H. Facilities shall be located on premises that are maintained free of the following:

1. disused equipment, waste, debris or other materials that may serve as harborages for or attractants to vermin;
2. overgrowth of vegetation;
3. poorly-drained areas; and
4. excessively-dusty areas.

I. Equipment used in manufacturing operations shall not be additive, reactive, or absorptive to any product or its components and shall be installed in such as manner as to facilitate cleaning and not to contribute to potential cross-contamination of finished products.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2980 (December 2022).

Chapter 9. Approved Laboratories for Testing Medical Marijuana

§901. General Requirements

A. Permittee facilities shall only utilize approved laboratories, as defined in this Section, for testing of medical marijuana.

B. Prior to testing medical marijuana to verify compliance, a laboratory shall apply for and receive a medical marijuana laboratory license from the Louisiana Department of Health.

C. A laboratory holding or seeking a medical marijuana laboratory license shall comply with all applicable requirements of R.S. Title 40, Chapter 4, Part X-E (R.S. 40:1046 et seq.).

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2981 (December 2022).

§903. Application Process

A. Applications for initial licensure and renewal of licensure shall be made using documents supplied by the department for this purpose.

B. Applicants shall be required to supply the following documentation as part of the application process:

1. proof of accreditation through the National Institute on Drug Abuse (NIDA), the National Environmental Laboratory Accreditation Conference (NELAC), or the International Organization for Standardization (ISO); or proof of operation of a licensed or permitted medical marijuana testing laboratory in another state for the previous 12 months, and accreditation or pending accreditation through ISO;
2. an affidavit that representatives of the State Health Officer shall be granted access to all areas of the facility utilized for medical marijuana testing upon request; and
3. documentation indicating that the firm is currently able to access and utilize the Louisiana Medical Marijuana Tracking System (LMMTS).

C. Approved medical marijuana testing laboratory licenses shall be renewable annually every December 31. Applications for renewal shall be submitted to the Louisiana Department of Health no later than October 31; applicants shall provide copies of current accreditation-verification and permit documents in order for a new license to be issued to the facility.

D. Failure to renew in a timely fashion shall trigger a requirement to destroy all medical marijuana located at the facility after midnight on December 31. Any product remaining on the premises at that time shall be subject to seizure under the provisions of La. R.S. 40:632 et seq.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2981 (December 2022).

§905. Exemptions

A. The Agricultural Chemistry Laboratory of the Louisiana Department of Agriculture and Forestry is exempt from the requirements of §901 and §903.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2981(December 2022).

§907. Records

A. Laboratories shall maintain all records related to testing of medical marijuana for no less than three years. Such records shall be made available for review to representatives of the State Health Officer upon request.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2981 (December 2022).

Dr. Joseph Kanter
State Health Officer
and
Dr. Courtney N. Phillips
Secretary

2212#045

RULE

Department of Health
Office of Public Health

Registration of Foods, Drugs, Cosmetics
and Prophylactic Devices—Hemp Products
(LAC 49:I.Chapter 5)

Under the authority of R.S. 40:4 and 40:5, and in accordance with R.S. 49:950 et seq., the Administrative Procedure Act, the state health officer, acting through the Department of Health, Office of Public Health (LDH-OPH), has reenacted and amended certain sections of Chapter 5 (Registration of Foods, Drugs, Cosmetics and Prophylactic Devices) of Title 49 (*Public Health—Food, Drugs, and Cosmetics*) of the *Louisiana Administrative Code*. The LDH/OPH finds it necessary to make changes to the *Louisiana Administrative Code* as a consequence of changes made to hemp regulations under Act No. 498 of the 2022 Louisiana Legislature. The following changes authorize the LDH/OPH the ability to properly register these items, inspect firms that manufacture such items for human consumption, and conduct oversight of labeling, which could affect the health of Louisiana's citizens and visitors.

This Rule amends §501 and §§517-537 of Chapter 5. §§517, 519 are recodified with new requirement language and the original §§531-533 are relocated to §§535-537. New language is implemented in the current §§531-533 to enact new requirements from the 2022 legislation. Changes to §501 amend existing definitions and add new definitions. This Rule is hereby adopted on the day of promulgation.

Title 49
PUBLIC HEALTH—FOOD, DRUGS, AND COSMETICS
Part I. Regulations
Chapter 5. Registration of Foods, Drugs, Cosmetics and Prophylactic Devices

§501. Definitions
[Formerly 49:2.2100]

A. Unless otherwise specifically provided herein, the following words and terms used in this Chapter of Title 49, and all other Chapters of Title 49 which are adopted or may be adopted, are defined for the purposes thereof as follows.

* * *

Adult-Use Consumable Hemp Product—any consumable hemp product that contains more than 0.5 milligrams of THC per package.

* * *

Package—container or wrapping in which any consumer commodity is enclosed for the purposes of display or delivery to retail purchasers.

* * *

Serving—total quantity of discrete units or of liquid in a package a processor recommends for consumption at one time.

* * *

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J), R.S. 40:4(A)(13), R.S. 40:5(A)(8)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by the Louisiana State Board of Health, September 1968, amended by the Department of Health, Office of Public Health, LR 46:358 (March 2020), amended LR 47:479 (April 2021), amended LR 48:1290 (May 2022), amended LR 48:2982 (December 2022).

§517. Registration of Consumable Hemp Products

A. - B. …

C. In lieu of the annual examination and administration charge normally collected under R.S. 40:628(B), the applicant for a consumable hemp product registration must provide (both initially and on or before July 1 of each year) the department with an application form, a cashier's check or money order made payable to the department in the amount of $50 per each separate and distinct product, specimen copies of labeling in paper or electronic format, laboratory accreditation verification documentation, a copy of the current grower or processor's license issued by the authority of competent jurisdiction for the firm responsible for hemp crop from which the products are derived, and a list of all products the applicant wishes to register with the department. If the packet meets these regulatory requirements, the department will issue to the applicant an FD-8a certificate of consumable hemp product registration and the application information will be entered into the consumable hemp products database.

D. No person is authorized to distribute any consumable hemp products in the state of Louisiana unless that person has first obtained a certificate of consumable hemp product registration from the department, except that if a firm submits product labeling and supporting documentation for review to the department and does not receive a response in writing within 15 business days of that initial submission, the product may be sold after the fifteenth business day by any permitted wholesaler or retailer until the submitting party receives notice in writing from the department that the product in question is accepted or rejected for registration.

E. Any firm may apply with the department for the designation of its products as "Louisiana hemp products," provided that those products are produced from hemp grown in Louisiana and are processed at a Louisiana-based manufacturer. These items will be designated with a special mark on the department's list of registered products once they have been registered with the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1483(L) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:359 (March 2020), amended LR 47:479 (April 2021), amended LR 48:1290 (May 2022), amended LR 48:2982 (December 2022).

§519. Consumable Hemp Products Labeling Requirements: Certificate of Analysis

A. Consumable hemp products must bear labeling that includes a scannable bar code, QR code, or a web address linked to a document or website containing the certificate of analysis for that product.

B. - C.4. …

5. a cannabinoid profile listing all major phytocannabinoid constituents by percentage of dry weight;

6. serving size for the product, total THC (as defined in R.S. 3:1481) per serving, number of servings per package, and total THC per package (expressed in terms of milligrams per gram);

7. the amount of any detected residual solvent in the product in the product in parts per million, except that this analyte will not be required for floral hemp material; detections may not meet or exceed the following amounts:

a. butanes—800 ppm;
b. heptanes—500 ppm;
c. benzene—1 ppm;
d. toluene—1 ppm;
e. hexanes—10 ppm;
f. xylenes—1 ppm;
g. ethanol—5,000 ppm;

8. the amount of any detected pesticide residues in the product in parts per million; any detection above the limit of quantitation for a category I pesticide (see Table 1 of this Section) is defined as an exceedance and a basis for rejection of the product by the department; category II pesticides have maximum contaminant levels as defined in Table 1;

9. the amount of any microbiological contaminants in the product in appropriate units; total yeast/mold may not meet or exceed 10,000 colony-forming units per gram and total pathogenic *Escherichia coli* bacteria or *Salmonella* spp. may not meet or exceed 1 colony-forming unit per gram;

10. the amount of any detected heavy metal traces in the product in parts per million; detections may not meet or exceed the following amounts:

a. arsenic (As)—10 ppm;
b. cadmium (Cd)—4.1 ppm;
c. lead (Pb)—10 ppm;
d. mercury (Hg)—2 ppm.

D. No consumable hemp product may contain more than 0.3 percent delta-9 THC or one percent total THC on a dry-weight basis. Except for floral hemp material, no

consumable hemp product may contain more than eight milligrams of total THC per serving. Products registered prior to the effective date of this rule exceeding the per-serving threshold may be sold until January 1, 2023.

E. Table 1: Category I and II Pesticides

Name	Maximum Contaminant Level (MCL) in ppm
Category I (includes aldicarb, carbofuran, chlorpyrifos, coumaphos, daminozide, dichloryos, dimethoate, ethoprop(hos), etofenprox, fenoxycarb, imazalil, methocarb, methyl parathion, meyinphos, paclobutrazol, propoxur, spiroxamine, and thiacloprid)	0
Category II	
Abamectin	0.3
Acephate	5
Acetamiprid	5
Acequinocyl	4
Azoxystrobin	40
Bifenazate	5
Bifenthrin	0.5
Boscalid	10
Captan	5
Carbaryl	0.5
Chlorantraniliprole	40
Clofentezine	0.5
Cyfluthrin	1
Cypermethrin	1
Diazinon	0.2
Dimethomorph	20
Etoxazole	1.5
Fenhexamid	10
Fenpyroximate	2
Flonicamid	2
Hexythiazox	2
Fludioxionil	30
Imidacloprid	3
Kresoxim-methyl	1
Malathion	5
Metalaxyl	15
Methomyl	0.1
Myclobutanil	9
Naled	0.5
Oxamyl	0.2
Pentachloronitrobenzene	0.2
Permethrin	20
Phosmet	0.2
Piperonylbutoxide	8
Prallethrin	0.4
Propiconazole	20
Pyrethrins	1
Pyradiben	3
Spinetoram	3
Spinosad	3
Spiromesifen	12
Spirotetramat	13
Tebuconazole	2
Thiamethoxam	4.5
Trifloxystrobin	30

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1483(L) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:359 (March 2020), amended LR 47:480 (April 2021), amended LR 48:1290 (May 2022), amended LR 48:2982 (December 2022).

§531. Consumable Hemp Products Labeling Requirements: Adult-Use Products

A. Any product meeting the definition of an "adult-use consumable hemp product" must bear a label statement to this effect.

B. Products registered prior to the effective date of this rule that do not bear the statement required by Subsection A may be sold until July 1, 2023.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1483 and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2983 (December 2022).

§533. Consumable Hemp Products Labeling Requirements: Serving Sizes and THC Content

A. Labeling must clearly indicate the amount of THC per serving in a product, the serving size, and the number of servings per package.

B. Serving sizes must be delineated by means of one of the following acceptable methods:

1. provision of a measuring device with the packaging;

2. markings on the label or package that indicate the amount of a serving;

3. use of discrete units (e.g., tablets, capsules, gummies, et cetera).

C. Products registered prior to the effective date of this rule that do not meet the requirements of this Section may be sold until July 1, 2023.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1483 and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2983 (December 2022).

§535. Penalties for Violations of Requirements to Register Consumable Hemp Products [Formerly §531]

A. Any person who violates the provisions requiring registration of industrial-hemp-derived cannabidiol products is subject to the penalties provided for by R.S. 3:1484 and other sanctions as provided for by the State Food, Drug, and Cosmetic Law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1482(J) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:359 (March 2020), amended by the Department of Health, Office of Public Health, LR 47:480 (April 2021), LR 48:1291 (May 2022), LR 48:2983 (December 2022).

§537. Exemptions [Formerly §533]

A. Consumable hemp products that have been produced in accordance with R.S. 40: 1046 or that are Food and Drug Administration (FDA)-approved pharmaceuticals are not subject to the requirements of this regulation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1482(J) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:359 (March 2020), amended LR 47:480 (April 2021), LR 48:1291 (May 2022), LR 48:2983 (December 2022).

Dr. Courtney N. Phillips
Secretary

2212#046