is experiencing meteoric growth, regulatory oversight has not moved as quickly. Industry associations[4,5] have petitioned for increased regulation all in an effort to ensure consumer trust and industry compliance clarity. FDA has asserted its commitment to rule-making while also reiterating that any decisions that it does make will be sound and science-based[6]. Recent media reports and class action lawsuits[7,8,9,10] have revealed some CBD consumers are testing positive for THC in work-mandated drug screens. Retailers and brands are both searching for solutions to secure consumer trust and minimize risk.

Under the 2018 Farm Bill, the industry and legal standard for any CBD product is one that contains less than 0.3% THC by weight. Anything above this threshold is categorized as marijuana and considered a controlled substance. However, just because a product does not exceed 0.3% THC by weight, does not make a product THC-Free. This variable industry interpretation is at the core of the consumer and regulatory confusion and debacle. The variability in the sensitivity of laboratory instrumentation used to test for the presence of THC further complicates the matter. With some laboratories only testing down to 100 parts per million (ppm) and others testing down to single digit parts per billion (ppb), the accuracy of a non-detect test result is conditional upon the sensitivity of the laboratory instrument used. This can result in a false sense of comfort and security for both brands, retailers, and consumers.

The Clean Label Project Code of Practice: THC-Free takes a strict stance on the testing and oversight of products making a THC-Free claims. Unlike other standards and protocols, the Clean Label Project Code of Practice: THC-Free aims to require and independently sample and perform unannounced routine finished product testing to provide consumers additional assurance as to the absence of THC in the CBD products they ingest, put on their skin, or provide for their family.

The purpose of the Code of Practice is to:

1. Provide a market tool and evaluation criteria for growers, suppliers, manufacturers, brand owners, and retailers to begin identifying, evaluating, ensuring products labeled as THC-Free meet a certain minimum standard for THC-Free
2. Create a market opportunity for manufacturers looking to communicate this commitment to consumers
3. Satisfy the growing consumer demand for transparency through an on-package market solution that is backed by testing and data
4. Create a certification standard with mandatory unannounced independent sampling and testing to ensure the products on retail shelves continue to meet the requirements of Clean Label Project Code of Practice: THC-Free

II. Scope

Growers, manufacturers, co-manufacturers, brand owners, and retailers are eligible to apply for the Clean Label Project Code of Practice: THC-Free Certification.

This Code of Practice outlines compliance documentation, supplier assurance, routine testing, and marketing requirements and guidelines.

III. Limitations

The contents of this document do require producing documentation demonstrating compliance to certain minimum applicable food safety standards. Certification to this Code of Practice does not constitute a guarantee of 100% of products are compliant to the stated limits. There is inherent variability in consumer-packaged goods batches, loads, and runs. However, QA programs that adhere to “best practices” should deliver high levels of consistency. There is a certain percent error that is assumed using analytical chemistry instrumentation at low detection levels. These shall be accounted for during the compliance evaluation process.

IV. References

[1] https://www.health.harvard.edu/blog/cannabidiol-cbd-what-we-know-and-what-we-dont-2018082414476

[2] https://www.farmers.gov/manage/farmbill

[3] https://www.forbes.com/sites/irisdorbian/2019/05/20/cbd-market-could-reach-20-billion-by-2024-says-new-study/#33720d3949d0

[4] https://www.supermarketnews.com/laws-regulations/fmi-nudges-fda-clarify-cbd-product-regulation

[5] http://www.ahpa.org/Resources/Regulations/GovernmentAdvocacy.aspx

[6] https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd

[7] https://www.westword.com/marijuana/colorado-hemp-companies-battle-over-millions-of-dollars-in-cbd-oil-lawsuit-11470254

[8] https://www.consumerreports.org/cbd/can-you-take-cbd-and-pass-a-drug-test/

[9] https://wjla.com/features/7-on-your-side/investigations/consumers-claiming-positive-drug-test-after-cbd-oil

[10] https://www.charlotteobserver.com/news/local/article232244097.html

V. Definitions

A. Administrator: the organization(s) contractually responsible for the Clean Label Project Code of Practice- THC-Free implementation and oversight

B. Certified: An Operator that has been formally recognized by the Administrator as fulfilling the requirements as outlined in the Clean Label Project Code of Practice- THC-Free

C. Non-Compliant: Nonconformance to established requirements within the Clean Label Project Code of Practice- THC-Free

D. Operator: the organization, business, entity, or person(s) responsible for Clean Label Project- THC-Free compliance oversight

E. Compliant: Compliance to the requirements outlined in the Clean Label Project: Code of Practice- THC-Free

VI. Compliance Framework

A. Initial Compliance Requirements

1. Proof of Food Safety/Good Manufacturing Practices (GMP) Compliance

Food safety and/or good manufacturing audits are now a normal and necessary component within the food and consumer product supply chain. An Operator shall provide proof of food safety or GMP compliance. Examples of food safety compliance include, but are not limited to, proof of certification under a Global Food Safety Initiative

benchmarked standard or proof of compliance to other third-party specified food safety or GMP standards.

Standards such as USDA National Organic Program, Kosher, or another food quality/marketing standards, shall not be deemed sufficient.

Proof of Food Safety/GMP Compliance documentation shall be dated within the past 18 months. The location listed on the Proof of Food Safety Compliance documentation shall match the location of product manufacture disclosed on application documentation. If an Operator uses multiple co-packers or co-manufacturers, proof of food safety shall be supplied for each location.

Disclosure of a recall or any governmental inquiry such as California government inquiry into California Proposition 65 compliance shall be disclosed.

2. **High-risk ingredient identification**

Only certain ingredients are considered high-risk for purposes of THC contamination. The Operator shall identify which ingredients and suppliers are considered high risk for purposes of Clean Label Project: Code of Practice- THC-Free compliance

3. **Mandatory internal lot/batch testing**

All finished product lots/batches shall be internally tested by the Operator using an accredited laboratory with instrumentation calibrated to detect down to the Clean Label Project: Code of Practice- THC-Free requirements

Proof of these tests results shall be randomly requested and audited by the Administrator to ensure ongoing compliance.

4. **Disclosure of co-manufacturing split operation (THC-Free & Marijuana)**

Any Operator that uses a co-manufacturer for production shall receive an affidavit attesting to whether the co-manufacturer manufacturers any products that contain marijuana (THC levels>0.3% THC by dry weight) or not. Any Operator that utilizes a co-manufacturer with split operations shall be deemed high-risk and should expect great random unannounced sampling and testing. All costs of sampling and testing shall be borne by the Operator. An Operator utilizing a split operation

co-manufacturer should request proof of how the operation prevents contamination and comingling of high-risk ingredients.

5. **Established Standard Operating Procedure for High-Risk Approved Supplier list**

The purpose of a Supplier Quality Assurance Program is to ensure a supplier's ability to deliver on a good or service that will satisfy the customer's needs. A Supplier Quality Assurance Program can be an effective means to control the quality of incoming products or materials and ensure the products meet necessary specifications.

To ensure ongoing compliance to the Clean Label Project Code of Practice: THC-Free, Operators shall have a Standard Operating Procedure in place to specify:

1) How the Operator will approve a high-risk ingredient supplier to their Approved High-Risk Supplier list
2) The compliance provisions that an Operator will use to oversee the Approved High-Risk Supplier list
3) How the Operator will remove a high-risk ingredient supplier from their Approved High-Risk Supplier list

Note: The Operator shall, at a minimum, perform independent testing as a condition of accepting the incoming material or in recognition that the finished product must comply with maximum tolerance levels as established by the Clean Label Project. Performing independent testing PRIOR to accepting an incoming high-risk ingredient and PRIOR to adding a high-risk ingredient supplier to the Approved High-Risk Supplier list.

The Standard Operating Procedure should include provisions for situations such as the following:

1) An Operator may elect to perform routine testing on all new and current suppliers
2) An Operator may elect to utilize a risk assessment to identify high risk ingredients or suppliers to minimize costs and optimize testing efficiency
3) An Operator may choose to do independent testing for some suppliers, and allow other suppliers to perform their own testing and supply the test results/Certificate of analysis.

6. Proof of Finished Product Test Compliance

Finished product testing is at the foundation of the Clean Label Project Code of Practice: THC-Free.

All products seeking Clean Label Project Code of Practice certification shall pass a test to ensure compliance to the Clean Label Project tolerances established in VIII.

B. Renewal/Ongoing Compliance

All requirements outlined in Section VI. A apply. However, it should be noted that the Administrator of the Clean Label Project will perform testing at the Operator's expense. It is recommended that the Operator perform routine finished product testing to ensure ongoing compliance with the Clean Label Project Code of Practice- THC-Free

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The Administrator of the Clean Label Project shall annually confirm proof of compliance with Section VI. A.

It should be noted that the Clean Label Project Code of Practice- THC-Free is a living document. The requirements and scope of testing will be revisited on a regular basis and proactively communicated to Operators. Operators shall be provided a minimum of 1-year implementation period when changes are made to the Clean Label Project Code of Practice- THC-Free.

VII. Administrator Requirements

A. Testing Requirements

1. The Administrator of the Clean Label Project shall perform the testing associated with Clean Label Project- Code of Practice: THC-Free compliance as outlined in VIII.
2. The Administrator shall perform random and unannounced sampling and testing of products. The Administrator may elect to perform risk-based testing. The cost of testing shall be borne by the Operator.
3. The Administrator shall inform Operators of their respective test results. If the Administrator tests a product resulting in a non-compliant test result (deemed as greater/less than 30% of the established limit), the Administrator shall inform the Operator in writing of the test results. To continue to comply with the Clean Label Project Code of Practice- THC-Free, the Operator shall perform a root cause analysis to determine the source of the non-compliant test result within 30 days of the non-compliant test result. This root cause analysis and corrective action plan

shall be supplied to the Administrator in writing. The Administrator shall review the root cause analysis and corrective action plan and determine if acceptable. The Operator should expect additional Administrative surveillance of this product.

4. In the event of a Non-Compliant test result, the Administrator reserves the right to perform increased surveillance testing on the product and brand to ensure ongoing compliance with the Clean Label Project Code of Practice- THC-Free requirements. The cost of this testing shall be borne by the Operator. The Operator may elect to perform increased surveillance testing on the ingredient/supplier in question.

B. Accreditation Requirements

1. The Administrator shall maintain ISO 17025 laboratory accreditation to ensure test result accuracy, consistency, team member training and best practice.

2. The Administrator shall remain in good standing with its ISO 17025 accreditation.

3. The Administrator may elect to outsource testing to a designated third-party laboratory if the scope of testing is outside its expertise. Any contract laboratory must provide proof of laboratory consistency, competency, and accuracy best practice, such as proof of ISO 17025 for the specified scope/matrix.

C. Sampling Requirements

1. The Administrator shall sample products by simulating the consumer shopping experience. The Administrator shall procure enough sample to fulfill testing needs. This may only require that one sample be selected for testing.

2. The Administrator shall ideally procure samples through local or online retailers. If not feasible, only in extreme circumstances shall the Administrator procure samples from the Operator's website or the Operator. In that specific circumstance, the sample provided by the Operator must be in a finished sealed (unopened) package that would be sold at retail. The cost of the samples shall be borne by the Operator.

3. Where applicable and feasible, the Administrator shall prepare/dilute samples in accordance with Operator packaging instructions.

4. The Administrator shall retain a picture of the product purchased, the lot number, and the receipt that shows the date, location, and retail of purchase. This information shall be provided to the Operator for purposes of root cause analysis, investigations, and continuous improvement.

D. Marketing Compliance Requirements

1. The Administrator shall be responsible for maintaining and publishing the list of all products bearing the Clean Label Project Certification Mark on the Clean Label Project website.

2. Any product not meeting the requirements outlined in the Clean Label Project Code of Practice Sections VI.A, VI.B, or preventing the Administrator from fulfilling its requirements outlined in VII shall be found to be non-compliant with the Clean Label Project Code of Practice-THC-Free and issued a Non-Compliance.

3. In the event that a Non-Compliance goes unmitigated in excess of 90 days, the Clean Label Project will remove the product from the online listing and issue a notification that the product has been dropped from listing. Additional adverse action may be executed if the Operator continues to use the Clean Label Project certification mark on the dropped product.

4. The Administrator shall confirm the Operator's compliance to the Mark Use Requirements outlined in the Brand Standard.

E. Other Requirements

1. In the process of ensuring compliance to the Clean Label Project Code of Practice, the Clean Label Project provides necessary authority to the Administrator to require additional testing, surveillance, or documentation requests as deemed necessary.

2. The Administrator shall maintain strict confidentiality of all Operator's documentation and test reports.

3. The Operator should include the following (or similarly worded) warning on product packaging and marketing materials

    a. The statements made regarding these products have not been evaluated by the Food and Drug Administration. The efficacy of these products has not been confirmed by FDA-approved research.

b. These products are not intended to diagnose, treat, cure or prevent any disease.
c. All information presented here is not meant as a substitute for or alternative to information from health care practitioners. Please consult your health care professional about potential interactions or other possible complications before using any product. The Federal Food, Drug and Cosmetic Act requires this notice.
d. This product is made of a derivative of hemp. While all effort has been taking to minimize the presence of THC, trace levels of THC may still exist. This product is under a quality system that tests for the presence of THC down to 0.05%.

VIII. Request Deviation

1. Any request for deviation to requirements of the Standard shall be provided in writing to the Technical Administrator.

2. The Technical Administrator in consultation with the CLP, shall consider but is not obligated to grant the request for deviation and shall not be obligated to return any portion of fees paid if the Applicant/ Operator chooses to discontinue certification as a result of the request for deviation decision.

3. Technical Administrator shall not be responsible for any costs incurred by Applicant/ Operator related to nonconforming product which is the subject of rejected deviation request or other noncompliance.

4. To apply for a deviation, the Applicant/ Operator shall request deviation in writing and submit to the Technical Administrator.

5. Requested variances, in instances of Force Majeure, shall be considered on a case by case basis. Operators shall provide a written request to Technical Administrator documenting the situation and proposed course of action for approval.

6. The Technical Administrator, in consultation with the CLP, shall produce a written response back to the Applicant/ Operator regarding the request for deviation within 10 business days.

IX. Testing Requirements

A. Analytical Equipment Administrator Requirements

Assay		Equipment		Detection Limit	
THC		LCMS-DAD		0.05%	

*LOD/LOQ subject to change depending on complexity of matrix