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Document No. 4483
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Section 44-1-140

61-47. Shellfish

Preamble:

Regulation R.61-47 was last substantively amended on June 27, 2008. The regulation contains requirements for the safe and sanitary harvesting, storing, processing, handling and transportation of molluscan shellfish (oysters and clams) to protect the health of consumers of shellfish. For South Carolina shellfish to be acceptable for interstate and international commerce, the regulation must be consistent with the requirements of the National Shellfish Sanitation Program (NSSP), as determined by the US Food and Drug Administration (FDA).

The purpose of this amendment is to improve R.61-47 and update the regulation to be consistent with the latest version of the NSSP Guide for the Control of Molluscan Shellfish (2013). The proposed amendments include the following changes:

- (1) Times allowed from harvest to mechanical refrigeration will be modified to limit the growth of pathogens after the harvest of shellfish,
- (2) A tempering plan for the gradual temperature reduction of harvested clams will be allowed to facilitate the summer harvest of clams,
- (3) The number and frequency of confirmed Vibro-related illnesses needed to trigger further temperature control measures will be modified,
- (4) Certified reshipping facilities no longer will be required to add additional labels to shellfish containers prior to further distribution,
- (5) Certified shippers will be required to receive annual training for the safe and sanitary handling of shellfish,
- (6) Time-temperature recording device will be required when shipping shellfish from one certified shipper to another certified shipper for shipments lasting greater than 4 hours, and
- (7) Stylistic changes are made including corrections for spelling, clarity, readability, grammar, and codification for overall improvement of the text of the regulation.

A Notice of Drafting for this proposed regulation was published in the *State Register* on April 25, 2014.

Section-by-Section Discussion of Proposed Regulations

The statutory authority for this regulation is added in the text under the title of the regulation and before the table of contents for consistency with other agency regulations.

61-47.A. General Provisions

Section 61-47.A.2.a(6) - Grammatical correction - the word “which” is deleted.

61-47.A. General Provisions

Section 61-47.A.2(II) is changed to reference the latest version of the document.

61-47.B. Growing Area Survey and Classification

Section 61-47.B.7(e)(4) - A computer transcription error was found in the current text whereas the superscript was published incorrectly. This subitem is being changed to write out in text form the correct

mathematical expression to avoid future computer software wordprocessing conversion problems in electronic publications of this regulation.

61-47.C. Harvesting, Handling, and Transportation of Shellfish

Section 61-47.C.1(e) is added to be consistent with the 2013 National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish and requires certified shippers to receive annual training for the safe and sanitary handling of shellfish.

61-47.C. Harvesting, Handling, and Transportation of Shellfish

Section 61-47.C.2(c) introductory paragraph, the word “environmental” is being replaced by “internal” to clarify that the “internal” temperature of the shellstock is the measurement criteria being addressed in this section.

61-47.C. Harvesting, Handling, and Transportation of Shellfish

Section 61-47.C.2(c)(1) is being changed to be consistent with the 2013 National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. The change is a modification to the time from harvest to mechanical refrigeration as determined by environmental conditions at the time of harvest and allows for a tempering plan to facilitate the summer harvest of clams.

61-47.C. Harvesting, Handling, and Transportation of Shellfish

Sections 61-47.C.2(c)(2) and (3) are being changed to be consistent with the 2013 National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. The change is a modification to the number and frequency of confirmed Vibro-related illnesses needed to trigger reductions in the time allowed from harvest to mechanical refrigeration.

61-47.C. Harvesting, Handling, and Transportation of Shellfish

Section 61-47.C.2(c)(4) is deleted because control measures for *Vibrio parahaemolyticus* now will be based on confirmed illnesses, not a risk evaluation as described in this section.

61-47.C. Harvesting, Handling, and Transportation of Shellfish

Section 61-47.C.2(d)(1) is changed to remove the retagging requirement for a certified reshipper.

61-47.C. Harvesting, Handling, and Transportation of Shellfish

Section 61-47.C.3(c)(3)(b)(5) is added to be consistent with the 2013 National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. This change requires that shellfish shipments that exceed a shipping time of greater than four (4) hours must include a time-temperature recording device when shipments are from one certified shipper to another certified shipper.

61-47.D.Special Shellstock Handling

61-47.D.3(d)(3)(j)(iv) revised the word “disinfections” to “disinfection.”

61-47.F.Laboratory Procedures

61-47.F.4(b) corrects the spelling of the word “bioassy” to “bioassay.”

Notice of DHEC Informational Forum and Public Comment Period:

Staff of the Department of Health and Environmental Control (DHEC/Department) invites the public and regulated community to attend a staff-conducted informational forum to be held on October 27, 2014, at 1:00 p.m. at the Department of Natural Resources (DNR) Auditorium, 217 Fort Johnson Road, Charleston, SC. The purpose of the forum is to expand opportunity for interested persons to contribute input on the proposed amendments of R.61-47.

Interested persons are also provided an opportunity to submit written comments on the proposed regulations by writing to Mike Pearson, Myrtle Beach EQC Office, South Carolina Department of Health and Environmental Control, 927 Shine Avenue, Myrtle Beach, SC 29577; by email at pearsodm@dhec.sc.gov or fax at (843) 238-4518. To be considered, comments must be received no later than 5:00 p.m. on October 31, 2014, the close of the public comment period. Comments received at the forum and/or submitted in writing by the close of the comment period on October 31, 2014, shall be considered by staff in formulating the final proposed regulations for public hearing on December 11, 2014, as noticed below. Comments received shall be submitted in a Summary of Public Comments and Department Responses for the Board of Health and Environmental Control's consideration at the public hearing.

Copies of the proposed amendments for public comment as published in the State Register on September 26, 2014, may be obtained online in the DHEC Regulation Development Update at <http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/>. In the Update, click on the Water category and scan down to the proposed amendments of R.61-47. A copy can also be obtained by contacting Mike Pearson at the above address or by calling (843) 238-4378, or by email at pearsodm@dhec.sc.gov.

Notice of Public Hearing and Opportunity for Public Comment:

Interested members of the public and regulated community are invited to make oral and/or written comments on the proposed amendments of R.61-47 at a public hearing to be conducted by the Board of Health and Environmental Control at its regularly scheduled meeting on December 11, 2014. The Board will conduct the public hearing in the Board Room, Third floor, Aycock Building of the Department of Health and Environmental Control at 2600 Bull Street, Columbia, South Carolina 29201. The Board meeting commences at 10:00 a.m. at which time the Board will consider items on its agenda in the order presented. The order of presentation for public hearings will be noted in the Board's agenda published by the Department 24 hours in advance of the meeting at the following address: <http://www.scdhec.gov/Agency/docs/AGENDA.PDF>. Persons desiring to make oral comments at the hearing are asked to limit their statements to five minutes or less and, as a courtesy, are asked to provide written copies of their presentation for the record. Due to admittance procedures at the DHEC Building, all visitors should enter through the Bull Street entrance and register at the front desk.

Preliminary Fiscal Impact Statement:

The proposed regulations will have no substantial fiscal or economic impact on the State or its political subdivisions. Implementation of this regulation will not require additional resources beyond those allowed. There is no anticipated additional cost by the Department or State government due to any inherent requirements of this regulation.

Statement of Need and Reasonableness:

The following is based on an analysis of the factors listed in 1976 Code Section 1-23-115(C)(1)-(3) and (9) through (11):

DESCRIPTION OF REGULATION: 61-47, Shellfish.

Purpose: The purpose of these amendments is to update R.61-47 to be consistent with the latest version of the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish (2013). The amendments include changes to certain control measures intended to limit the growth of pathogens after

the harvest of shellfish, a simplification of the retagging requirements for certified reshippers, a requirement for certified shippers to receive annual training for the safe and sanitary handling of shellfish, and stylistic changes are made including corrections for spelling, clarity, readability, grammar, and codification for overall improvement of the text of the regulation.

Legal Authority: 1976 Code Section 44-1-140.

Plan for Implementation: Upon approval by the General Assembly and publication in the State Register as final regulations, a copy of R.61-47, to include these amendments, will be available electronically on the Department's internet site at <http://www.scdhec.gov/Agency/RegulationsAndUpdates/LawsAndRegulations/Water/> under the Water category and subsequently in the Code of Regulations of the S.C. Code of Regulations. Printed copies will be available for a fee from the Department's Freedom of Information Office.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The proposed amendments are needed and reasonable because they will incorporate National Shellfish Sanitation Program minimum guidance criteria that have been implemented since the last revision of this regulation. Regulatory adoption of National Shellfish Sanitation Program minimum guidance criteria and standards are necessary to ensure a high degree of public health protection for consumers of shellfish. State and industry compliance with these minimum criteria and standards ensures that South Carolina shellfish are acceptable for interstate and international commerce.

DETERMINATION OF COSTS AND BENEFITS:

Internal Costs: Implementation of these amendments will not require additional resources. There is no anticipated additional cost by the Department or State government due to any inherent requirements of these amendments.

External Costs: There are minimal external costs for implementing the proposed amendments to this regulation.

External Benefits: These amendments will affect consumers, harvesters, processors and transporters of molluscan shellfish. The amended regulation seeks to benefit consumers of shellfish, because the amendments include requirements for the safe and sanitary harvesting, storing, processing, handling and transportation of molluscan shellfish to protect the health of consumers of shellfish. The regulation seeks to benefit the Shellfish industry (harvesters, processors and transporters) by incorporating National Shellfish Sanitation Program minimum guidance criteria that have been implemented since the last revision of this regulation. The regulation must be consistent with the requirements of the National Shellfish Sanitation Program, as determined by the US Food and Drug Administration, for South Carolina molluscan shellfish to be acceptable for interstate and international commerce.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The amendments will have no effect on the environment.

The amendments seek to benefit human health including requirements for the safe and sanitary harvesting, storing, processing, handling and transportation of molluscan shellfish to protect the health of consumers of shellfish.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There would not be a detrimental effect on the environment.

If the amendments are not implemented, consumers of shellfish will not realize potential benefit from new or revised requirements for the safe and sanitary harvesting, storing, processing, handling and transportation of molluscan shellfish.

Statement of Rationale:

The Department is amending this regulation to be consistent with the latest version of the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish (2013). The regulation prescribes requirements for producers, processors, harvesters, and transporters of shellfish and is intended to protect the health of consumers of molluscan shellfish (oysters and clams).

The regulation closely follows the requirements in the National Shellfish Sanitation Program (NSSP), Guide for the Control of Molluscan Shellfish. This document was developed and is routinely updated by the Interstate Shellfish Sanitation Conference (ISSC), which includes representatives from the shellfish industry, academia, and state and federal government agencies. Department staff in the shellfish program represent South Carolina on the ISSC. The U.S. Food and Drug Administration (FDA) is the federal government agency that oversees national and international compliance with the substantive requirements of the NSSP, Guide for the Control of Molluscan Shellfish. The Department and shellfish industry in South Carolina must meet these requirements, as determined by the FDA, for South Carolina shellfish to be acceptable for interstate and international commerce. The FDA expects states to implement and enforce the latest additions and modifications to NSSP, Guide for the Control of Molluscan Shellfish as adopted by the ISSC. To implement and enforce many of the latest additions and modifications to NSSP, Guide for the Control of Molluscan Shellfish, R.61-47 must be amended as is the case with these proposed amendments to the regulation.

~~Indicates Matter Stricken~~

Indicates New Matter

Text:

Add statutory authority for 61-47 under the title of the regulation and before the table of contents.

Statutory Authority: 1976 Code Section 44-1-140

Revise 61-47.A.2(a)(6) to read:

Shellfish ~~which~~ that contain any added substance, unless the substance is authorized by the Department or the United States Food and Drug Administration;

Revise 61-47.A.2(II) to read:

A. GENERAL PROVISIONS.

2. Definitions. For the purpose of this regulation:

(ll) National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish means the ~~2005~~ 2013 version of the United States Food and Drug Administration document with that title that consists of a Model Ordinance, supporting guidance documents, recommended forms, and other related materials associated with the National Shellfish Sanitation Program. Portions of the document are incorporated by reference herein and such referenced sections shall have effect as if fully recited within the text of this regulation. Copies can be obtained through the U.S. Food and Drug Administration or the S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC 29201.

Revise 61-47.B.7(e)(4) to read:

(4) A rate of discharge of 2×10^9 to the ninth power fecal coliform ~~per person~~ per day;

Add new subitem 61-47.C.1(e) to read:

(e) Prior to licensing each certified shipper shall obtain Department approved training annually.

Revise 61-47.C.2(c) introductory paragraph to read:

2. Handling.

(c) Shellstock Temperature Control. For purposes of initial processing, shellstock temperature control shall be defined as the management of the ~~environmental~~ internal temperature of shellstock by means of ice, mechanical refrigeration or other approved means which is capable of lowering the temperature of the shellstock and will maintain it at fifty (50) degrees Fahrenheit [ten (10) degrees Centigrade] or less. Shellstock shall:

Revise 61-47.2(c)(1) to read:

(1) Be placed under temperature control by the receiving certified shipper within ~~twenty (20)~~ eighteen (18) hours from the time of harvest during months when additional controls are not required. Shellfish harvested during months that do require additional controls must be placed under temperature controls within twelve (12) hours from the time of harvest. Clams harvested during these control months may be tempered using a Department approved tempering plan. ; and

Revise 61-47.2(c)(2) and (3) to read:

(2) ~~if~~ In the event a growing area or portion of a growing area waters of the State are is confirmed as the original source of product associated with ~~two (2)~~ three (3) or more Vibrio vulnificus illnesses within the past (10) years, the maximum hours to temperature control for shellfish ~~intended for raw consumption~~ shall, upon notice provided by the Department, be in accordance with the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance, VIII. Control of Shellfish Harvesting, ~~03 Shellstock Temperature Control, Option 1, Action Level 2, Action Level 3, or Action Level 4 (as applicable); and.~~ Shellfish not meeting times and temperature controls may, with Department approval, be diverted to post-harvest processing as defined in this regulation or be deemed adulterated.

(3) ~~In the event a growing area or portion of a growing area is confirmed as the original source of product associated with two (2) three (3) or more Vibrio parahaemolyticus illnesses within the past three (3) five (5) years, the maximum hours to temperature control for shellstock shellfish harvested from the affected growing area(s) shall, upon notice provided by the Department, be in accordance with the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance, VIII. Control of Shellfish Harvesting, .03 Shellstock Temperature Control, Option 2, Action Level 2 or Action Level 3 (as applicable); and. Shellfish not meeting times and temperature controls may, with Department approval, be diverted to post-harvest processing as defined in this regulation or be deemed adulterated.~~

Delete 61-47.2(c)(4):

~~(4) in the event that a Vibrio parahaemolyticus risk evaluation determines that illness is reasonably likely to occur from the consumption of oysters harvested from an aquaculture facility during times when the average monthly daytime water temperature exceeds 81 degrees Fahrenheit, the maximum allowable time from harvest to temperature control for oysters harvested from the facility shall be five (5) hours.~~

Revise 61-47.2(d)(1) to read

(d) Identification of Shellstock in the Marketplace.

(1) When at the facilities of a certified shipper, unless certified as a reshipper (RS), shellstock shall be tagged in accordance with the provisions of item C.1.(c) or item C.2.(d)(2) at all times.

Add new subsection item 61-47.C.3(c)(3)(b)(5) to read:

(5) Shipments must include a time-temperature recording device when shipping from one certified shipper to another certified shipper.

Revise 61-47.D.3(d)(3)(j)(iv) to read:

(iv) When multiple tube ultra-violet treatment with redundant capacity is used as a water disinfectant, each time a bulb change is required to replace a burned out bulb, or for periodic servicing, new ultra-violet bulbs shall be installed and old bulbs discarded. When a single tube ultra-violet treatment unit or a multi tube unit without redundancy is utilized, each time a bulb change is required either to replace a burned out bulb or for periodic servicing, new ultra-violet bulbs shall be installed and old bulbs discarded, a set of three (3) samples of disinfected water and one sample of the source water prior to disinfection shall be collected within a twenty four (24) hour period to reaffirm the ability of the system to produce water free from the coliform group. Ultra-violet systems using either a single tube or multiple-tube unit with no redundancy as their disinfections system may utilize an approved ultra-violet wavelength intensity monitoring unit to demonstrate bulb integrity.

Revise 61-47.F.4(b) to read:

(b) The current APHA method used in the bioassay for *Karenia brevis* toxins.