

DECLARATION OF EMERGENCY

Department of Health Office of Public Health

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

The Department of Health, Office of Public Health (LDH/OPH), pursuant to the emergency rulemaking authority granted by R.S. 40:4(A)(13) and R.S. 3:1483(L), hereby adopts the following Emergency Rule for the protection of public health. This Emergency Rule is effective on May 2, 2025, and is adopted in accordance with R.S. 49:962 of the Administrative Procedure Act (R.S. 49:950, et seq.).

This Emergency Rule amends §501 to provide for additional definitions, to amend existing definitions, and to repeal certain existing definitions; adds a new §516 to provide for the issuance of permits to in-state and out-of-state processing facilities; amends §§517-519; adds a new §521 to provide for distillate potency testing, batch testing, and certificate of analysis; repeals §§527-531 in accordance with Act 752 of the 2024 Regular Session; amends §533 and §535; adds a new §534 regarding variances in package contents; and adds §539 regarding additional enforcement provisions. New language is adopted in §516, §§517-521, §533, §535, and §539, including disclosure of ownership information of hemp firms, allowing for the revocation of the registration of a hemp product for the cause of failure to provide a certificate of analysis meeting regulatory requirements, and allowing for exemptions to provisions triggering automatic revocation of all productions from a firm when multiple registrations are revoked within a two-year period when those revocations are the direct result of regulatory changes implemented by the department.

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Adult-Use Consumable Hemp Product—Repealed.

Consumable Hemp Product—any product derived from industrial hemp that contains any cannabinoid, including cannabidiol, or THC, and is intended for consumption or topical use. This special class of products includes, but is not limited to, the following: food, animal foods or feed, hemp flower, and pet products.

Consumable Hemp Products Database—repository of information on products and firms that are registered with the Cannabis Program of LDH/OPH that fall into the category of consumable hemp products.

Department—for the purposes of this Chapter, the Office of Public Health, Louisiana Department of Health.

Distillate—the product of condensation of an evaporated substance to produce a highly-concentrated solution.

Industrial Hemp-Derived Cannabidiol Products (IHDCP)—Repealed.

Industrial Hemp-Derived Cannabidiol Products Database—Repealed.

Liquid Concentrate—concentrated water-soluble liquid containing THC components derived from consumable hemp that can be consumed directly or added to a food or beverage.

Manufacturer—the person, whether permitted or not by the department as a consumable hemp processor, who manufactures a consumable hemp product into the final form in which it will be distributed or offered for sale.

Package—container or wrapping in which any consumer commodity is enclosed for the purposes of display or delivery to retail purchasers; in the context of consumable hemp products, this term refers to a group of individual servings offered together as a single unit.

Related Entity—an entity that shares at least 50 percent direct or indirect common ownership with another entity.

Serving—total quantity of discrete units or of liquid in a package a processor recommends for consumption at one time; in the context of consumable hemp products, this term refers to discrete (i.e., separate and completely unattached to other servings) pieces of a solid substance, containers of a beverage, or one milliliter of a tincture, extract or distillate designed for oral or sublingual use.

THC—any combination of tetrahydrocannabinol, THC components, and tetrahydrocannabinolic acid.

THC Components—any isomer, analog or derivative of the tetrahydrocannabinol molecule.

Tincture—an extract of plant material produced using an organic solvent, frequently mixed with a carrier oil and optional flavorants to generate a finished product; this category does not include liquid concentrates.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1483(L), R.S. 40:4(A)(13), R.S. 40:5(A)(8)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by the State Board of Health, September 1968, amended by the Department of Health, Office of Public Health, LR 46:358 (March 2020), LR 47:479 (April 2021), LR 48:1290 (May 2022), LR 48:2982 (December 2022), LR 49:1940 (November 2023), amended LR 51:

§516. Consumable Hemp Processors; Permits

A. Any person seeking to manufacture or process consumable hemp products in Louisiana must first obtain from the department a separate annual consumable hemp processor permit for each facility in which such manufacturing or processing will occur. No person shall process or manufacture any consumable hemp product in Louisiana at a facility for which a current valid annual consumable hemp processor permit has not been issued by the department.

B. The department shall issue an annual consumable hemp processor permit, or renewal thereof, for a processing

or manufacturing facility located in Louisiana if all of the following conditions are met.

1. The applicant and facility comply with all applicable requirements of LAC Title 51, Part VI, §103.

2. The applicant pays the annual permit fee as required by R.S. 3:1483(A)(1) or successor statute.

3. The applicant discloses the legal name and ownership interest of each person owning more than a 5 percent interest in the applicant.

4. The applicant submits the online or physical application form prescribed by the department.

5. The applicant and facility comply with all applicable requirements of Part VI of Chapter 10-a of R.S. Title 3, this Section, and this Chapter.

C. The department shall issue an annual consumable hemp processor permit, or renewal thereof, by endorsement for a processing or manufacturing facility located in another state if all of the following conditions are met.

1. The applicant demonstrates that it holds a current valid permit for the facility issued by the state's health department, or equivalent agency, pursuant to a regulatory scheme under which an inspection of the facility is conducted prior to initial permit issuance to ensure compliance with compulsory sanitary and manufacturing requirements substantially equivalent to those set forth in LAC 51, Part VI and the issuing agency has authority to conduct additional inspections as it deems necessary to ensure continuing compliance therewith.

2. The applicant pays the annual permit fee as required by R.S. 3:1483(A)(1) or successor statute.

3. The applicant discloses the legal name and ownership interest of each person owning more than a 5 percent interest in the applicant.

4. The applicant submits the online or physical application form prescribed by the department.

5. The applicant and facility comply with all applicable requirements of Part VI of Chapter 10-a of R.S. Title 3, this Section, and this Chapter.

6. The applicant consents to the personal jurisdiction of Louisiana courts and administrative tribunals for matters related to denial, issuance, revocation, or suspension of a permit, license, or registration under this Chapter.

D. Annual consumable hemp processor permits shall be issued on a fiscal year basis, expiring on June 30 of the fiscal year of issuance. The department shall prorate the annual fee for permits applied for and issued subsequent to July 1 of a fiscal year. Permit renewal applications, together with the required fee, must be submitted to the department no later than 30 days prior to permit expiration. The provisions of R.S. 49:977.3(B) shall apply to a timely-submitted renewal application.

E. Individuals seeking an annual consumable hemp processor permit shall provide to the department proof of being at least 21 years of age and a notarized attestation, given under penalty of perjury, stating that the individual has not been convicted of a felony under the laws of the United States, the state of Louisiana, or any other state or country, or been convicted in this or in any other state or by the United States of soliciting for prostitution, pandering, letting premises for prostitution, contributing to the delinquency of juveniles, keeping a disorderly place, letting a disorderly place, or illegally dealing in controlled dangerous substances.

F. Juridical entities (e.g. corporations or limited liability companies) seeking an annual consumable hemp processor permit shall provide to the department a notarized attestation, given under penalty of perjury and executed by the secretary, managing member, or other authorized individual, stating that no officer or shareholder/member owning more than five percent of the entity has been convicted of a felony under the laws of the United States, the state of Louisiana, or any other state or country, or been convicted in this or in any other state or by the United States of soliciting for prostitution, pandering, letting premises for prostitution, contributing to the delinquency of juveniles, keeping a disorderly place, letting a disorderly place, or illegally dealing in controlled dangerous substances.

G. Notice of final denial of a requested facility permit shall state the specific reason(s) for the denial and shall include notice of right to an administrative hearing concerning same, which right shall expire unless the applicant files, in the manner specified therein, a written request for an administrative hearing with the department within 20 calendar days of receipt of the notice. Any such request timely received shall be forwarded by the department to the Louisiana Division of Administrative Law. In addition to any method of service authorized by this Title, service of the notice on the applicant may be effected through any means authorized by LAC 51:I.109. Additionally, service may be made by electronic mail sent to any email address provided by the registrant to the department as part of or subsequent to the permitting or registration process, and shall be deemed effective even if returned as undeliverable.

H. The department may revoke or suspend a consumable hemp processor permit if the permit holder, or the facility for which the permit was issued, no longer complies with the prerequisites and conditions for obtaining or holding such permit set forth in this Chapter. Except as otherwise provided in Subsection I of this Section, revocation or suspension shall occur by issuance of an Order Revoking/Suspending Permit, the issuance, format, service, and administrative appeal of which shall be in accordance with the applicable requirements set forth in §518.B-C of this Chapter. If the state health officer determines, in his sole discretion, that immediate implementation of the order is necessary to abate a potential danger to the public life, health, or safety, and includes that finding in the order, the order shall be deemed an emergency order and shall not be stayed pending the decision of the Division of Administrative Law.

I. A permit issued by endorsement pursuant to Subsection C of this Section shall be automatically suspended or revoked if the out-of-state permit upon which it is based lapses, expires, or is suspended or revoked by the issuing agency. It shall be the affirmative duty of the holder of a permit issued by endorsement to inform the department of any such lapse, expiration, suspension, or revocation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1483(L), R.S. 40:4(A)(13), R.S. 40:5(A)(8)(17) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§517. Registration of Consumable Hemp Products

A. Each separate and distinct consumable hemp product must be registered with the department-annually and initially within 90 days of the effective date of these regulations or

prior to marketing the products in the state of Louisiana, whichever comes first.

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 subsequent year) the department with a packet that includes:

1. - 6. ...

7. for each separate and distinct product, photographs or renderings of the product that accurately depict the Title 49, Part I entirety of the product, including all accessories or physical items included or sold with the product, whether attached or not. The department may require the submission of a specimen of the actual product and all included accessories if it determines in its sole discretion that submitted renderings or photographs do not allow a sufficient determination that the product meets all applicable requirements of this Chapter;

8. for each separate and distinct product, a detailed written description of how individual servings will be packaged and marketed for sale. A product whose label fails to comply with the requirements of §533 of this Chapter will not be registered. A product packaged, labeled, or marketed in a manner that physically or functionally combines individual servings, resulting in a functional or suggested product serving size that exceeds five milligrams of total THC per serving, shall not be registered and shall be subject to revocation of registration pursuant to §518 of this Chapter;

9. the address and identifying information of any facility in which the product will be manufactured or processed, together with an indication of whether a current valid annual consumable hemp processor permit has been issued by the department for the facility; and

10. the legal name of the manufacturer of the product, together with the legal name and ownership interest of each person owning more than a five percent interest in the manufacturer.

D. ...

E. No person is authorized to distribute any consumable hemp product in the state of Louisiana unless such product is currently registered and entered into the consumable hemp products database by the department, except that if a firm submits product labeling and supporting documentation for review to the department and does not receive a written response within 60 business days of that initial submission, the product may be sold after the sixtieth 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. Upon the expiration of the 60 business days, the department will send written notice, via electronic mail only, confirming the "pending" status of any application and, if known, a date by which a final determination will be made.

F. ...

G. No consumable hemp product shall be registered if one or more of the following conditions concerning dosage vehicles apply:

1. - 3. ...

4. it is explicitly or clearly intended or characterized as being for rectal or vaginal insertion, including, but not limited to, vaginal or anal suppositories; this prohibition

shall not apply to products that are topical personal lubricants;

5. it includes floral hemp material, or constitutes a vape cartridge, vape pen, e-cigarette or a substantially similar item designed to facilitate inhalation; or

6. it is an alcoholic beverage as defined in R.S. 26:2.

H. ...

I. The department shall not register any consumable hemp product whose sale in Louisiana is prohibited under Part VI of Chapter 10-a of R.S. Title 3, particularly 3:1484(A)(3), 3:1484(B)(1)(b)(iii), and 3:1484(B)(4), or any rules of the department promulgated thereunder. Except as provided in Subsection J of this Section, the department shall only register consumable hemp products manufactured in a facility for which a consumable hemp processor permit has been issued by the department; any existing registration of consumable hemp products manufactured in a facility for which a consumable hemp processor permit has been not been issued by the department shall be deemed to meet the criteria for revocation under an Emergency Order pursuant to §518.D of this Chapter. This Subsection shall take effect on July 15, 2025.

J. Notwithstanding any provision of this Chapter to the contrary, a consumable hemp product manufactured in a facility for which a consumable hemp processor permit has not been issued by the department may be registered only by a person holding a consumable hemp processing permit issued by the department for a facility located in Louisiana, who shall ensure that the manufacturer meets all applicable requirements of §516 of this Chapter, that the facility meets applicable sanitary and manufacturing requirements substantially equivalent to those set forth in LAC 51, Part VI, and that such product meets all applicable requirements of this Chapter and of Part VI of Chapter 10-a of R.S. Title 3. Such person must have access to and retain for at least three years the records required by §521 of this Chapter, and shall make such records available to the department upon request.

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), LR 48:1290 (May 2022), LR 48:2982 (December 2022), LR 49:1940 (November 2023), amended LR 51:

§518. Revocation of a Consumable Hemp Product Registration

A. The department may revoke the registration of a consumable hemp product if:

1. - 2. ...

3. the product, including any accessories or physical items included therewith, is materially modified in a way that makes the photographs, renderings, or specimen submitted in connection with the registration no longer an accurate depiction thereof;

4. the product, product label, product packaging, or product marketing no longer complies with the prerequisites for registration set forth in, or otherwise violates any applicable provision or requirement of, this Chapter or Part VI of Chapter 10-a of R.S. Title 3;

5. The manufacturer of the product fails to comply with any requirement of this Chapter concerning the product, including §521; or

6. The sale of the product in Louisiana is prohibited under Part VI of Chapter 10-a of R.S. Title 3, particularly 3:1484(A)(3), 3:1484(B)(1)(b)(iii), and 3:1484(B)(4), or any rules of the department promulgated thereunder.

B. - E. ...

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 49:1941 (November 2023), amended LR 51:

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

A. - C.4. ...

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

6. - 10.d. ...

11. a cannabinoid profile for the “active ingredient” (cannabinoid-containing distillate or isolate used in formulating the finished product) listing all major cannabinoid constituents by percentage of dry weight.

D. Repealed.

E. ...

* * *

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), LR 48:1290 (May 2022), LR 48:2982 (December 2022), LR 49:1940 (November 2023), amended LR 51:

§521. Distillate Potency Test; Batch Testing; Certificates of Analysis

A. A consumable hemp processor or manufacturer shall obtain a certificate of analysis (COA) of the distillate or concentrate used to produce any consumable hemp product. The COA shall include the information required by §519.C.5 of this Chapter.

B. A manufacturer shall obtain a COA of each batch of consumable hemp product that it manufactures. The COA shall include the information required by §519.C.1-10 of this Chapter.

C. A consumable hemp processor or manufacturer shall not sell or distribute in Louisiana any consumable hemp product from a batch whose COA indicates an exceedance of any of the maximum contaminant limits set forth in §519.C.1-10 of this Chapter or indicates that the product otherwise violates any requirements of this Chapter or Part VI of Chapter 10-a of R.S. Title 3.

D. The COAs required by this Section shall be retained for at least three years and shall be made available to the department upon request.

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 51:

§527. Consumable Hemp Products Labeling Requirements: Marketing for Inhalation Prohibited

Repealed.

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

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 47:480 (April 2021), amended LR 48:1291 (May 2022), repealed LR 51:

§529. Consumable Hemp Products Packaging Requirements: Hemp Flower Packaging

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1483(J) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:1291 (May 2022), repealed LR 51:

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

Repealed.

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), repealed LR 51:

§533. Consumable Hemp Products Labeling and Packaging Requirements: Serving Sizes, Packaging Limits, 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. Consumable hemp beverages must meet the following requirements:

1. a serving must be 12 fluid ounces or greater;
2. a serving must not include more than 5 mg THC;
3. a container may not contain more than one serving;
4. a container must be tamper-evident;
5. a package may not include more than four containers.

C. Consumable hemp tinctures must meet the following requirements:

1. a serving must be one milliliter and may not contain more than one milligram of THC;
2. a container may not exceed 30 mL;
3. containers must include a dropper that readily dispenses precisely one serving.
4. tinctures must be oil-based and may not include any concentrated water-soluble liquid that can be consumed directly or added to any food or beverage
5. packaging must be child-resistant by design.

D. Products other than beverages and tinctures must meet the following requirements:

1. an individual serving must not include more than 5 mg THC;
2. a package must not contain more than 40 mg THC;
3. packaging must be child-resistant by design;
4. each serving must be a discrete unit.

E. Packaging of consumable hemp products may not be designed explicitly to appeal to children by means of the employment of naming, branding, or use of a logo bearing a substantial similarity to that of conventional food or beverage products already on the market.

F. Labeling on THC-containing products must bear a disclaimer that consumption of such products may cause the user to fail a pre-employment or routine drug screen.

G. Nonedible topical consumable hemp products shall not be subject to the requirements of this Section.

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 48:2982 (December 2022), LR 49:1940 (November 2023), amended LR 51:

§534. Consumable Hemp Products Labeling Requirements; THC Content

A. Labels on consumable hemp products must accurately reflect the contents of the packaging with a variation of no greater than 15 percent. This 15 percent variance allowance shall not be construed to allow a product to exceed the THC content maximum limits, including the per serving maximums, set forth in Part VI of Chapter 10-a of R.S. Title 3 and §533 of this Chapter.

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 51:

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

A. Any person who violates the provisions requiring registration of consumable hemp 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. Any person who violates the provisions requiring registration of consumable hemp products is subject to the penalties provided for by R.S. 3:1482 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. 3:1483 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 48:1290 (May 2022), LR 48:2982 (December 2022), LR 49:1940 (November 2023), amended LR 51:

§539. Additional Enforcement Provisions

A. The department may, randomly or based upon a complaint, procure a COA on a specimen of any registered consumable hemp product offered for sale in Louisiana to determine compliance with applicable requirements of this Chapter and Part VI of Chapter 10-a of R.S. Title 3. An appropriate Chain of Custody document shall be utilized for such purpose.

B. If a COA obtained in accordance with Subsection A of this Section shows that the product does not meet the requirements of this Chapter or Part VI of Chapter 10-a of R.S. Title 3, the registration of such product may be revoked by order issued pursuant to §518 of this Chapter, which order shall note the costs paid to procure the COA, including laboratory and shipping costs. Such product shall not thereafter be registered by any person for two years.

C. If the department revokes a product registration pursuant to Subsection B of this Section, the registration holder shall reimburse the department for the costs paid to procure the COA within 30 days of the revocation becoming final (i.e. not subject to further appeal or review). If such reimbursement is not received within 30 days, the registration holder shall additionally owe the department a civil penalty equal to three times the costs paid to procure the COA. If such additional civil penalty is not paid within 30 days of demand, the department may revoke all other product registrations held by the registration holder.

D. The department may revoke all other consumable hemp product registrations held by a person who has more than two consumable hemp products registrations revoked by the department within a two-year period. For three years thereafter, the department shall not accept any product registrations from such person or related entity, nor register any product manufactured by such person or related entity.

E. The department may revoke all consumable hemp processor permits held by a person who has more than two consumable hemp products registrations revoked by the department within a two-year period. For three years thereafter, the department shall not issue a consumable hemp processor permit to such person or to any related entity.

F. If the department revokes within a two-year period the registration of more than two consumable hemp products produced by a manufacturer, then the registration of all other consumable hemp products produced by such manufacturer may also be revoked. For three years thereafter, the department shall not register any products produced by such manufacturer or related entity.

G. A revocation of a consumable hemp product registration that occurs solely due to a change in law shall not be considered a revocation for the purposes of Subsections D, E, and F of this Section.

H. The provisions of this Section shall apply to the extent that they are more specific than any conflicting general enforcement provisions set forth in this Chapter or Title.

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 51:

Public Comments

Comments on this Emergency Rule may be directed to the attention of Tiffany Meche, Director of Sanitarian Services, at 628 North 4th Street, P.O. Box 4489, Baton Rouge, LA 70821-4489.

Bruce D. Greenstein
Secretary

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