




State of Louisiana

Louisiana Department of Health
Office of the Secretary

June 8, 2022

Via Statutorily Prescribed Email

To: The Honorable Fred H. Mills, Jr., Chairman, Senate Health & Welfare Committee
The Honorable Larry Bagley, Chairman, House Health & Welfare Committee

From: Dr. Courtney N. Phillips
Secretary 

Re: Second Report LAC 51:IX.101, 123, 125, 127, 129, 133, 135, 141, 143, 145, 147, 149, 303, 311, 313, 330, 331, 339, 343, 501, 503, 505, 507, and 509 – Marine and Fresh Water Animal Food Products

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Bureau of Health Services Financing, submits its second report regarding the Marine and Fresh Water Animal Food Products, LAC 51:IX.101, 123, 125, 127, 129, 133, 135, 141, 143, 145, 147, 149, 303, 311, 313, 330, 331, 339, 343, 501, 503, 505, 507, and 509.

A Notice of Intent on the proposed amendments was published in the April 20, 2022 issue of the *Louisiana Register* (LR 48:1225). No written comments were received and there was no request for a public hearing were received during the notice period. Because there were no requests for a public hearing, one was not held for these proposed amendments. Additionally, no substantive changes were made to the proposed amendments since the report provide for in R.S. 49:968B-C was submitted.

Unless otherwise directed, the Department anticipates adopting the April 20, 2022, Notice of Intent when it is published as a final rule in the July 20, 2022, issue of the *Louisiana Register*.

Please contact Justin Gremillion, at Justin.Gremillion@la.gov, if you have any questions or require additional information about this matter.

Cc: Joseph Kanter, MD, State Health Officer
Kimberly Hood, JD, MPH, OPH Assistant Secretary, LDH
Michael Vidrine, Chief Sanitarian, Bureau of Sanitarian Services, OPH, LDH
Bethany Blackson, Legislative Liaison, LDH
Catherine Brindley, Editor, *Louisiana Register*, Office of the State Register

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 (eater 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

NOTICE OF INTENT

**Department of Health
Office of Public Health**

Marine and Fresh Water Animal Food Products
(LAC 51:IX.101, 123, 125, 127, 129, 133, 135,
141, 143, 145, 147, 149, 303, 311, 313, 330,
331, 339, 343, 501, 503, 505, 507 and 509)

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES
RULE TITLE: Outpatient Hospital Services**

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

~~It is anticipated that implementation of this proposed rule will increase state costs by approximately \$10,944 for FY 21-22 as a result of the reimbursement for COVID-19 laboratory testing separately from the outpatient hospital surgery flat fee reimbursement amount, and will reduce state costs by approximately \$789,304 for FY 22-23 and \$887,167 for FY 23-24. It is anticipated that \$1,512 (\$756 SGF and \$756 FED) will be expended in FY 21-22 for the state's administrative expense for promulgation of this proposed rule and final rule.~~

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

~~It is anticipated that the implementation of this proposed rule will increase federal revenue collections by approximately \$27,641 for FY 21-22, and decrease federal revenue collections by approximately \$2,666,175 for FY 22-23 and \$2,996,745 for FY 23-24. It is anticipated that \$756 will be collected in FY 21-22 for the federal share of the expense for promulgation of this proposed rule and the final rule.~~

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS (Summary)

~~This proposed rule continues the provisions of the February 10, 2022 Emergency Rule which amended the provisions governing outpatient hospital services in order to provide reimbursement for laboratory testing for Coronavirus Disease 2019 (COVID-19) separately from outpatient hospital surgery fee schedule payments. Secondly, the proposed rule amends the provisions governing reimbursement to out of state hospitals to ensure consistency with in state rates. In addition, it repeals outdated, uncodified outpatient hospital rules. Beneficiaries and providers of outpatient hospital services will benefit from implementation of this proposed rule since it provides coverage for COVID-19 laboratory tests. It is anticipated that implementation of this proposed rule will increase expenditures in the Medicaid program by approximately \$37,073 for FY 21-22, \$139,500 for FY 22-23, and \$139,500 for FY 23-24 due to Medicaid reimbursement for COVID-19 laboratory testing separately from the outpatient hospital surgery flat fee reimbursement amount, but will reduce expenditures by approximately \$3,594,979 for FY 22-23 and \$4,023,412 for FY 23-24 as a result of the alignment of out of state hospital reimbursement rates with in state rates. This will result in a net savings of \$3,455,479 for FY 22-23 and \$3,883,912 for FY 23-24.~~

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

~~This rule has no known effect on competition and employment.~~

Patrick Gillies
Medicaid Executive Director

Evan Brasseaux
Interim Deputy Fiscal Officer

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 amend certain Sections of Chapters 1 and 3 of Part IX (Marine and Fresh Water Animal Food Products) of Title 51 (Public Health—Sanitary Code). In addition, Chapter 5 is proposed to be promulgated as an addition to this Part to address the regulation of molluscan shellfish aquaculture.

**Title 51
PUBLIC HEALTH—SANITARY CODE
Part IX. Marine and Fresh Water Animal Food
Products**

Chapter 1. Shellfish Growing Areas

§101. Definitions

[formerly paragraph 9:001]

A. ...

Adverse Pollution Conditions—a state or situation caused by meteorological, hydrological, or seasonal events or point source discharges that has historically resulted in elevate fecal coliform levels in a particular growing area.

Approved Area—the classification of a Louisiana shellfish growing area which has been approved by the state health officer with the assistance of the secretary of the Department of Wildlife and Fisheries for growing or harvesting shellfish for direct marketing. The classification of an approved area is determined through a sanitary survey conducted by the Department of Health in accordance with the guidelines set out in this rule and as hereafter amended and duly promulgated. An approved shellfish growing area may be temporarily made a closed area when a public health emergency resulting from, for instance a hurricane or flooding, is declared by the state health officer.

Aquaculture—cultivating shellfish in controlled conditions for human consumption. Cultivation includes propagation and growing of shellfish. These activities may occur in natural or man-made water bodies. These activities include seed collection, production, and cultivation in natural water bodies when shellfish are held off the bottom such as the use of racks, bags, or cages, and when shellfish are held in man-made water bodies such as the use of tanks, ponds, or raceways. These activities do not include depuration or wet storage.

Central Laboratory, in New Orleans, Public Health Laboratory for the State—Repealed.

Certified Laboratory—a laboratory conducting analysis for the Louisiana Molluscan Shellfish Program that has received a satisfactory rating during an on-site evaluation by

or point source discharges that has historically resulted in elevated fecal coliform levels in a particular growing area.

Approved Area—the classification of a Louisiana shellfish growing area which has been approved by the state health officer with the assistance of the secretary of the Department of Wildlife and Fisheries for growing or harvesting shellfish for direct marketing. The classification of an approved area is determined through a sanitary survey conducted by the Department of Health in accordance with the guidelines set out in this rule and as hereafter amended and duly promulgated. An approved shellfish growing area may be temporarily made a closed area when a public health emergency resulting from, for instance a hurricane or flooding, is declared by the state health officer.

Aquaculture—cultivating shellfish in controlled conditions for human consumption. Cultivation includes propagation and growing of shellfish. These activities may occur in natural or man-made water bodies. These activities include seed collection, production, and cultivation in natural water bodies when shellfish are held off the bottom such as the use of racks, bags, or cages, and when shellfish are held in man-made water bodies such as the use of tanks, ponds, or raceways. These activities do not include depuration or wet storage.

Central Laboratory, in New Orleans, Public Health Laboratory for the State—Repealed.

Certified Laboratory—a laboratory conducting analysis for the Louisiana Molluscan Shellfish Program that has received a satisfactory rating during an on-site evaluation by the shellfish evaluation officer for the state of Louisiana or the federal Food and Drug Administration (FDA) evaluation officer. The purpose of the evaluation will be to assure the uniform application of standard procedures and methods in the sampling and analytical examination of shellfish growing waters and to determine and assure the adequacy of facilities, equipment, and personnel to perform analytical testing necessary to meet the requirements recommended by the National Shellfish Sanitation Program and found to be acceptable by the Louisiana Molluscan Shellfish Program. This evaluation only certifies that the laboratory facility and its staff meet the specifications of the National Shellfish Sanitation Program at the time of the evaluation.

Cull—to remove dead or unsafe shellstock from a lot of shellstock.

Department—the Louisiana Department of Health, Office of Public Health.

FDA Evaluation Officer—Repealed.

Habitable Structure—any structure capable of giving shelter from the environment and producing sewage waste.

Harvest—the act of removing shellstock from growing areas and its placement on or in a manmade conveyance or other means of transport.

Harvest Area—an area that contains commercial quantities of shellstock and may include aquaculture sites and facilities.

Hazard Analysis Critical Control Point (HACCP)—a systematic, science-based approach used in food production as a means to assure food safety. The concept is built upon the seven principles identified by the National Advisory Committee on Microbiological Criteria for Foods (1992).

Hazard Analysis Critical Control Point Plan—a written document that delineates the formal procedures that a dealer follows to implement the HACCP requirements set forth in 21 Code of Federal Regulations (CFR) 123.6 as adopted by the Interstate Shellfish Sanitation Conference.

In-Shell Product—nonliving, processed shellfish with one or both shells present.

Interstate Shellfish Sanitation Conference (ISCC)—the organization which consists of agencies from shellfish producing and receiving states, FDA, the shellfish industry, NOAA, and the Environmental Protection Agency (EPA). The ISCC provides the formal structure wherein state regulatory authorities, with FDA concurrence, can establish updated guidelines and procedures for sanitary control of the shellfish industry.

Laboratory Evaluation Officer (LEO)—a person from either a state, federal or foreign authority that has met the personnel training requirements for implementing the NSSP.

Louisiana Molluscan Shellfish Laboratory System—all laboratories that have been successfully evaluated during an on-site evaluation by the Laboratory Evaluation Officer for the state of Louisiana and have been consequently officially designated as a shellfish sanitation laboratory for the Louisiana Molluscan Shellfish Sanitation Program.

Louisiana State Shellfish Sanitation Program, Oyster Water Monitoring Program—Repealed.

Marina—any water area with a structure (docks, basin, floating docks, etc) which is used for docking and constructed to provide temporary or permanent docking space for more than 10 boats.

Marine Biotoxin—any poisonous compound produced by marine microorganisms and accumulated by shellstock. Examples include toxins produced by *Alexandrium spp* [*Protogonyaulax* species] and *Karenia brevis*.

Molluscan Shellfish Program—the program which regulates and monitors the growing, harvesting, handling and shipping of shellfish in the state of Louisiana. The program is with the Louisiana Department of Health, Office of Public Health, Sanitation Services Section.

Narrative Report—a report submitted by the shellfish evaluation officer for the state of Louisiana or the FDA evaluation officer following an on-site evaluation. The report shall include the identity of the laboratory, the date of evaluation, name of evaluator, information on personnel and procedures and conclusions and shall precisely and accurately describe the conditions which existed during the evaluation, including what recommendations were made to correct deficiencies and proposed timetable for any corrective action necessary to bring the laboratory into substantial conformity with the requirements of the National Shellfish Sanitation Program (NSSP) as approved by the Louisiana Molluscan Shellfish Program.

National Shellfish Sanitation Program (NSSP)—the cooperative State-FDA-Industry program for the certification of interstate shellfish shippers as described in the National Shellfish Sanitation Program for the Control of Molluscan Shellfish. The National Shellfish Sanitation Program for the Control of Molluscan Shellfish guide may be obtained from the Interstate Shellfish Sanitation Conference.

On-Site Evaluation—inspection of a laboratory and all appropriate personnel at the physical laboratory site by the Laboratory Evaluation Officer for the purpose of conducting evaluation according to the NSSP Guide for the Control of Molluscan Shellfish.

Open Water Aquaculture—the cultivation of bivalve shellfish in natural shellfish growing areas.

Poisonous or Deleterious Substance—a toxic substance occurring naturally or added to the environment for which a regulatory tolerance limit or action level has been established in shellfish to protect public health.

Pollution—the contamination of the shellfish waters by the discharge of microbiological substances into these waters (chemicals, bacterial, or biotoxins).

Post-Harvest Processing (PHP)—any process which has been validated using NSSP validation procedures which reduces levels of pathogenic hazards to below the appropriate FDA action level or in absence of such a level, below the appropriate level as determined by the ISCC.

Processing—any activity associated with the handling, shucking, freezing, packing, labeling or storing of shellfish in preparation for distribution. This would include the activities of a shellstock shipper, shucker packer, repacker, reshipper, or depuration processor.

Prohibited Area—Louisiana waters that have been classified by the state health officer as prohibited for the harvesting of shellfish for any purpose except depletion and production of seed for aquaculture. A prohibited shellfish growing area is a closed area for the harvesting of shellfish at all times. Harvesting of shellfish from a closed area may result in criminal charges pursuant to R.S. 56:424.

Restricted Area—a classification used to identify a growing area where harvesting shall be by special permit and the shellstock, following harvest, is subjected to a suitable and effective treatment process.

Sanitary Survey—the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on shellfish growing area water quality.

Satisfactory Rating—Repealed.

Seed—shellstock which is less than market size.

Shellfish Evaluation Officer for the State of Louisiana—state health officer or his/her designee approved by letter by the federal Department of Health and Human Services, Public Health Service, Food and Drug Administration, Bureau of Food Technology, Shellfish Sanitation Branch to conduct on-site evaluations of laboratories deserving official recognition as a member of

the shellfish sanitation laboratory system other than the Certified Laboratory i. Official approval is based upon the individual meeting the requirements of Shellfish Sanitation Interpretation S.S. 35 entitled "Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers."

Worst Pollution Conditions—Repealed.

AUTHORITY NOTE: The first source of authority for promulgation of the sanitary code is in R.S. 36:258.B, with more particular provisions found in Chapters 1 and 4 of Title 40 of the Louisiana Revised Statutes. This Part is promulgated in accordance with the specific provisions of R.S. 40:4.A(1), R.S. 40:5.A(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1289 (June 2002), amended LR 28:1591 (July 2002), LR 31:2895 (November 2005), LR 34:2175 (October 2008); amended by the Department of Health, Office of Public Health, LR 48:

§103. Harvesting and/or Sales Shellfish—In Open Status

[formerly paragraph 9:002-1]

A. No shellfish shall be harvested and/or sold in the state of Louisiana for food unless taken from areas sanctioned by the state health officer, or if taken from sources outside of the state, from areas sanctioned by the state authorities having jurisdiction, and unless secured from shellfish dealers whose state certifications have been endorsed by the United States Food and Drug Administration, Public Health Service for interstate shipment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A(1), R.S. 40:5.A(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1291 (June 2002); repromulgated by the Department of Health, Office of Public Health, LR 48:

§105. Sanitary Surveys of Growing Areas—Satisfactory Compliance **[formerly paragraph 9:002-2]**

A. ...

1. Before an area is classified as approved, conditionally approved, or restricted, a sanitary survey shall be completed. The survey is a report completed prior to allowing harvesting from the area.

2. Each sanitary survey report shall identify and evaluate all actual and potential sources of pollution which may affect the growing area; determine the distance of such sources to the growing area; assess the effectiveness and reliability of sewage treatment systems; and ascertain the presence of poisonous or deleterious substances, e.g., industrial, and agricultural wastes, pesticides or radionuclides. The presence and location of small sources of pollution such as boats which might contribute direct fresh fecal matter and poisonous or deleterious substances to the area shall be evaluated. The presence of domestic, wild animal, or migrating bird populations shall be considered for possible adverse effects upon water quality. Offshore growing areas located in the vicinity of ocean dump sites shall be evaluated for biological and chemical wastes and radiological materials. Other environmental health factors that may affect the quality of the shellfish resources should also be evaluated in the sanitary survey report.

3. Each sanitary survey report shall evaluate any meteorological and hydrodynamic effects and geographic

characteristics that may affect the distribution of pollutants over the growing area. These factors shall be assessed to determine their maximum effect on water quality.

4. Each sanitary survey report shall include the collection of growing area water samples and their analysis for bacteriological quality. The number and location of sampling stations selected shall be adequate to produce the data necessary to effectively evaluate all point and non-point pollution sources. Recommended that sampling stations shall be established to evaluate all freshwater discharges into the growing area. The collection of samples shall form a profile reflecting adverse meteorological, hydrographic, seasonal, and point source, and geographic pollution conditions to assure the requirements for classifying growing areas as approved (§109), conditionally approved (§111), or restricted (§113) are met.

5. - 9. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1) , R.S. 40:5.A(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1292 (June 2002), amended by the Department of Health, Office of Public Health, LR 48:

§107. Classification of Growing Areas—Satisfactory Compliance

[formerly paragraph 9:002-3]

A. This item will be satisfied when:

1. all actual and potential shellfish growing areas in the state of Louisiana are correctly designated with one of the following classifications on the basis of sanitary survey information: approved, conditionally approved, restricted or prohibited. Unclassified areas are managed as prohibited;

2. an area classified as prohibited will be established adjacent to all identified actual or potential pollution discharges, including sewage treatment plants outfall, which have a direct or indirect impact and, which have been determined to be of a significant nature in the growing area;

a. the determination of the size of the area to be classified as prohibited adjacent to each outfall shall include the following minimum criteria:

i. the volume flow rate, location of discharge, performance of the wastewater treatment plant and microbial quality of the effluent;

ii. the decay rate of the contaminants of public health significance in the wastewater discharge;

iii. the wastewater's dispersion and dilution, and the time of waste transport to the area where shellstock may be harvested; and

iv. the location of shellstock resources, classification of adjacent waters and identifiable landmarks and boundaries.

3. an upward revision of an area classification shall be supported by an adequate sanitary survey report. This report shall include a written analysis of the data and shall be part of the growing area central file. The reopening of an area temporarily closed because of an emergency, the failure to meet the performance standards for a conditional area, or the presence of biotoxins shall be supported by appropriate data showing that the original classification criteria are met, and

documented by a written record in the central file of the Molluscan Shellfish Program, Office of Public Health, Department of Health;

4. maps showing the boundaries and classification of each shellfish growing area are maintained in the central file by the Molluscan Shellfish Program, Office of Public Health, Department of Health;

5. maps showing the boundaries and status (opened or closed) of each shellfish growing area are posted at designated locations. These locations are listed in the *Louisiana Register*, Vol. 13, pages 413-415.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1) , R.S. 40:5.A(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1292 (June 2002), LR 48:

§109. Approved Areas—Satisfactory Compliance **[formerly paragraph 9:002-4]**

A. ...

1. Results of sampling under adverse pollution conditions indicate that the fecal coliform median or geometric mean MPN of the water does not exceed 14 per 100 ml and not more than 10 percent of the samples exceed an MPN of 43 for a five-tube dilution test (or an MPN of 49 per 100 ml for a three-tube decimal dilution test);

2. Sanitary Survey Report, as required in §§105 and 107, are on file with the Molluscan Shellfish Program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1293 (June 2002), LR 48:

§111. Conditionally Approved Areas—Satisfactory Compliance **[formerly paragraph 9:002-5]**

A. - A.1. ...

2. a current sanitary survey is on file with the Molluscan Shellfish Program;

3. - 4. ...

5. statistical analysis shows the factor(s) to be a significant contributor to the microbiological pollution event.

B. - D. ...

E. Reevaluation of Conditional Classification

1. The classification shall be reevaluated at least once each year. The reevaluation shall include:

a. evaluation of compliance with the management plan;

b. determination of adequacy of reporting of failure to meet performance standards;

c. review of cooperation of all parties involved;

d. evaluation of water quality in the growing area with respect to the bacteriological standards for its classification;

e. field inspection of critical pollution sources, where necessary; and

f. written findings, evaluations, and recommendations.

F. - G.3. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1), R.S. 40:5.A(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 28:1293 (June 2002), LR 48:

§113. Restricted Area—Satisfactory Compliance
[formerly paragraph 9:002-6]

A. An area may be classified as restricted when a sanitary survey indicates a limited degree of pollution. This option may arise when levels of fecal pollution or poisonous or deleterious substances are low enough that relaying will make the shellfish safe to market. This item will be satisfied when the following criteria are met in areas designated as restricted.

1. ...
2. The area is not so contaminated with fecal material, poisonous or deleterious substances that consumption of the shellfish might be hazardous after relaying. Verification of these findings shall be done by a laboratory found to conform by a laboratory evaluation officer.
3. For restricted areas to be used for harvest of shellfish for controlled purification the bacteriological quality of every sampling station in those portions of the area exposed to fecal contamination during adverse pollution conditions shall meet one of the following standards.

a. - b. ...

4. Shellfish quality specifications are established by the Louisiana state health officer for the use in classifying areas. These specifications are based on the data obtained from surveys, water samples and product samples taken from the potential restricted area. With this information the Louisiana state health officer may evaluate the bacteriological and chemical quality of the shellfish and determine whether the shellfish may be used for relaying.

5. ...

6. All data, criteria, and protocols relating to the operation of a restricted area including survey reports, treatment effectiveness studies, classification criteria, harvesting permits, and harvesting control records are maintained in a central file.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1), R.S. 40:5.A(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1294 (June 2002), LR 48:

§115. Prohibited Areas—Satisfactory Compliance
[formerly paragraph 9:002-7]

A. Louisiana state shellfish growing water areas shall be classified as prohibited if:

1. no current sanitary survey exists; or
2. sanitary survey determines
 - a. the growing area is adjacent to a sewage treatment plant outfall or other point source of outfall with public health significance;
 - b. pollution sources may unpredictably contaminate the growing area;
 - c. the growing area is contaminated with fecal waste so that the shellfish may be vectors for disease microorganisms;
 - d. the concentration of biotoxin is sufficient to cause a public health risk; or

e. the area is contaminated with poisonous or deleterious substances cause the shellfish to be adulterated; or

3. risk assessment determines shellstock are not safe for human consumption; or

4. wastewater discharges are adjacent to sewage treatment plant outfall or any other point source outfall of public health significance. The determination of the size of the area to be classified as prohibited adjacent to each outfall shall include the following:

- a. the volume flow rate, location of discharge, performance of the wastewater treatment plant and the microbiological quality of the effluent;
- b. the decay rate of the contaminants of public health significance in the wastewater discharged;
- c. the wastewater's dispersion and dilution, and the time of waste transport to the area where shellstock may be harvested; and
- d. the location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.

B. No shellfish shall be taken from prohibited areas for human food use unless it is seed to be cultured in accordance with aquaculture requirements.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1), R.S. 40:5.A(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health Office of Public Health, LR 28:1294 (June 2002), LR 48:

§123. Procedure for the Analysis of Shellfish Growing Waters

[formerly paragraph 9:002-11]

A. Analysis of shellfish growing waters for the Louisiana Molluscan Shellfish Program shall be performed by a laboratory officially designated as part of the Louisiana shellfish sanitation laboratory system. Procedures and methods for analysis of shellfish growing water shall conform to criteria stipulated in the 4th edition of American Public Health Association (APHA) Recommended Procedures for the Examination of Sea Water and Shellfish published August 29, 2011, and appropriate sections in Official Methods of Analysis, 21st Edition, published in 2019, of the Association of Official Analytical Chemists (A.O.A.C.).

1. Microbiological examinations shall be conducted as follows: Appropriate dilutions shall be made with Butterfield's buffered phosphate diluent. Shake the sample and each successive dilution bottle 25 times vigorously using up and down movements of about 30 cm in seven seconds. Inoculate the water sample directly into tubes containing A-1 medium in suitable decimal dilutions using three or five tubes/dilution and a minimum of three dilutions. Place inoculated tubes into air incubator and incubate three hours plus/minus 0.5 hour at 35° plus/minus 0.5°Centrigade (C). Transfer tubes to water bath and incubate 21 plus/minus two hours at 44.5° plus/minus 0.2°C. Maintain the water level above the level of liquid in the inoculated tubes. Examine the inoculated tubes at the end of this period and record the results.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1296 (June 2002), amended by the Department of Health, Office of Public Health, LR 48:

§125. Determination of Results, Records and Data Reporting
[formerly paragraph 9:002-12]

A. Test result data for use by the Louisiana Molluscan Shellfish Program shall be generated by an officially designated laboratory of the Louisiana molluscan shellfish sanitation laboratory system.

B. - D. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1) , R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1296 (June 2002), amended by the Department of Health, Office of Public Health, LR 48:

§127. Qualification for Laboratories Conducting Analysis of Shellfish Growing Waters for the Louisiana Molluscan Shellfish Program
[formerly paragraph 9:002-13]

A. Laboratories conducting microbiological analysis of shellfish growing waters for the Louisiana Molluscan Shellfish Program shall be officially designated as part of the Louisiana state shellfish sanitation laboratory system. To be so designated, laboratories shall be evaluated by the Laboratory Evaluation Officer and shall maintain a satisfactory rating.

1. The Certified Laboratory shall be evaluated by the FDA Laboratory Evaluation Officer, Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Safety, Division of Seafood Safety, Shellfish Aquaculture and Policy Branch.

B. - B.4. ...

5. at the request of the FDA, Director, Shellfish and Aquaculture Policy Branch or the Louisiana Molluscan Shellfish Program control authorities.

C. - H.10. ...

11. In laboratories where there is more than one analyst, analysts shall make parallel analyses on at least one positive sample quarterly.

12. ...

13. Glass/mercury thermometer calibration should be checked annually against a reference National Institute of Standards and Technology (NIST) thermometer or one which meets the requirements of NIST monograph 150, 2020 edition, published August 2020.

14. - 17. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1297 (June 2002), amended by the Department of Health and Hospitals, Office of Public Health, Center for Environmental Health Services, LR 34:445 (March 2008); amended by the Department of Health, Office of Public Health, LR 48:

§129. Qualification for Personnel Conducting Analysis of Shellfish Growing Waters
[formerly paragraph 9:002-14]

A. ...

1. Analysts in the Certified Laboratory in Baton Rouge shall be evaluated by the FDA Laboratory Evaluation Officer, Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Safety, Division of Seafood Safety, Shellfish Aquaculture and Policy Branch.

B. - C.2. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1298 (June 2002), amended by the Department of Health, Office of Public Health, LR 48:

§131. Qualifications, Requirements for Laboratory Evaluation Officer for the State of Louisiana
[formerly Paragraph 9:002-15]

A. The shellfish evaluation officer for the state of Louisiana shall be designated by letter by the Federal Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Safety, Division of Seafood Safety, Shellfish Aquaculture and Policy Branch. Designation is based upon meeting the requirements of the NSSP Guide Guidance document.

1. The individual shall be administratively attached to a Louisiana Molluscan Shellfish Laboratory which has been found by the FDA to conform or provisionally conform with the National Shellfish Sanitation Program (NSSP).

2. ...

3. If deemed necessary by an FDA laboratory evaluation officer, the individual shall conduct several laboratory evaluations jointly with FDA Shellfish and Aquaculture Policy Branch laboratory evaluation officers.

4. During a joint on-site evaluation with an FDA laboratory evaluation officer, the individual shall demonstrate competence in evaluating analysts' performance of the applicable shellfish laboratory test methods in the 4th edition of the APHA Recommended Procedures for the Examination of Sea Water and Shellfish and the Official Methods of Analysis of the Association of Official Analytical Chemists (A.O.A.C). The evaluation will be recorded on the FDA Evaluation Laboratory Checklist.

5. The individual shall submit a written report to all evaluations conducted to the FDA Division of Cooperative Programs, Shellfish Sanitation Branch with a copy to the appropriate FDA shellfish specialist. The report should consist of the FDA Shellfish Standard Laboratory Evaluation Form, a summary list of qualified analysts and a narrative discussion for each laboratory evaluated. The narrative discussions shall include the identity of the laboratory, the date of evaluation, name of evaluator, a precise and accurate description of the conditions which existed during the evaluation, including what recommendations were made to correct deviations necessary to bring the laboratory into substantial conformity with the requirements of NSSP as approved by the Louisiana State Shellfish Sanitation Program and appropriate information on personnel and procedures and conclusions.

B. - B.2. ...

3. The individual shall submit a written report of the joint laboratory evaluation to the FDA Shellfish and

Aquaculture Policy Branch laboratory evaluation officers with a copy to the appropriate FDA shellfish specialist.

B.4. - C. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1) , R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 28:1298 (June 2002), amended by the Department of Health, Office of Public Health, LR 48:

§133. Requirements for Laboratory Certification
[formerly paragraph 9:002-16]

A. ...

1. The purpose of the evaluation will be to assure the uniform application of standard procedures and methods in the sampling and analytical examination of shellfish growing waters and to determine and assure the adequacy of facilities, equipment and personnel to perform analytical testing necessary to meet the requirements recommended by the National Shellfish Sanitation Program and found to be acceptable by the Louisiana Molluscan Shellfish Program, administered by the Department of Health , Office of Public Health. Evaluation is not an endorsement of the laboratory facility, its staff the operation as this implies continuing guarantee of performance.

2. A satisfactory rating is achieved by demonstration during an on-site evaluation that the laboratory and laboratory personnel are found to conform or conditionally conform with all requirements as listed in the Shellfish Laboratory Evaluation Check Lists provided by the Federal Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Safety, Shellfish Aquaculture and Policy Branch. A satisfactory rating indicates that FDA recognizes that the laboratory complies with recommended procedures and capabilities and that the analytical results produced by the laboratory are in support of the Louisiana Shellfish Sanitation Program and are acceptable to FDA.

3. ...

B. An applicable, currently dated (i.e., the last satisfactory on-site evaluation shall be documented to have been held within the prior three year period) satisfactory FDA Shellfish Standard Laboratory Evaluation Form and narrative report submitted by the appropriate laboratory evaluation officer to the FDA Division of Cooperative Programs, Shellfish Sanitation Branch with a copy to the appropriate FDA shellfish specialist and the public health laboratory director shall be on file or available upon request.

1. - 2. ...

3. Failure to be found to conform or provisionally conform during the on-site evaluation by the appropriate Laboratory Evaluation Officer and/or failure to correct or address deficiencies or recommendations as noted in the narrative report within the stated timetable shall result in loss of satisfactory evaluation.

C. - D. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1299 (June 2002), amended by the Department of Health, Office of Public Health, LR 48:

§135. Fees for Services

[formerly paragraph 9:002-17]

A. Fees for evaluations, analysis, determination, processing and reporting of results shall be incorporated into the Louisiana Molluscan Shellfish Program fee and assessed in accordance with rules and regulations controlling their collection.

B. The department shall charge and collect an imported seafood safety fee of one hundred dollars annually from each holder of a commercial seafood permit fee who sells imported seafood. The proceeds of such fee shall be used for the purposes described in R.S. 40:5.10.1. Pursuant to said statute, the department or its agents or contractors may conduct sampling of imported seafood stored on the premises of any business holding a commercial seafood permit issued pursuant to R.S. 40:31.35, the scope and frequency of which shall be within the discretion of the department. Samples collected pursuant to this Subsection may be laboratory tested at the discretion of the Department for any substances prohibited in applicable types or categories of seafood by the U.S. Food and Drug Administration (FDA). Such testing shall be conducted by laboratories accredited therefor by the FDA or an FDA-recognized accreditation body.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1) , R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20), R.S. 40:5.3 and R.S.40:31:35.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1300 (June 2002), amended by the Department of Health, Office of Public Health, LR 48:

§139. Records of Shellfish Purchases and Sales
[formerly paragraph 9:003]

A. Every person, firm or corporation who conducts any wholesale business of buying, selling or shipping shellfish shall keep an accurate daily record which shall include shipping documents.

1. Each shellfish shipment shall be accompanied by a shipping document which shall contain:

- a. the name, address, and certification number of the shipping dealer;
- b. the name and address of the major consignee; and
- c. the kind and quantity of the shellfish product.

2. The receiving dealer shall:

- a. maintain in his files a copy of the completed shipping document; and
- b. make the shipping document available to the authority upon request.

3. If the shipment is subdivided to different dealers, each receiving dealer shall maintain records sufficient to trace his portion back to the original shipment.

B. Transaction and Shipping Records. Each dealer shall have a business address at which transaction records are maintained. Each dealer shall maintain accurate and legible transaction records that are sufficient to:

1. document that the shellfish are from an authorized source;

2. permit a container of shellfish to be traced back to the specific incoming lot of shucked shellfish from which it was taken;

3. permit a lot of shucked shellfish or a lot of shellstock to be traced back to the growing area(s), date(s) of

harvest, date and location of wet storage, if applicable, and if possible, the harvester or group of harvesters.

4. trace the wet storage history of the shellstock including, original harvest site, original harvest date, wet storage site(s) and dates.

5. purchase and sales shall be recorded within 72 hours of any purchase or sales:

- a. in a permanently bound ledger book; or
- b. computer record, or other method acceptable to and authorized by the Molluscan Shellfish Program;

6. the transaction records shall be retained:

- a. in the case of fresh shellfish, for a minimum of one year; and
- b. in the case of frozen shellfish, for at least two years or the shelf life of the product, whichever is longer.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1300 (June 2002), amended by the Department of Health, Office of Public Health, LR 48:

§141. Relaying of Shellfish

[formerly paragraph 9:004]

A. No person shall engage in the business of relaying shellfish from waters not approved for direct market harvesting by the state health officer prior to obtaining a permit for that purpose from the Department of Health, Office of Public Health. Growing waters to be utilized for shellfish relaying purposes must meet or exceed the Department of Health's criteria for a restricted area classification. Applications shall be completed and submitted with a fee of \$100, which shall be paid by cashiers check or money order and filed not less than 14 days prior to the beginning of such proposed relaying. Relaying of shellfish shall be permitted only during the first two weeks of each calendar month. The Louisiana Molluscan Shellfish Program shall allow the relay of suitable shellstock during all 12 months of the year.

B. The Louisiana Molluscan Shellfish Program hereby establishes species-specific critical values for water temperature and salinity, which may affect the natural treatment process in the growing area to which the shell stock *Crassostrea virginica* (American Oyster, Eastern Oyster) will be relayed.

1. The critical salinity tolerances *Crassostrea virginica* shall be established as 3 to 36 parts per thousand. Salinities shall be measured at approximately twelve inches below the water surface.

2. The critical temperature for *Crassostrea virginica* shall be established at temperatures 44-89 degrees Fahrenheit. Water temperatures shall be measured at approximately 12 inches below the water surface.

3. The species-specific critical pollution criteria shall be that the growing area for relay shall demonstrate through its historical data that the water quality can reasonably be expected to meet the approved or conditionally approved criteria.

4. Relay activities which expose shell stock to this range of temperature and salinity values for a minimum of fourteen days shall be considered as meeting the species-specific critical values for relay of *Crassostrea virginica*.

5. The requirement for monitoring environmental conditions of the relay area shall be accomplished by

collecting bacteriological water sample data and salinity data from sample stations nearest the relay area which are actively collected each month by the program. Three sample stations which triangulate, if possible, the relay area will be selected to meet this monitoring requirement.

6. No studies of contaminant levels of poisonous or deleterious substances in shellstock shall be conducted on shellstock for relay unless there exists scientific evidence which indicates the relay shellstock contains a poisonous or deleterious substance(s) which exceed a FDA tolerance level(s), or it is known that relay shellstock have been exposed to high levels of poisonous or deleterious substances.

7. The growing area to be used for the treatment process shall be monitored with sufficient frequency to identify when limiting critical value of water temperature of 44-89 degrees Fahrenheit and salinity 3-36 parts per thousand may be approached.

8. The effectiveness of species-specific contaminated reduction shall be determined based on a study. The study report shall demonstrate that, after the completion of the relay activity, the microbiological quality of shellstock is the same microbiological quality as that of the same shellstock already present in the approved or conditionally approved area.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1300 (June 2002), amended by the Department of Health, Office of Public Health, LR 48:

§143. Performance Bond Required

[formerly paragraph 9:004-1]

A. A \$5,000 cash performance bond consisting of a bank cashiers check made payable to the Department of Health shall be submitted with each completed application. In addition to the bond, a permittee, at his own expense shall secure the services of a surveillance officer approved by the Department of Health and the Department of Wildlife and Fisheries for the purpose of monitoring all harvesting, transporting, and bedding of shellfish for relaying purposes. In order to satisfy the monitoring requirements, all harvesting, transporting and bedding of shellfish for relaying purposes shall take place in the direct line of sight of the state-approved surveillance officer.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1300 (June 2002), amended by the Department of Health, Office of Public Health, LR 48:

§145. Permit Required for Relaying

[formerly paragraph 9:004-2]

A. Permits are required prior to performing any relaying at the discretion of the Department of Health, Office of Public Health under the following restrictions.

1. ...

2. Should environmental conditions in the growing area used for relay exceed the limits of classification of the growing area, the relay area shall be closed along with all other affected growing area. The minimum 14-day treatment time shall only be during the time that relay area is

characterized by water temperatures and salinity units that are within critical limits.

3. Shellfish harvested for relaying purposes from restricted waters shall not be laid down within 500 feet of any adjoining lease where shellfish may be taken for sale as food during the active period of the relay permit.

4. Sacking of shellfish, storage of empty shellfish sacks on board permitted or authorized relaying vessels and/or the direct marketing of shellfish taken from waters not approved for that purpose by the state health officer shall be strictly prohibited.

5. Culling of shellfish shall be permitted only when container relaying is practiced and written authorization is obtained from the Department of Health a.

6. Only two leases in the restricted area and approved bedding area, each pre-approved by the Department of Health, shall be utilized in the relaying of shellfish.

a. Shellfish relayed from a restricted area of a public oyster seed ground will be allowed at the discretion of the Louisiana Department of Wildlife and Fisheries (LDWF) only during the open oyster season. Shellstock from the public oyster seed ground will be allowed to be bedded on only two approved leases which will be pre-approved by the Department of Health. Relaying from a public oyster seed ground area shall be for the purpose of moving the live oyster resource. The removal of excessive amounts of non-living reef material in relay loads shall result in the forfeiture of the relay permit and/or the closure of the public oyster seed ground area to transplanting. Permit-holders shall allow on-board inspection and sampling of relay loads by the LDWF.

7. The permittee shall be responsible for notifying the Department of Wildlife and Fisheries prior to leaving port to relay shellfish and immediately upon returning from the permitted trip each day. The Department of Wildlife and Fisheries shall be notified by calling (800) 442-2511.

8. All leases shall be "red flagged" so that they may be easily spotted by both aircraft and boats. "Red flagged" as used in this Paragraph, means that the four outside corners of the lease must be marked with poles with red flags attached.

9. All activities relative to the relaying of shellfish shall be permitted only during daylight hours with all activities completed no later than 30 minutes after official sunset. Applicants may apply for a written exemption to this requirement when the distance between the restricted area and bedding area is such that compliance is not possible.

10. Both sides of the permitted vessel shall be marked with the permit number in at least 6-inch-high letters on a contrasting background so as to be visible from low flying aircraft or from any other vessel in the immediate vicinity.

11. A copy of the complete relay permit and applicable rules shall be on board each authorized vessel at all times during the active period of the relay permit.

12. The harvesting of shellfish for relaying purposes within 150 feet of any sewage discharge point emanating from any camp, home, or other habitable structure shall be prohibited.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1), R.S. 40:5 (2)(3)(5)(7)(15), and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 28:1300 (June 2002), amended by the Department of Health, Office of Public Health, Center for

Environmental Health Services, LR 34:445 (March 2008), LR 34:2175 (October 2008), LR 48:

§147. Surveillance Officer's Daily Trip Report [formerly paragraph 9:004-3]

A. An official Department of Health's "Surveillance Officers Daily Trip Report" must be completed each day by the surveillance officer and mailed to the Department of Health, Seafood Sanitation Unit after each completed day of relaying.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1301 (June 2002), amended by the Department of Health, Office of Public Health, LR 48:

§149. Enforcement Provisions [formerly paragraph 9:004-4]

A. Failure to comply with any of the permitting requirements specified in §§141-147 shall result in the following administrative action.

1. The relay permit and all relay permitting privileges shall be immediately suspended by the Department of Health or the Department of Wildlife and Fisheries.

2. All shellfish harvested for relaying purposes in violation of permitting requirements shall be returned to the original growing waters or destroyed at a permittee's own expense.

3. If said charges are upheld in an administrative hearing, the following additional penalties shall be imposed.

a. Relay permitting privileges shall be denied for a period of three years.

b. The \$5,000 cash bond posted by the permittee shall be forfeited and retained by the state.

AUTHORITY NOTE: Promulgated in accordance with R.S.40:4.A.(1)). R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1301 (June 2002), amended by the Department of Health, Office of Public Health, LR 48:

Chapter 3. Preparation and Handling of Seafood for Market

§303. Construction and Cleanliness of Shellfish Boats [formerly paragraph 9:006]

A. All boats utilized for the harvesting or transporting of shellfish shall be provided with a false deck or bottom to prevent the contamination of shellfish with bilge water. For the purpose of this regulation, bilge water may be defined as any water that collects in the lowest inner part of a boat's hull. Decks, holds or binds used for storage of shellfish shall be washed daily with either potable water, or water drawn from an approved growing area or Conditionally Approved area in open status. Unless otherwise exempted in writing by the Louisiana Department of Health, a suspended awning shall be provided on harvest boats to protect shellfish from direct exposure to sun, birds and other adverse conditions. The suspended awning shall be a minimum of 12 inches above the shellfish with a maximum height of 7 feet. The suspended awning shall be of such width and length so as to extend to the outer edges of the harvesting or transporting vessel. The provisions of this rule shall apply to all types of harvesting and transporting vessels. Small children in

diapers, dogs, cats or other forms of wildlife shall not be permitted on board harvesting vessels while shellfish are being fished or transported. Violation of any of the requirements in this Section shall result in one of the following penalties.

1. Shellfish shall be seized and destroyed at violator's expense.

2. Shellfish shall be bedded on a Department of Wildlife and Fisheries managed seed reservation at violator's expense.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 28:1301 (June 2002), repromulgated LR 29:173 (February 2003); repromulgated by the Department of Health, Office of Public Health, LR 48:

§311. Permits to Operate Seafood Establishments
[formerly paragraph 9:010]

A. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1),

R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20), R.S. 40:5.3, R.S. 40:5.10.1 and R.S. 40:31.35(C).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1302 (June 2002), repromulgated by the Department of Health, Office of Public Health, LR 48:

§313. Plant Construction
[formerly paragraph 9:011]

A. - G. ...

1. The establishment shall be provided with an abundant supply of water under pressure from a source approved by the Louisiana state health officer. No cross connections with unapproved water supplies shall be permitted. The requirements of Parts XII (Water Supplies) of this Code shall be met.

H. ...

I. [formerly paragraph 9:019] Sanitary toilets of approved construction and location shall be provided for the use of employees. Toilets shall not open directly into rooms used for cleaning, shucking, picking, peeling, packing or storage of food products. Where sewerage facilities are available, water flush toilets connected to the sewerage system shall be provided. No insanitary privy shall be permitted or maintained on the premises of any seafood establishment. Self-closing doors must be provided for toilet room facilities.

J. [formerly paragraph 9:020] Refrigeration rooms, coolers or ice boxes for the storage or retention of marine and fresh-water animal food products shall be so constructed, painted or otherwise treated as to provide a smooth, impervious surface for easy and thorough cleaning. Floors of refrigeration rooms or walk-in coolers shall be of concrete, tile, glazed brick or other impervious material with adequate floor drains, or the floor so sloped as to ensure complete and rapid drainage. Walls shall be of concrete, metal, glass board or other material approved by the state health officer. Ice boxes shall be metal, fiberglass or plastic lined with seams welded, soldered, or otherwise treated, to give a smooth, impervious, easily cleaned surface.

K. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1302 (June 2002), amended by the Department of Health, Office of Public Health, LR 48:

§317. Seafood Plant Operation
[formerly paragraph 9:027 and 9:027-1]

A. - A.10.c. ...

d. maintenance of hand washing and toilet facilities, hereinafter referred to as: maintenance of hand washing and toilet facilities;

A.10.e. - F.3. ...

4. by immersion in an iodine solution concentration between 12.5 mg/L and 25 mg/L(ppm); or

5. by immersion in a quarternary ammonium compound solution concentration of 200 mg/L (ppm) or as indicated by the manufacturer's use directions included in labeling; or.

6. by immersion in hot water at a temperature of 170°F or more for not less than two minutes; or

7. by exposure to hot air at a temperature of not less than 180°F for not less than 20 minutes, in a properly designed oven or hot air cabinet equipped with an indicating thermometer located in the coldest zone or other method of eliminating pathogenic bacteria as approved by the state health officer.

G. - N. ...

O. [formerly paragraph 9:041] A single individual shall be designated by the management to supervise the shucking and packing of shellfish, the packing of peeled and cooked shrimp and picked crabs. They shall be responsible for the cleanliness the shucking, picking, or packing rooms and shall see that the requirements with reference to washing of hands after interruption of working operations is carried out by all persons engaged in the establishment. They shall be responsible at the end of each day's operations for the thorough cleansing and sanitizing of all equipment such as pails, knives, breaking blocks, finger cots, aprons, and so forth.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1303 (June 2002), amended by the Department of Health, Office of Public Health, LR 48:

§323. Tags
[formerly paragraph 9:051]

A. In order that information may be available to inspectors and others with reference to the origin of shell-stock oysters, clams and mussels from all areas, all containers holding shell-stock shall be identified by a tag or label, form and substance of which shall be approved by the state health officer, and the Secretary of the Department of Wildlife and Fisheries.

B. - B.6. ...

a. THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR RETAGGED AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS. "RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE)";

NOTE: Shellstock tagged for restricted use (Green Tag) should not include the retailer guidance language "RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE)

B.6.b. - C.3. ...

4. A blue-colored tag indicates that the shell stock has been post-harvest processed by a certified dealer and may now be sold for raw (half shell) consumption in both interstate and intrastate commerce. This tag must also include a "SELL BY" date which is a reasonable subsequent shelf-life or the words "BEST IF USED BY" followed by a date when the product would be expected to reach the end of its shelf-life. The date shall include month, day, and year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(1), R.S. 40:5(2)(3)(5)(7)(15), and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1308 (June 2002), amended LR 28:1591 (July 2002), LR 33:850 (May 2007), LR 40:1009 (May 2014), amended by the Department of Health, Office of Public Health, LR 48:

§329. Refrigeration Requirements for Shellstock Harvested for Raw Consumption during the Months of January through December [formerly paragraph 9:052-1]

A. Time to refrigeration requirements for shell-stock harvested for raw consumption during the months January through December shall be based on the Average Monthly Maximum Water Temperatures based on the *Vibrio vulnificus* control plan developed by the Office of Public Health Molluscan Shellfish Program according to the following schedule.

A.1. - C.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(1), R.S. 40:5(2)(3)(5)(7)(15), and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1308 (June 2002), amended LR 31:2896 (November 2005), LR 34:2175 (October 2008), LR 36:1016 (May 2010), LR 38:2789 (November 2012), LR 40:1009 (May 2014), amended by the Department of Health, Office of Public Health, LR 48:

§330. Refrigeration Requirements for Shellstock Harvested during the months of May through October for Raw Consumption only by Persons Located within the State of Louisiana

A. ...

B. The Department of Health and the Department of Wildlife and Fisheries have cooperatively developed a single tag which purpose is to immediately and specifically indicate by its fuchsia (pinkish-purple) color that the oysters contained in the sack or box have been harvested following the requirements of this Section. Language shall be printed on the tag which shall explicitly state "oysters contained herein must not be sold for use outside of the state of Louisiana" and the oysters contained in the sack or box (excluding post-harvest process product) shall not be sold for use outside of the state of Louisiana. This tag shall be in addition to any tag(s) required under §323 of this Part.

C. - D. ...

E. Records relating to oysters which will only be sold for raw consumption within the state of Louisiana shall be completed by both the harvester and dealer(s) and shall be kept separate from records for shellstock product intended for interstate shipment. These records shall be maintained for a period of one year (two years if frozen) and be made

readily available for examination by agents of the Department of Health and the Department of Wildlife and Fisheries. Approved log sheets properly completed and maintained, for the current and previous 15 days harvest shall be kept aboard the harvest vessel for immediate examination. A copy of the log sheet form required to be kept and maintained is shown below in §345 of this Part.

F. - G. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20), R.S. 40:5.3 and R.S. 56:437.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 38:96 (January 2012), amended by the Department of Health, Office of Public Health, LR 48:

§331. Refrigeration Requirements for Shellstock Harvested for Shucking or Post-Harvest Processing by a Certified Dealer during the Months of January through December [formerly paragraph 9:052-2]

A. Time to refrigeration requirements for shell-stock harvested for shucking or post-harvest processing by a certified dealer during the months January through December shall be based on the Average Monthly Maximum Air Temperature developed by the Office of Public Health Molluscan Shellfish Program according to the following schedule.

1. Air Temperature: <50°F. Shellstock shall be placed under mechanical refrigeration at an air temperature not to exceed 45°F within 36 hours from the time harvesting begins.

2. Air Temperature: 50°F to 60°F. Shellstock shall be placed under mechanical refrigeration at an air temperature not to exceed 45°F within 24 hours from the time harvesting begins.

3. Air Temperature: >60°F - 80°F. Shellstock shall be placed under mechanical refrigeration at an air temperature not to exceed 45°F within 18 hours from the time harvesting begins.

4. Air Temperature: >80°F. Shellstock shall be placed under mechanical refrigeration at an air temperature not to exceed 45°F within 12 hours from the time harvesting begins.

B. - E. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20), and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1309 (June 2002), amended LR 31:2896 (November 2005), LR 34:2175 (October 2008), LR 35:1239 (July 2009), LR 36:1017 (May 2010), LR 38:97 (January 2012), LR 38:2789 (November 2012), amended by the Department of Health, Office of Public Health, LR 48:

§333. General Provisions [formerly paragraph 9:052-3]

A. - E. ...

F. Post-Harvest Processing

1. - 1.a. ...

i. for processes that target *Vibrio vulnificus*, the level of *Vibrio vulnificus* in product that has been subjected to the process shall be non-detectable (<30 pergram) to be determined by use of the *Vibrio vulnificus* FDA approved EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, 1992;

ii. for processes that target *Vibrio parahaemolyticus*, the level of *Vibrio parahaemolyticus* in product that has been subjected to the process shall be non-detectable (<30 per gram)

iii. - v. ...

b. package and label all shellfish in accordance with all requirements of the Model Ordinance. This includes labeling all shellfish which have been subjected to the process but which are not frozen in accordance with applicable shellfish tagging and labeling requirements in Chapter X.05 and X.06 and X.07 of the National Shellfish Sanitation Program Model Ordinance;

c. keep records in accordance with Chapter X.08 of the National Shellfish Sanitation Program Model Ordinance.

2. ...

3. For the purpose of product temperature the receiving and storage critical control points of shucked product apply to shell stock prior to PHP processing. Following PHP processing, if the end product is dead, the product shall be treated as shucked product. If the end product is live, the product shall be treated as shellstock.

4. A harvester-dealer oyster tag, blue in color, shall be used for In-Shell Product that has undergone a Post-Harvest Treatment Process.

F.5. - G. ...

1. Certified dealers shall adopt written procedures for conducting recalls of adulterated or misbranded shellfish products. These written procedures for conducting recalls shall be based on, and complementary to, the FDA Enforcement Policy on Recalls published in the April 1, 2003 Code of Federal Regulations, Title 21, Chapter 1, Subchapter A, Part 7-Enforcement Policy which is also contained in the 2019 NSSP Guide for the Control of Molluscan Shellfish under Section VII (Federal Regulations) thereof.

G.2. - H. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(1), R.S. 40:5(2)(3)(5)(7)(15)(17)(19)(20)(21), and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1309 (June 2002), amended LR 28:1592 (July 2002), repromulgated LR 29:173 (February 2003), amended LR 34:2176 (October 2008). LR 38:97 (January 2012), LR 40:1009 (May 2014), amended LR 48:

§337. Checking on Condition of Molluscan Shellfish in Growing Waters Closed by the State Health Officer
[formerly paragraph 9:053]

A. No person shall engage in the business of checking on the condition of molluscan shellfish in growing waters closed by the state health officer prior to obtaining a permit for that purpose from the state health officer. Applications shall be and filed not less than 14 days prior to the beginning of such proposed checking activities. Permits will be applicable for one day only.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1310 (June 2002), amended by the Department of Health, Office of Public Health, LR 48:

§339. Performance Bond and Security Guard Monitoring Requirements
[formerly paragraph 9:053-1]

A. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1), R.S. 40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1310 (June 2002), repealed by the Department of Health, Office of Public Health, LR 48:

§343. Permit Enforcement
[formerly paragraph 9:053-3]

A. Failure to comply with any of the permitting requirements specified in §§327-333 shall result in the following administrative actions.

1. The shellfish checking permit and all applicable privileges shall be immediately suspended by the Department of Wildlife and Fisheries or the Department of Health.

2. If said charges are upheld in an administrative hearing, shellfish checking and shellfish relay permitting privileges shall be denied for a period of three years.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1310 (June 2002), amended by the Department of Health, Office of Public Health, LR 48:

Chapter 5. Molluscan Shellfish Aquaculture
§501. General

A. Aquaculture activities which may pose a significant public health concern are regulated in this chapter and include, but not limited to:

1. seed production in waters classified as prohibited or unclassified;

2. aquaculture structures that attract birds or mammals; and

3. land based aquaculture.

B. Requirements:

1. approved written operational plan;

2. an annual inspection by representative of the department, including operator records, to verify that appropriate permits are up to date and operational plans are being implemented;

3. when aquaculture attracts birds or mammals, their presence should be considered for possible adverse effects on growing area water quality.

C. The maximum seed size for *Cassostrea virginica* (eastern oyster) that can be produced in prohibited waters is 1 inch. If seed size produced in prohibited waters exceeds 1 inch, the seed shall be deemed adulterated and shall be subject to seizure and destruction.

D. Any person who performs aquaculture as defined in §101 of this Part or operates an aquaculture facility to raise shellfish for human consumption shall obtain:

1. a permit from the department for the activity and functioning of their facility;

2. a harvester's license; and
3. certification as a dealer, where necessary.

E. Shellfish aquaculture as defined in §101 of this Part shall be practiced only in strict compliance with the provisions of the permit issued by the department for the shellfish aquaculture activity. Authorization shall be based on the operator's written operational plan.

F. Prior to beginning their activity, a harvester shall obtain permission of the department for use of their facility.

G. Any shellfish seed raised in aquaculture shall be subjected to relaying prior to direct marketing if the culture are or facility is located in or using water which is in:

1. the closed status of the conditionally approved classification;
2. the restricted classification; or
3. the open status of the conditionally restricted classification.

H. Only drugs sanctioned by the FDA shall be used for shellfish treatment.

I. Harvesting, processing, storage, and shipping requirements for shellfish raised in a land-based aquaculture facility shall be the same as the requirements for wild molluscan shellfish specified in this Part of Title 51.

J. Complete and accurate records shall be maintained for at least two years by the operator of the aquaculture facility and shall include the:

1. source of shellfish, including seed if the seed is from growing areas which are not in the approved classification; and
2. water source, its treatment method, if necessary, and its quality in land-based systems.

AUTHORITY NOTE: Promulgated in accordance with R.S.40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:

§503. Exceptions

A. Hatcheries and nurseries rearing larvae and/or seed that are located in:

1. approved or conditionally approved growing areas are exempt from the requirements of this part; or
2. restricted, or conditionally restricted, growing areas would be exempt from the requirements of this part but subject to relay requirements for seed that exceeds the maximum seed size established by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S.40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:

§505. Seed Production in Water Classified as Prohibited or Unclassified

A. Seed may come from any growing area, or from any growing area which is not in an approved classification, provided that:

1. the source of the seed is approved by the department;
2. each aquaculture site that cultures seed in waters classified as prohibited or unclassified shall have a written operational plan. The plan shall be approved by the department prior to its implementation and shall include the following:

a. a description of the design and activities of the culture facility;

b. the specific site and boundaries in which shellfish aquaculture activities will be conducted;

c. the types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;

d. the species of shellfish to be cultured and harvested;

e. the procedures to assure that no poisonous or deleterious substances are introduced from the seed production activities;

f. the corrective actions for addressing seed exceeding the maximum seed size as defined by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S.40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:

§507. Aquaculture That Attracts Birds or Mammals

A. Operational Plan. Each aquaculture site that the department determines may attract sufficient birds and/or mammals that their waste presents a human health risk shall have a written operational plan. The operational plan shall be approved by the department prior to its implementation and shall include:

1. a description of the design and activities of the aquaculture facility;

2. the specific site and boundaries in which shellfish aquaculture activities will be conducted;

3. the types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;

4. the genus and species of shellfish to be cultured and harvested;

5. procedures to assure that no poisonous or deleterious substances are introduced from the aquaculture activities;

6. a description of the mitigation or deterrent measures to minimize the potential pollution impact of birds and/or mammals; and

7. maintenance of the required records.

AUTHORITY NOTE: Promulgated in accordance with R.S.40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:

§509. Land Based Aquaculture

A. Operational Plan. Each land-based aquaculture facility shall have a written operational plan. The facility must obtain approval from the department prior to its implementation and shall include:

1. a description of the design and activities of the aquaculture facility;

2. the specific site and boundaries in which shellfish aquaculture activities will be conducted;

3. the types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats which will be placed in the waters;

4. the genus and species of shellfish to be cultured and harvested;

5. procedures to assure that no poisonous or deleterious substances are introduced into the activities;

6. a program of sanitation, maintenance, and supervision to prevent contamination of the shellfish products;

7. a description of the water source, including the details of any water treatment process or method;

8. a program to maintain water quality, which includes collection of microbial water samples and their method of analysis and routine temperature and salinity monitoring (the bacterial indicator monitored shall be the same as used for monitoring natural growing areas);

9. if applicable, collection of data concerning the quality of food production (algae or other) used in the artificial harvest system; and

10. maintenance of the required records.

B. Each land-based facility conducting aquaculture as defined by Section 101 of this Part shall maintain the following records while the aquaculture activity continues:

1. construction and remodeling plans for any permitted aquaculture facility;

2. aquaculture operational plans; and

3. aquaculture permits.

C. Water Systems. If the land-based aquaculture system is of continuous flow through design, water from a growing area classified as approved, or in the open status of the conditionally approved classification at all times shellfish are held, may be used without treatment.

AUTHORITY NOTE: Promulgated in accordance with R.S.40:4.A.(1), R.S. 40:5.A.(2)(3)(5)(7)(9)(15)(17)(19)(20) and R.S. 40:5.3.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, 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; or

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; or

5. the effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

Small Business Statement

The proposed Rule should have no adverse impact on small businesses as defined in the Small Business Protection 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 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 Wednesday, May 25, 2022 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 Tuesday, May 10, 2022. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9:00AM on Wednesday, May 25, 2022 in Room 173 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 Tuesday, May 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 the Bienville Building's front security desk.

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

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: Marine and Fresh Water Animal Food Products

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

The Office of Public Health (OPH) will incur annual expenses of \$7,500 to sample, analyze, test, and monitor imported seafood to detect the presence of harmful substances. There will also be a one time cost in FY 22 of \$1,810

associated with publishing this rule. OPH will use the revenue generated from permitting seafood distributors to cover these costs.

This rule amends Sections of Chapters 1 and 3 of Part IX (Marine and Fresh Water Animal Food Products) of Title 51 (Public Health—Sanitary Code) and adds Chapter 5 (Molluscan Shellfish Aquaculture) to comply with the Interstate Shellfish Sanitation Conference (ISSC) guidelines and Act 306 of the 2021 RLS.

In chapters 1, 2 and 3, the rule makes technical changes, updates definitions, clarifies the criteria for classifying a growing area as prohibited, updates the record keeping requirements related to the sale of shellfish, updates safety specifications, and updates tagging requirements for shellfish. The changes bring the rules in line with the ISSC guideline and reflect current practice.

In accordance with Act 306 of the 2021 RLS, the rule requires OPH to sample, analyze, test, and monitor imported seafood to detect the presence of harmful substances. The rule also provides the framework for molluscan shellfish aquaculture, creating a new state industry.

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

The rule expands the categories of commercial seafood providers that LDH must permit and is estimated to generate annual collections of \$7,500 for imported seafood permits and a minimal but indeterminable amount for molluscan shellfish aquaculture permits.

This rule provides that LDH shall issue permits for a fee of \$100 to commercial seafood companies that import seafood. LDH estimates that 75 additional permits will be issued as a result. Therefore, this fee is anticipated to generate \$7,500 per year (75 permits x \$100 fee).

The rule also provides that LDH shall issue permits to companies engaged in molluscan shellfish aquaculture. The fee is based on the company's revenue and can range from \$150 for revenue under one million dollars to \$500 for revenue over five million dollars. LDH anticipates that approximately 10-30 companies will apply for a permit. The revenue generated from these permits depends on the actual number of permits issued and the revenue of those companies.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS (Summary)

The proposed rule expands the categories of commercial seafood providers to include businesses that import seafood and business that engage in molluscan shellfish aquaculture. This is a benefit to these businesses, given that this allows them to operate in the state. The rule also benefits existing shellfish growers as it expands the areas where they can grow their products.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule increases competition among commercial shellfish providers, given that it expands the market to include molluscan shellfish aquaculture. However, due to sufficient product differentiation and the expected number of new providers, the competition is not anticipated to be impactful enough to effect existing providers' revenue.

This rule is expected to increase employment opportunities within the commercial shellfish industry, given that it allows for additional businesses to operate in the state.

Kim Hood, JD, MPH
Assistant Secretary
2204#050

Evan Brasseaux
Interim Deputy Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

**Department of Public Safety and Corrections
Gaming Control Board**

Louisiana Sports Wagering
(LAC 42:III.301, 303, 304 and IV.103,
501, 503, 505, 509, 517 and 707)

~~The Department of Public Safety and Corrections, Gaming Control Board, in accordance with R.S. 27:15, R.S. 27:24, R.S. 27:603, and the provisions of the Administrative Procedures Act, R.S. 49:950 et seq., hereby gives notice that it intends to amend Sections 301, 303, and 304 of Part III of Title 42 of the Louisiana Administrative Code, and amend Sections 103, 501, 503, 505, 509, 517, and 707 of Part VI of Title 42 of the Louisiana Administrative Code. These rule changes clarify practices already required to take place in the industry and create uniformity with the amended statutes and the newly enacted statutes as a result of Acts 80, 435, and 440 of the 2021 Legislative Session and Act 215 of the 2020 Regular Legislative Session. The rule change allows for the conducting, application, licensing, permitting, enforcement, and regulation of sports wagering.~~

Title 42

LOUISIANA GAMING

Part III. Gaming Control Board

Chapter 3. Compulsive and Problem Gambling

§301. Problem Gambling Programs

~~A. As used in this Chapter, licensee shall mean all persons licensed or otherwise authorized to conduct gaming operations pursuant to the provisions of Chapters 4, 5, 7, and 10 of the Louisiana Gaming Control Law, R.S. 27:1 et seq., including the casino operator, casino manager, sports wagering licensees, and sports wagering platform providers, but not including persons only licensed pursuant to Chapter 8 of the Louisiana Gaming Control Law. As used in this Chapter, sports wagering platform includes all websites and mobile applications used to place sports wagers.~~

~~B. Each licensee shall post or provide written materials concerning the nature and symptoms of problem gambling in or conspicuous places within the gaming establishment in or near gaming areas and areas where cash or credit is made available to patrons, including cash dispensing machines. Licensees shall include access to such information on its sports wagering platform.~~

~~C. Each licensee shall post one or more signs, as approved by the division, at points of entry to casino gaming establishments to inform customers of the toll free telephone number available to provide information and referral services regarding compulsive or problem gambling. The toll free number shall be provided by the division. Licensees shall include such information and toll free number on its sports wagering platform.~~

~~D. ---~~

~~E.1. All licensees shall develop a comprehensive program for its property or properties and sports wagering platform(s), that address, at a minimum, the areas of concern described in R.S. 27:27.1.C which are designed to:~~