

OVERSIGHT OF CONSUMABLE HEMP PRODUCTS

**LOUISIANA DEPARTMENT OF HEALTH -
OFFICE OF PUBLIC HEALTH**

PERFORMANCE AUDIT SERVICES

**Informational Brief
April 10, 2023**

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April 10, 2023

The Honorable Patrick Page Cortez,
President of the Senate
The Honorable Clay Schexnayder,
Speaker of the House of Representatives

Dear Senator Cortez and Representative Schexnayder:

This informational brief provides the results of our review of the Louisiana Department of Health's oversight of consumable hemp products. This brief is intended to provide timely information related to an area of interest to the legislature or based on a legislative request. I hope this information will benefit you in your legislative decision-making process.

Respectfully submitted,



Michael J. "Mike" Waguespack, CPA
Legislative Auditor

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CHP OVERSIGHT





Informational Brief

Oversight of Consumable Hemp Products

Louisiana Department of Health – Office of Public Health

MICHAEL J. "MIKE"
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Audit Control #40230011
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Background

Act 164 of the 2019 Regular Legislative Session¹ enacted laws² for the regulation of consumable hemp products (CHPs), which are products derived from industrial hemp³ that contain cannabinoids⁴ and are intended for consumption or topical use. Any CHP that is manufactured, distributed, imported, or sold in Louisiana must be registered and receive label approval from the Louisiana Department of Health (LDH).⁵ According to LDH, there are 2,564 registered CHPs as of March 16, 2023.

Multiple agencies are involved in the regulation of industrial hemp and CHPs, as shown in Exhibit 1. This report focuses only on LDH’s responsibilities.

Exhibit 1 Agency Responsibilities	
Agency	Responsibilities
Louisiana Department of Agriculture and Forestry	License and regulate growers, seed producers, processors, and handlers of industrial hemp; test industrial hemp crops
Louisiana Department of Health	License, regulate, and inspect consumable hemp processors; approve labels for and register consumable hemp products; provide a list of registered products to the public and ATC
Louisiana Office of Alcohol Tobacco Control (ATC)*	Permit and inspect retailers that sell CHPs
*A division of the Department of Revenue Source: Prepared by legislative auditor’s staff using information from Louisiana Revised Statutes.	

Why We Compiled This Informational Brief

We conducted this review in response to a legislative request asking us to look into LDH’s registration of consumable hemp products that were not in compliance with current law. We reviewed state law, LDH policies and processes, and data provided by LDH on registered products.

Informational briefs are intended to provide more timely information than standards-based performance audits. While these informational briefs do not follow all *Government Auditing Standards*, we conduct quality assurance activities to ensure the information presented is accurate. In addition, we incorporated feedback we received from LDH throughout the report.

¹ <https://www.legis.la.gov/legis/ViewDocument.aspx?d=1143697>

² Louisiana Revised Statutes (La. R.S.) 3:1481 through 3:1484

³ Industrial hemp is defined as the plant *Cannabis sativa* L. and any part of such plant, including the seeds and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a total delta-9 THC concentration of not more than 0.3% on a dry weight basis.

⁴ Cannabinoids are the various naturally occurring, biologically active, chemical constituents of cannabis such as tetrahydrocannabinol (THC), which is the primary psychoactive compound of cannabis, and cannabidiol (CBD).

⁵ La. R.S. 3:1483

What We Found

Laws regarding CHPs have evolved since initially enacted by Act 164 of the 2019 Regular Legislative Session. The legislature has subsequently enacted new legislation that modified the maximum amount of tetrahydrocannabinol (THC), which is the primary psychoactive compound that some CHPs contain (*see text box at right*). Most recently, Act 498 of the 2022 Regular Legislative Session⁶ added a new maximum of eight milligrams per serving. This new limit took effect on June 16, 2022, but the law provided a grace period for any CHP that exceeded the new THC limits and was already registered with LDH prior to June 16, 2022. These products could be sold until January 1, 2023. Exhibit 2 shows the changes in allowable THC levels.

Cannabis sativa L. plants contain various forms of THC, including delta-8 and delta-9. The concentration of these compounds comprise the total THC concentration of a CHP.

Exhibit 2 Timeline of Statutory Changes to Allowable THC Levels in CHPs Legislative Sessions 2019 to 2022	
THC Levels	
Act 164 of 2019	Maximum delta-9 THC concentration of 0.3%
Act 344 of 2020	No change
Act 336 of 2021	Added maximum total THC concentration of 1% (i.e., the combination of the different types of THC such as delta-8 and delta-9, etc. cannot exceed 1%)
Act 498 of 2022	Added maximum of eight milligrams of THC per serving; effective June 16, 2022, but these products could be sold until January 1, 2023, if already registered by LDH by June 16, 2022
Source: Prepared by legislative auditor's staff using information from www.legis.la.gov .	

As shown in Exhibit 2, the maximum allowable THC levels in CHPs changed twice in three years after being established in 2019. These multiple changes, coupled with the fact that CHP is an emerging industry in Louisiana, present challenges to regulators such as LDH. According to CHP industry stakeholders, the lack of clarity for what products are allowed and the costs associated with changing regulations are a challenge. Industry stakeholders also said they have struggled with receiving timely approvals from LDH which has affected them financially.

LDH is responsible for registering products and reviewing labels to ensure CHPs sold for use in Louisiana comply with maximum THC limits. To register a CHP, firms must pay a fee of \$50 per product to LDH and provide an image of the label that will go on the packaging. According to state law,⁷ labels must not contain any medical claims (e.g., claims that a product may reduce the risk of a disease or a health-related condition) and must clearly state the amount of THC per serving, serving size,⁸ and servings per package.⁹ In addition, the label

⁶ <https://legis.la.gov/Legis/ViewDocument.aspx?d=1289568>

⁷ La. R.S. 3:1483

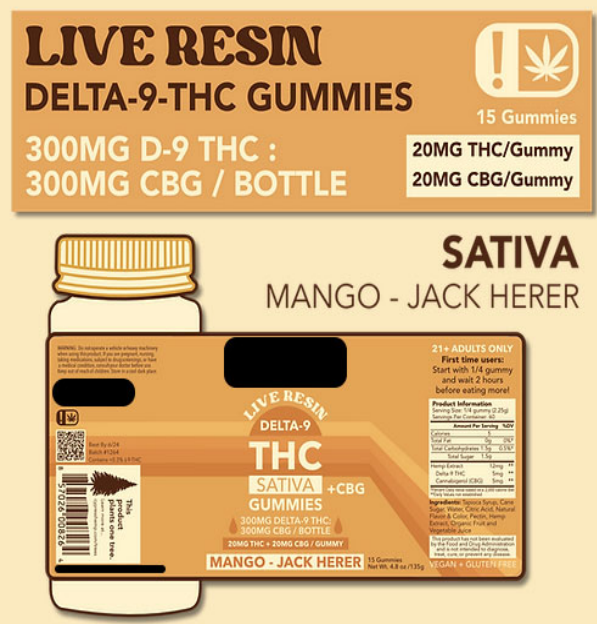
⁸ Serving sizes must be delineated by means of one of the following acceptable methods: provision of a measuring device with the packaging; markings on the label or package that indicate the amount of a serving; use of discrete units (e.g., tablets, capsules, gummies, etc.).

⁹ Labels also must identify any adult-use CHPs, which are products that contain more than 0.5 milligrams of total THC per package.

must include a scannable bar code, QR code, or web address linked to a document or website that contains a certificate of analysis (COA) (see text box at right). The COA must be completed by an accredited laboratory and include test results identifying the cannabinoid profile by percentage of weight and a potency test of the final product indicating the serving size, total THC per serving, total number of servings, and total THC per package.¹⁰ Exhibit 3 shows an example of a label and a cannabinoid profile from the COA for the same product.

A certificate of analysis (COA) is a document produced by an approved laboratory attesting to the composition of a product.

Exhibit 3
Example Label and Cannabinoid Profile from Certificate of Analysis

Label	Cannabinoid Profile from COA*																																																								
	<p>Cannabinoid Profile</p> <p>1 Unit = 1/4 gummy, 4 servings per gummy, 2.17g.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="border-top: 2px solid black; border-bottom: 2px solid black;"> <th style="text-align: left;">Analyte</th> <th style="text-align: center;">%</th> <th style="text-align: center;">mg/g</th> <th style="text-align: center;">mg/unit</th> </tr> </thead> <tbody> <tr><td>THCa</td><td style="text-align: center;">ND</td><td style="text-align: center;">ND</td><td style="text-align: center;">ND</td></tr> <tr><td>Delta-9 THC</td><td style="text-align: center;">0.267</td><td style="text-align: center;">2.67</td><td style="text-align: center;">5.79</td></tr> <tr><td>Delta-8 THC</td><td style="text-align: center;">ND</td><td style="text-align: center;">ND</td><td style="text-align: center;">ND</td></tr> <tr><td>THCV</td><td style="text-align: center;">ND</td><td style="text-align: center;">ND</td><td style="text-align: center;">ND</td></tr> <tr><td>CBDa</td><td style="text-align: center;">ND</td><td style="text-align: center;">ND</td><td style="text-align: center;">ND</td></tr> <tr><td>CBD</td><td style="text-align: center;">0.002</td><td style="text-align: center;">0.02</td><td style="text-align: center;">0.05</td></tr> <tr><td>CBDV</td><td style="text-align: center;">ND</td><td style="text-align: center;">ND</td><td style="text-align: center;">ND</td></tr> <tr><td>CBN</td><td style="text-align: center;">0.002</td><td style="text-align: center;">0.02</td><td style="text-align: center;">0.04</td></tr> <tr><td>CBGa</td><td style="text-align: center;">ND</td><td style="text-align: center;">ND</td><td style="text-align: center;">ND</td></tr> <tr><td>CBG</td><td style="text-align: center;">0.3</td><td style="text-align: center;">3.00</td><td style="text-align: center;">6.51</td></tr> <tr><td>CBC</td><td style="text-align: center;">0.005</td><td style="text-align: center;">0.05</td><td style="text-align: center;">0.10</td></tr> <tr><td>Total THC</td><td style="text-align: center;">0.27</td><td style="text-align: center;">2.67</td><td style="text-align: center;">5.79</td></tr> <tr><td>Total CBD</td><td style="text-align: center;">0</td><td style="text-align: center;">0.02</td><td style="text-align: center;">0.05</td></tr> </tbody> </table>	Analyte	%	mg/g	mg/unit	THCa	ND	ND	ND	Delta-9 THC	0.267	2.67	5.79	Delta-8 THC	ND	ND	ND	THCV	ND	ND	ND	CBDa	ND	ND	ND	CBD	0.002	0.02	0.05	CBDV	ND	ND	ND	CBN	0.002	0.02	0.04	CBGa	ND	ND	ND	CBG	0.3	3.00	6.51	CBC	0.005	0.05	0.10	Total THC	0.27	2.67	5.79	Total CBD	0	0.02	0.05
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<p>*ND means none detected. Source: Prepared by legislative auditor’s staff using information from the COA of one of LDH’s registered products.</p>																																																									

LDH reviews the label to ensure compliance with state and federal¹¹ requirements, such as serving sizes, and reviews the COA to ensure compliance with CHP requirements, such as maximum THC levels. For example, the CHP in Exhibit 3 is one gummy that the processor says should be split into four pieces, so ¼ of a gummy constitutes one serving. That serving is 2.17 grams and contains 5.79 milligrams of delta-9 THC, which meets the current requirements for maximum THC levels per serving. If a CHP meets regulatory requirements, LDH approves the label and adds the product to its list of registered products which can be accessed on LDH’s website.¹² ATC uses this list of registered products to regulate retailers that sell CHPs.

¹⁰ COAs also include the results of other tests such as residual solvents and pesticides. In addition, the lab must not have direct or indirect interest in a grower, processor, or distributor of hemp or hemp products.

¹¹ The Food and Drug Administration also promulgates rules for food and drug labels.

¹² <https://ldh.la.gov/page/4080>

LDH's process for registering CHPs had multiple issues. For example, LDH registered CHPs that are prohibited by law such as those intended for inhalation and those exceeding maximum THC levels. As of March 2023, LDH has not yet removed these products from its list of registered products, despite promulgating an emergency rule (ER) effective January 20, 2023 to do so. These issues are discussed in more detail below.

LDH's stance is that several of these products, particularly vape pens, were properly registered. However, the registration did not eliminate the fact that they were still illegal for sale for inhalation.

- **According to LDH, as of March 2023, its list of registered products includes 36 CHPs intended for inhalation that are prohibited by law, such as vape pens, because LDH was only required to approve product labels and did not require entities to submit product images when they registered.** State law¹³ prohibits the sale or offer for sale of any part of hemp for inhalation. According to LDH, it registered CHPs without realizing they were for inhalation because it did not require that the entity registering the CHP submit an image of the product. LDH became aware in September 2022, via a complaint, that it had added two CHPs intended for inhalation to the list of registered products and removed the products on September 7, 2022. Subsequently, LDH recognized that it had not established a process, which includes due process, to remove CHPs from the list of registered products so it put the products for inhalation back on the list on September 13, 2022. After this date, LDH registered 34 additional products intended for inhalation including 12 products registered on November 10, 2022. To address these issues, LDH promulgated an ER effective January 20, 2023, that develops a removal process and requires, among other things, that applicants for registration include an image of the CHP to help LDH identify products intended for inhalation. However, as of March 2023 LDH has not enforced the new provisions of the ER as discussed later in the report.
- **LDH inadvertently removed prohibited dosage methods from its rules in May 2022.** Act 344 of the 2020 Regular Legislative Session¹⁴ gave LDH authority to make rules that allowed it to deny products with specific prohibited dosage methods. In response to that Act, LDH promulgated new rules in April 2021 that prohibited several dosage methods including inhalation.¹⁵ However, according to LDH, it inadvertently removed those prohibited dosage methods in subsequent rule changes that were promulgated in May 2022. The ER that became effective January 20, 2023, added back those prohibitions that allow LDH to deny applications for CHPs that are intended for use via prohibited dosage methods.

LDH's stance is that it also put the vape pens back on the list because the labels were proper and met the criteria. It did not have a rule related to dosage vehicles.

¹³ La. R.S. 3:1482

¹⁴ <https://legis.la.gov/Legis/ViewDocument.aspx?d=1182597>

¹⁵ The rule also specifically prohibited CHPs intended for subcutaneous use, intravenous use, and rectal insertion.

- **As of March 2023, LDH’s list of registered products also includes 198 edible CHPs¹⁶ that exceed the eight-milligram maximum THC per serving requirement, 52 of which LDH approved after the law became effective on June 16, 2022.¹⁷ According to LDH, it registered 52 of these prohibited products because it did not begin enforcing the new maximum until August 1, 2022.** Act 498 of the 2022 Regular Legislative Session added a new maximum of eight milligrams of THC per serving for CHPs effective June 16, 2022. According to LDH, the ER that it promulgated to operationalize this new law was not effective until August 1, 2022; however, this date contradicts the effective date in state law. We reviewed LDH data and found that LDH registered an edible CHP that exceeds the eight-milligram maximum as recently as October 14, 2022, which is after LDH stated it started enforcing the new maximum.
- **LDH has not enforced its ER that became effective January 20, 2023. As a result, products that do not comply with state law are still on LDH’s list of registered products.** As previously mentioned, the ER establishes a process to remove CHPs from the list of registered products effective January 20, 2023. However, LDH stated that it has not implemented this process as of March 2023 because it wanted to get feedback from the legislature first, and because it wanted to ensure it complied with the statute and removed only noncompliant products. On February 3, 2023, and March 1, 2023, the House Health and Welfare Committee held oversight hearings to discuss the ER. According to LDH, based on input from committee members it has delayed enforcement of the ER until it receives direction from the legislature. As a result, the 36 CHPs intended for inhalation and the 198 edible CHPs that exceed the eight-milligram maximum are still on LDH’s list of registered products as of March 2023.
- **We reviewed LDH’s CHP data and found additional edible CHPs that appear to exceed the eight-milligram maximum.** In addition to the 198 edible CHPs that LDH identified as exceeding the eight-milligram maximum THC per serving, we identified at least another nine during our review. We did not review the entirety of LDH’s list of 2,564 registered products, but the list may contain additional prohibited products that LDH needs to remove. According to LDH, multiple staff have reviewed the list of CHPs that exceed the eight-milligram maximum so that when it implements the new provisions of the ER to revoke products and remove them from the list of registered products, it will have an accurate list.
- **According to LDH, staffing issues have affected its ability to timely review and register CHPs.** Act 498 of the 2022 Regular Legislative Session added a requirement that LDH must notify the submitting party of any deficiencies which prevent LDH from approving the CHP label within 15 business days of the date of submission. If LDH fails to notify the submitting party within 15 business days, the product may be sold from the day following the 15th business day until the

¹⁶ Includes 137 gummies and 61 other types of edibles such as cookies and chocolates. LDH also registered 26 CHPs in other forms such as lotions and beverages that exceed the eight-milligram THC limit; however, this report only focuses on edible forms of CHPs.

¹⁷ LDH approved additional CHPs after June 16, 2022; however, LDH received the applications for those products before the June 16th effective date so they were not included in the analysis.

submitting party receives final approval or denial from LDH. In addition, state law¹⁸ requires that LDH employ a minimum of two full-time employees to review and approve products. However, according to LDH, it has struggled since 2019 to hire and retain staff, and has lost eight staff members since December 2021. According to LDH, as of January 2023, it has hired three employees to review and register CHPs and plans to hire and train additional staff.

¹⁸ La. R.S. 3:1483