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Document No. 4736

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: 1976 Code Section 44‑1‑140

61-47. Shellfish

**Synopsis:**

Regulation R.61‑47 was last substantively amended on June 26, 2015. 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. The Department amends R.61-47 to provide specific technical requirements regarding the harvesting and handling of clams and maricultured triploid oysters during the summer months (*i.e.,* months that require additional temperature controls) in a manner that is consistent with the national shellfish sanitation program and protects the health of the consumers of shellfish. The time period for additional temperature controls for the summer harvesting and handling of shellfish is May 16th through September 30th, unless otherwise specified. The amendment includes a requirement for certified shippers to only accept shellfish from harvesters that have received annual training on key regulatory requirements and the safe and sanitary practices related to the harvesting and handling of shellfish in South Carolina. The amendment updates several documents referenced in the regulation to the latest versions of the documents and adds a definition for “mariculture” and “triploid oyster.” The amendment also includes stylistic changes to correct for spelling, clarity, readability, grammar, and codification for overall improvement of the text of the regulation.

A Notice of Drafting for these amendments was published in the *State Register* on May 27, 2016.

Section-by-Section Discussion of Amendments

Pursuant to letter dated February 28, 2017 from the Senate Medical Affairs Committee, the Department withdrew and resubmitted revised Document 4736 on February 28, 2017 for legislative review to indicate that oysters harvested during months that required additional temperature controls (i.e. summer months) will be limited only to triploid oysters. The changes are reflected in Document 4736 where applicable.

61-47.A.2.(jj)

Added definition of mariculture pursuant to a public comment. This definition is from the Marine Resources Act, Section 50‑5‑15(33). The Marine Resources Act is implemented by the South Carolina Department of Natural Resources. Because the Department and the South Carolina Department of Natural Resources both regulate shellfish mariculture activities in the state, it is appropriate to use a consistent definition for mariculture.

61-47.A.2.(jj) and (kk)

Subsections were renumbered pursuant to a public comment.

61-47.A.2.(ll)

Subsection was renumbered pursuant to a public comment. The amendment is to change the reference date of the document to the latest version of the document.

61-47.A.2.(mm) through (kkk)

Subsections were renumbered pursuant to a public comment.

61-47.A.2.(mmm)

Add definition of triploid oyster for clarity and consistency. The definition was provided by a geneticist with the South Carolina Department of Natural Resources.

61-47.A.2.(lll) through (nnn)

Subsections renumbered.

61-47.C.1.(f)

This amendment is added to require harvesters to have Department approved annual training and certified shippers to only receive shellfish from harvesters that have completed Department approved annual training. The annual training for harvesters will include a discussion of state regulations and overview of best practices for the safe and sanitary harvesting and handling of shellfish. The training is needed given the more stringent harvesting and handling requirements on the harvester during the summer months. The training will be provided at no cost to the harvesters.

61-47.C.2.(b)

Two subsections (61-71.C.2.(b) and (c)) are combined to create this new subsection. This amendment is to improve readability and to more clearly explain the meaning of shellstock temperature control and how and when shellstock temperature control is to be applied by certified shippers.

61-47.C.2.(c)

This subsection includes the same text found in the first sentence in the current subsection 61-47.C.2.(c)(1).

61-47.C.2.(d)

This subsection is added to indicate that the months that require additional temperature controls will be determined annually and presented in the South Carolina Vibrio Control Plan. This plan uses existing data, such as air and water temperatures, to develop the procedures that South Carolina will follow to reduce the health risk posed by Vibrio bacteria to the consumers of shellfish harvested in the state. The plan is a requirement for South Carolina to remain in compliance with the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.

61-47.C.2.(e)

This text is new and clarifies that only maricultured triploid oysters and clams of the species *Mercenaria mercenaria*, unless other clam species are approved by Department, can be harvested in the state during months that require additional temperature controls. Triploid oysters, which are only maricultured, can be genetically tested and verified not to be naturally occurring diploid oysters. Limiting summer harvest to only maricultured triploid oysters will enhance compliance and enforcement and protect public health by ensuring that only maricultured oysters reach the market.

61-47.C.2.(e)(1)

This subsection includes similar text to the text found in the second and third sentences of the current item 61-47.C.2.(c)(1) and describes the temperature control requirements for clams during months that require additional temperature controls. Text is added to clarify that clams in this subsection means clams of the species *Mercenaria mercenaria*. This is the only clam species commercially harvested in the state and is specifically required to have controls for Vibrio bacteria by the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. The text does allow the Department to consider other clam species under this subsection.

61-47.C.2.(e)(2)

This subsection is new text and includes technical requirements for the harvesting and handling of maricultured triploid oysters during months that require additional temperature controls. These harvesting and handling requirements are based on the following: the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish that is administered by the U.S. Food and Drug Administration (“FDA”), the Vibrio bacteria risk calculator provided by FDA, requirements used by other states for months that require additional temperature controls, and consultation with FDA Shellfish Specialists. For maricultured triploid oysters harvested during months that require additional temperature controls, it is proposed that the oysters be continuously submerged for a minimum of 14 days before being harvested for sale and consumption. The oysters are submerged to prevent exposure to the higher temperatures experienced by naturally occurring oysters that are exposed to the warm air and sunlight during daily tidal cycles.

61-47.C.2.(e)(2)(d)

Pursuant to a public comment, this new subsection is added to clarify that certified shippers that choose to receive and distribute oysters harvested from South Carolina waters are responsible for ensuring that the oysters have been maricultured and harvested and handled in compliance with the requirements proposed for the summer harvest of oysters included in subsection 61-47.C.2.(e)(2).

61-47.C.2.(f)

This is a new subsection with a new heading to clarify the contents of this subsection.

61-47.C.2.(f)(1) and (2)

These subsections include text found in the current regulation under items 61-47.C.2.(c)(2) and (3). These items are moved to this subsection to provide clarity about the purpose of the items and to accommodate new subsections that have been added.

61-47.C.2.(g)

Subsection renumbered and subsection cross reference renumbered to match amended text.

61-47.C.2.(g)(10)

Pursuant to a public comment, this subsection is amended to change the reference date of the document to the latest version of the document.

61-47.C.2.(h)

Subsection renumbered.

61-47.C.2.(i)

Subsection renumbered.

61-47.C.3.(b)(4)

Subsection cross reference added to include newly added text.

61-47.I.4

Wording change to be consistent with wording of amended text in C.2.(b).

61-47.I.5

Subsection cross reference added to include newly added text and renumbered subsection.

61-47.I.6

Subsection cross reference renumbered to match amended text.

61-47.I.7

Subsection cross reference renumbered to match amended text.

61-47.O.6.(a)

Text is added to clarify that the required operation plan should include the operational requirements found in 61-47.C.2.(e)(2).

61-47.O.6.(e)

Change punctuation.

61-47.O.6.(f)

This subsection is added to require the operational plan to include the record keeping procedures that will be used to document compliance with the requirements found in item C.2.(e)(2).

**Instructions:** Amend Regulation 61-47 pursuant to each individual instruction provided with the text of the amendments below.

**Text:**

**Add new subitem 61-47.A.2.(jj):**

 (jj) Mariculture means controlled cultivation in confinement of marine and estuarine organisms in salt waters.

**Revise 61-47.A.2.(jj) and (kk) to read:**

 (kk) Marina means any of the following:

 (1) locked harbor facility;

 (2) any facility which provides fueling, pump-out, maintenance or repair services (regardless of length);

 (3) any facility which has effective docking space of greater than 250 linear feet or provides moorage for more than 10 boats;

 (4) any water area with a structure which is used for docking or otherwise mooring vessels and constructed to provide temporary or permanent docking space for more than ten boats, such as a mooring field; or

 (5) a dry stack facility.

 (ll) National Shellfish Sanitation Program means the program cooperatively developed by state, United States Food and Drug Administration, and shellfish industry representatives resulting in sanitary control guidelines that ensure that the shellfish produced in accordance with guidelines will be safe and sanitary.

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

 (mm) National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish means the 2015 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.A.2.(mm) through (kkk) to read:**

 (nn) Person means any individual, partnership, company, corporation, trustee, association, agency, or any public or private entity.

 (oo) Poisonous or Deleterious Substance means a toxic compound occurring naturally or added to the environment that may be found in shellfish or shellfish growing waters for which a regulatory tolerance limit or action level has been established or may be considered harmful to public health. Examples of naturally occurring substances would include paralytic shellfish toxins and trace elements geologically leached from the environment, such as mercury; examples of added substances would include agricultural pesticides and polynuclear aromatics.

 (pp) Post Harvest Processing means processing of shellfish for the purpose of added safety or quality that involve hazards not addressed by controls in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance for shucker-packers, repackers, shellstock shippers, or reshippers.

 (qq) Process means those actions related to the operation of the Certified Shipper facilities of Depuration Processors(DP), Shucker-Packers(SP), Repackers(RP), Shellstock Shippers(SS), and Reshippers(RS).

 (rr) Processor means a certified shipper.

 (ss) Prohibited means an administrative classification that disallows shellfish harvest for human consumption.

 (tt) Prohibited Area means a growing area that has been closed by the Department for the harvesting of shellfish for any purpose related to direct human consumption.

 (uu) Raw means shellfish that have not been thermally processed:

 (1) to an internal temperature of one hundred and forty-five (145) degrees Fahrenheit or greater for fifteen (15) seconds (or equivalent); or

 (2) to alter the organoleptic characteristics.

 (vv) Relaying means the transfer of shellstock from restricted areas or conditionally restricted areas to approved or conditionally approved areas for natural biological cleansing using the ambient environment as a treatment system.

 (ww) Repacker (RP) means a certified shipper who packs shucked shellfish into containers other than those in which they were originally packaged. A repacker may act as a shellstock shipper.

 (xx) Repacking means the transfer of shucked shellfish into containers other than those in which they were originally packaged.

 (yy) Reshipper (RS) means certified shippers who purchase shellfish from other certified shippers and sell or distribute the shellfish without repackaging.

 (zz) Restricted means a shellfish water quality classification that does not meet approved water quality criteria, disallows direct marketing of shellfish, and allows shellfish harvest only by special permit.

 (aaa) Restricted Area means a growing area that has been classified by the Department as not meeting water quality criteria that would allow harvesting shellfish for direct marketing for human consumption. In a restricted area, shellfish may be harvested only by special permit and direct marketing of harvested shellfish is not allowed.

 (bbb) Sanitary Survey Report means a written evaluation of all actual and potential pollution sources and environmental factors that affect shellfish growing area water quality.

 (ccc) Sanitize means adequate treatment of food contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance and in substantially reducing the number of other microorganisms. Such treatment shall be safe and not adversely affect shellfish.

 (ddd) Scheduled Depuration Process means the process that places shellfish harvested from conditionally restricted, restricted, or approved waters into a controlled aquatic environment selected by the processor and that has been demonstrated to the Department to effectively reduce the level of fecal coliform bacteria in live shellfish.

 (eee) Seed means juvenile shellstock intended for growth to market size.

 (fff) Shellfish means all edible species of oysters, clams, mussels, and scallops; either shucked or in the shell; fresh or fresh frozen; whole or in part, except that scallops shall be excluded when the final product is the adductor muscle only.

 (ggg) Shellstock means live molluscan shellfish in the shell.

 (hhh) Shellstock Shipper (SS) means a certified shipper who grows, harvests, buys, or sells shellstock. A shellstock shipper is not certified to shuck shellfish or repack shucked shellfish. A shellstock shipper may repackage shellstock or act as a reshipper.

 (iii) Shucked Shellfish means shellfish that have been removed from their shells.

 (jjj) Shucker-Packer (SP) means a certified shipper who shucks and packs shellfish. A shucker-packer may act as a repacker, shellstock shipper, or reshipper.

 (kkk) State Shellfish Control Authority or Authority means the South Carolina Department of Health and Environmental Control or, if in reference to another state, the state agency having the primary authority to implement public health-related shellfish regulations.

 (lll) Systematic Random Sampling is a field sampling and data analysis design that employs a preestablished sampling schedule and assumes that a statistically representative cross section of all meteorological, hydrographic, and/or other pollution events will be included in the data set.

**Add new subitem 61-47.A.2.(mmm):**

 (mmm) Triploid oyster means an oyster having three sets of homologous chromosomes.

**Revise 61-47.A.2.(lll) through (nnn) to read:**

 (nnn) Vehicle means any truck, car, bus, trailer, railcar, aircraft, boat, ship, barge, dredge, or other means of conveyance by which shellfish is transported from one location to another.

 (ooo) Vessel means any boat, ship, barge, dredge, or other type of watercraft used for the commercial harvest or transport of shellfish for human consumption.

 (ppp) Wet Storage means storage of marketable shellfish in water after initial harvest.

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

 (f) Harvesters shall complete Department approved training annually. The certified shippers shall only receive shellstock from harvesters who have completed Department approved training annually.

**Revise 61-47.C.2.(b) and (c) and add new subitems 61-47.C.2.(d), (e) and (f) to read:**

 (b) Shellstock Temperature Control.

 (1) Shellstock Temperature Control is the management of the 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 shellstock at fifty (50) degrees Fahrenheit (ten (10) degrees Centigrade) or less. Ice must be from a Department approved source.

 (2) Within two (2) hours of receiving shellstock from a harvester, certified shippers shall implement procedures to control shellstock temperature as described in item C.2.(b)(1). For purposes of this item, shellstock shall be considered received when the shellstock are located in any portion of a certified shipper facility. Nothing in this item shall be construed to increase the maximum allowable time period for shellstock temperature control.

 (c) Shellstock harvested during months that do not require additional temperature controls shall be placed under temperature control by the receiving certified shipper within eighteen (18) hours from the time of harvest.

 (d) Months that do require additional temperature controls will be designated in the latest version of the South Carolina Vibrio Control Plan, which is updated annually in accordance with the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.

 (e) Shellstock harvested during months that do require additional temperature controls shall be limited to clams as described in item C.2.(e)(1) and maricultured triploid oysters and shall be managed as follows:

 (1) Clams shall be under temperature control by the receiving certified shipper within twelve (12) hours from the time of harvest or may be tempered for a longer period of time using a Department approved tempering plan. For the purpose of this item, clams means the species *Mercenaria mercenaria*, unless otherwise approved by the Department.

 (2) Harvesters shall only harvest maricultured triploid oysters submerged for a minimum of 14 days prior to harvest. The certified shipper shall place the triploid oysters under temperature controls sufficient to reach an internal temperature of fifty (50) degrees Fahrenheit (ten (10) degrees Centigrade) or less within two (2) hours from the time the triploid oysters are received by the certified shipper. For purposes of this item, triploid oysters shall be considered received by the certified shipper when the triploid oysters are located in any portion of a certified shipper facility. The time from harvest to receipt by a certified shipper shall be managed as follows:

 (a) The certified shipper shall only receive triploid oysters harvested on the same calendar day. The certified shipper shall not receive triploid oysters after 10:00 A.M. unless the triploid oysters are iced or mechanically refrigerated as described in item C.2.(e)(2)(c).

 (b) For triploid oysters received by the certified shipper after 10:00 AM, the certified shipper shall only receive triploid oysters that are:

 (i) within 4 hours from the start of harvest; and

 (ii) completely covered by ice or mechanically refrigerated at an ambient air temperature of forty-five (45) degrees Fahrenheit (seven (7) degrees Centigrade) or less.

 (c) The harvester shall only deliver triploid oysters harvested on the same calendar day to a certified shipper. For triploid oysters received by the certified shipper after 10:00 AM, the harvester shall place triploid oysters into cooling immediately after harvesting by completely covering the triploid oysters with ice or by mechanical refrigeration maintained at an ambient air temperature of forty-five (45) degrees Fahrenheit (seven (7) degrees Centigrade) or less. After being placed into cooling, the harvester shall keep the triploid oysters in cooling continuously until received by the certified shipper. The harvester shall follow the procedures for cooling and maintaining continuous cooling for the triploid oysters that are included in the operational plan required in item O.6. The harvester shall use ice from a Department approved source.

 (d) It shall be unlawful for a certified shipper to receive at their facility oysters harvested from South Carolina waters during the months that require additional controls that have not been maricultured and harvested and handled in compliance with the requirements of item C.2.(e)(2)(a)(b) and (c). Certified shippers that choose to receive and distribute oysters harvested from South Carolina waters during the months that require additional controls must incorporate into their HACCP plan additional receiving controls to ensure the triploid oysters being received and distributed have been maricultured and harvested and handled in compliance with the requirements of item C.2.(e)(2)(a)(b) and (c).

 (f) Temperature control requirements for confirmed illnesses.

 (1) In the event a growing area or portion of a growing area is confirmed as the original source of product associated with two (2) or more Vibrio vulnificus illnesses within the past (10) years, the maximum hours to temperature control for shellfish 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. 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.

 (2) In the event a growing area or portion of a growing area is confirmed as the original source of product associated with two (2) or more Vibrio parahaemolyticus illnesses within the past five (5) years, the maximum hours to temperature control for shellfish 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. 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.

**Revise 61-47.C.2.(d) to read:**

 (g) 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.(g)(2) at all times.

**Revise 61-47.C.2.(d)(10) to read:**

 (10) All shellstock intended for raw consumption shall include a consumer advisory. The following statement, based upon guidance provided in Section 3-603.11 of the United States Food and Drug Administration 2013 Food Code (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.), or an equivalent statement, shall be included on all shellstock: "RETAILERS, INFORM YOUR CUSTOMERS: Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions.";

**Revise 61-47.C.2.(e) to read:**

 (h) Shucked Shellfish Temperature Control. Shucked shellfish shall be stored and maintained in accordance with the following:

**Revise 61-47.C.2.(f) to read:**

 (i) Shucked Shellfish Labeling. Prior to sale or distribution, each individual container of shucked shellfish shall be labeled as follows:

**Revise 61-47.C.3.(b)(4) to read:**

 (4) Nothing in item C.3.(c)(3) shall be construed to make unlawful the intrastate shipment of shellstock harvested from within the State provided such shellstock have not exceeded any maximum allowable time period for temperature control as established by item C.2.(c) and C.2.(e).

**Revise 61-47.I.4 to read:**

 4. Shellstock Temperature Control. Certified shippers shall manage shellstock temperature in accordance with the provisions of item C.2(b).

**Revise 61-47.I.5 to read:**

 5. Temperature Control. Certified shippers shall control shellfish temperatures in accordance with the provisions of items C.2.(c), C.2.(e) and C.2(h).

**Revise 61-47.I.6 to read:**

 6. Shell stock Identification. Certified shippers shall identify shell stock in accordance with item C.2. (g)(1) Of this Regulation.

**Revise 61-47.I.7 to read:**

 7. Shucked Shellfish Labeling. Certified shippers shall label shucked shellfish in accordance with item C.2. (i)(1) Of this Regulation.

**Revise 61-47.O.6 to read:**

 6. Mariculture Permit Areas. Operators of shellfish mariculture permit areas permitted by the South Carolina Department of Natural Resources shall provide the Department with a written operational plan that shall include:

 (a) A description of activities associated with the operation including, but not limited to, the operational requirements in C.2. (e)(2);

 (b) The specific site and boundaries in which shellfish culture activities will be conducted;

 (c) The types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats utilized in the aquaculture operation;

 (d) The type and source of shellfish, including seed, to be cultured and harvested;

 (e) Documentation of the source of seed shell stock

 (f) Record keeping to document compliance with the requirements described in item C.2. (e)(2) For maricultured shellfish harvested during months that do require additional temperature controls.

**Fiscal Impact Statement:**

Implementation of these amendments may require additional resources to support the increased number of field and facility compliance inspections needed to monitor the increased shellfish harvesting and sales during the summer months. For example, inspections will be needed to ensure maricultured triploid oysters are brought under temperature control in accordance with the regulation to protect public health. The resource demands on the Department and State government will depend on how much the shellfish industry grows and harvesting activities increase during the summer months in response to the additional business opportunities created by this amendment.

**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

Purpose: The Department amends R.61-47 to provide specific technical requirements regarding the harvesting and handling of clams and maricultured triploid oysters during the summer months (*i.e.,* months that require additional temperature controls) in a manner that is consistent with the national shellfish sanitation program and protects the health of the consumers of shellfish. The time period for additional temperature controls for the summer harvesting and handling of shellfish is May 16th through September 30th, unless otherwise specified. The amendment includes a requirement for certified shippers to only accept shellfish from harvesters that have received annual training on key regulatory requirements and the safe and sanitary practices related to the harvesting and handling of shellfish in South Carolina. The amendment updates several documents referenced in the regulation to the latest versions of the documents and adds a definition for “mariculture” and “triploid oyster.” The amendment also includes stylistic changes to correct 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 REGULATION AMENDMENT AND EXPECTED BENEFITS:

The amendment is needed and reasonable because it clarifies the harvest and handling requirements for clams during summer months and allows the harvest of maricultured triploid oysters during summer months. The amendment allows the South Carolina shellfish industry to expand their markets through the sale of maricultured triploid oysters harvested during the summer months in a manner that is consistent with the national shellfish sanitation program and protects the health of the consumers of shellfish. Historically, South Carolina oysters have not been available for sale during the summer months. Oysters currently are available for purchase during the summer in South Carolina and other states. These oysters are obtained from other states that allow the summer harvest of oysters. Most other states that produce oysters allow the summer harvest of oysters for sale and consumption. Oysters harvested during summer months in other states are harvested and handled under more restrictive conditions than oysters harvested during cooler months to protect the public that consumes summer-harvested oysters. The amendment includes more restrictive harvesting and handling requirements for the summer months to protect public health.

DETERMINATION OF COSTS AND BENEFITS:

Internal Costs: Implementation of these amendments may require additional resources to support the increased number of field and facility compliance inspections needed to monitor the increased shellfish harvesting and sales during the summer months. For example, inspections will be needed to ensure maricultured triploid oysters are brought under temperature control in accordance with the regulation to protect public health. The resource demands on the Department and State government will depend on how much the shellfish industry grows and harvesting activities increase during the summer months in response to the additional business opportunities created by this amendment.

External Costs: There will be external costs for implementing the amendment to this regulation. The external costs will be incurred by shellfish harvesters and certified shippers that decide to expand their operations to participate in the harvesting, handling or sale of maricultured triploid oysters during the summer months. However, those who incur these costs may now realize the below External Benefits.

External Benefits: The amendments will provide the South Carolina shellfish industry the opportunity to sell South Carolina maricultured triploid oysters during months of the year when, historically, South Carolina oysters have not been available for sale.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

There is no anticipated detrimental effect on the environment.

The amendment can affect public health by allowing the public to consume South Carolina maricultured triploid oysters that have been harvested during the summer months. Naturally occurring harmful bacteria, such as Vibrio bacteria, occur at higher levels in shellfish during the summer months due to the higher water and air temperatures. Vibrio bacteria can cause severe illness or death if consumed by individuals with compromised immune systems. The amendments include more restrictive harvesting and handling requirements for shellfish during the summer months to mitigate the increased risk posed by harmful bacteria, especially Vibrio bacteria, during those months.

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

There is no anticipated detrimental effect on the environment.

If the amendment is not implemented, there will be no detrimental effect on public health because molluscan shellfish harvesting and sales during the summer months would remain limited to only clams as is currently the case in South Carolina.

**Statement of Rationale:**

The Department is amending R.61-47, Shellfish to provide specific technical requirements regarding the harvesting and handling of clams and maricultured triploid oysters during the summer months (i.e., months that need additional temperature controls). The time period for additional temperature controls for the summer harvesting and handling of shellfish is May 16th through September 30th, unless otherwise specified. The amendment allows the South Carolina shellfish industry to expand their markets through the sale of maricultured triploid oysters harvested during the summer months in a manner that is consistent with national shellfish sanitation program and protects the health of the consumers of shellfish.