

NOTICE OF INTENT
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

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, notice is hereby given that the state health officer, acting through the Louisiana Department of Health, Office of Public Health (LDH-OPH), intends to reenact and amend 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 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.

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.

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 by the Department of Health, Office of Public Health, LR 48:

§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 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 by the Department of Health, Office of Public Health, 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 of this Part) 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, dichloroys, 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
Fludioxonil	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

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:

§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 (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:

Family Impact Statement

The proposed Rule should not have any known or foreseeable impact on family formation, stability, and autonomy. In particular, the proposed Rule has no known or foreseeable impact on:

1. the stability of the family;
2. the authority and rights of persons regarding the education and supervision of their children;
3. the functioning of the family;
4. family earnings and family budget;
5. the behavior and personal responsibility of children;
6. the ability of the family or a local government to perform the function as contained in the proposed Rule.

Poverty Impact Statement

The proposed Rule should not have any known or foreseeable impact on any child, individual or family as defined by R.S. 49:973(B). In particular, there should be no known or foreseeable effect on:

1. the effect on household income, assets, and financial security;
2. the effect on early childhood development and preschool through postsecondary education development;
3. the effect on employment and workforce development;
4. the effect on taxes and tax credits;
5. the effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

Small Business Analysis

The proposed Rule should have no adverse impact on small businesses as defined in the Regulatory Flexibility Act.

Provider Impact Statement

The proposed Rule should not have any known or foreseeable impact on providers as defined by HCR 170 of the 2014 Regular Legislative Session. In particular, there should be no known or foreseeable effect on:

1. the effect on the staffing level requirements or qualifications required to provide the same level of service;
2. the total direct and indirect effect on the cost to the providers to provide the same level of service; or
3. the overall effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments on the proposed rule. Such comments must be received no later than Tuesday, October 25, 2022 at COB, 4:30 p.m., and should be addressed to Michael Vidrine, Director, Sanitarian Services, P.O. Box 4489, Baton Rouge, LA 70821.

Public Hearing

Interested persons may submit a written request to conduct a public hearing either by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on Monday, October 10, 2022. If the criteria set forth in R.S. 49:961(B)(1) are satisfied, LDH will conduct a public hearing at 9:00 a.m. on October 25, 2022 in Room 118 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Allen Enger at (225) 342-1342 after October 10, 2022. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing attendees when the parking ticket is presented to LDH staff at the hearing.

Dr. Courtney N. Phillips
Secretary

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES**

Person Preparing Statement:	<u>Brian R. Warren</u>	Dept.:	<u>Louisiana Department of Health</u>
Phone:	<u>225-342-7514</u>	Office:	<u>Office of Public Health</u>
Return Address:	<u>628 N. 4th Street</u> <u>Baton Rouge, LA 70802</u>	Rule Title:	Registration of Foods, Drugs, Cosmetics, and Prophylactic Devices

Date Rule Takes Effect: December 20, 2022

SUMMARY

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL

GOVERNMENTAL UNITS (Summary)

The Office of Public Health (OPH) will incur \$905 SGF in expenses associated with the publication of this proposed rule change.

This proposed rule amends Chapter 5 Registration of Foods, Drugs, Cosmetics and Prophylactic Devices of Title 49 – Public Health – Food, Drugs, and Cosmetics in accordance with Act 498 of the 2022 RLS. Specifically, the rule:

- adds definitions for Adult-Use Consumable Hemp Product, Package and Serving,
- updates the documentation needed to register consumable hemp products to include the laboratory accreditation verification documentation and a copy of the current grower or processor’s license,
- provides an exception that specifies when hemp can be distributed without a Certificate of consumable hemp product registration from the department,
- provides terms under which a firm may apply for the “Louisiana Hemp Products” designation,
- updates the labeling requirements for consumable hemp products; and
- updates the permissible amounts of pesticide residues, microbiological contaminants, and residual solvents that may be present in consumable hemp products.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed rule change will not affect revenue collections for state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES OR NON-GOVERNMENTAL GROUPS

It is anticipated that this proposed rule may have an economic cost to businesses associated with growing, processing, or selling consumable hemp products. To the extent that a business’ existing product contains above the permissible amount of pesticide residues, microbiological contaminants, and residual solvent for consumable hemp products, then the product cannot be sold in Louisiana. Additionally, there may be costs associated with updating product labels to meet the revised labeling requirements.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule will not impact competition or employment.

Signature of Agency Head or Designee

Doris Brown
Assistant Secretary, Office of Public Health
Typed Name & Title of Agency Head or Designee

Date of Signature

Legislative Fiscal Officer or Designee

Date of Signature