DECLARATION OF EMERGENCY
Louisiana Department of Health
Office of Public Health
Registration of Foods, Drugs, Cosmetics and
Prophylactic Devices
LAC 49:501, 517, 519, 531, 533, 535, 537

The Louisiana Department of Health, Office of Public Health (LDH/OPH), pursuant to the emergency rulemaking authority granted by R.S. 40:4(A)(13), hereby adopts the following Emergency Rule for the protection of public health. This Emergency Rule is promulgated specifically in accordance with R.S. 49:962 of the Administrative Procedure Act (R.S. 49:950, *et seq.*) and Section 1 of Act 498 of the 2022 Regular Session.

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 will 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. Further, this Emergency Rule will provide the state health officer the ability to make critical decisions that protect human health. Accordingly, the following Emergency Rule, effective August 1, 2022, shall remain in effect for a maximum of 180 days, or until the final Rule is promulgated, whichever occurs first.

This rule amends §501 and §§517 – 537 of Chapter 5 of Title 49—Public Health—Food, Drugs, and Cosmetics. §§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.

Title 49
PUBLIC HEALTH—FOOD, DRUGS, AND COSMETICS

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.

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

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

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

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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:

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§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 (fifteen) business days of that initial submission, the product may be sold after the fifteenth business day by any permitted wholesaler or retailer until the product in question is accepted or rejected in writing by the department 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. 3:1482(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 47:479 (April 2021), LR 48:1290 (May 2022), amended LR 48:

§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.1-4 . . .

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) 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.

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), amended by the Department of Health, Office of Public Health, LR 48:1290 (May 2022), amended by the Department of Health, Office of Public Health, LR 48:

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§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:

§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:

§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 LR 47:480 (April 2021), amended LR 48:1290 (May 2022), amended LR 48:

§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), amended LR 48:1290 (May 2022), amended LR 48:

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

Interested persons may submit written comments to Michael Vidrine, Director, Sanitarian Services, Office of Public Health, Louisiana Department of Health, P.O. Box 4489, Baton Rouge, LA 70821-4489. He is responsible for responding to inquiries regarding this Emergency Rule.

Dr. Courtney N. Phillips, Secretary

8/1/22