

DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL

DIVISION OF WATERSHED STEWARDSHIP

Statutory Authority: 7 Delaware Code, Section 1902(a) (7 Del.C. §1902(a))
7 DE Admin. Code 7402

PROPOSED

REGISTER NOTICE

SAN # 2018-12

7402 Shellfish Sanitation Regulations

1. TITLE OF THE REGULATIONS:

Delaware Administrative Code 7402 *Shellfish Sanitation Regulations*

2. BRIEF SYNOPSIS OF THE SUBJECT, SUBSTANCE AND ISSUES:

The Atlantic Ocean is currently classified as an Approved Shellfish Growing Area (GA-7) but there is no commercial or recreational bi-valve shellfish harvest that occurs in this growing area and the State resources to maintain current sampling and classification work are costly and provide no added benefit to the State. The purpose of this action is to change the classification of the Atlantic Ocean from an Approved Shellfish Growing Area to a Prohibited Shellfish Growing Area. By changing the classification status, it will save the State thousands of dollars annually with no impact to the public which utilizes the State's shellfish resources. If a viable fishery was determined to exist in the Atlantic Ocean in the future, the area could be reclassified to support the fishery.

The Delaware Fishing Guide has listed that clamming cannot occur within seagrass beds. This addition will make the Prohibited Shellfish Growing Area classification consistent with the restriction of clamming in seagrass beds referenced in the Delaware Fishing Guide for over ten years.

The definition of Shellfish Seed and Maximum Seed Size will be added to Shellfish Sanitation Regulations to be consistent with current Fish and Wildlife Shellfish Aquaculture Regulations for the Inland Bays.

There are no costs associated with these regulatory changes and there is minimal or no impact to commercial or recreational bi-valve shellfish harvesters. This action will save the State of Delaware thousands of dollars annually and continue to protect the State's seagrass restoration efforts.

3. POSSIBLE TERMS OF THE AGENCY ACTION:

There is no sunset date for the proposed regulation change.

4. STATUTORY BASIS OR LEGAL AUTHORITY TO ACT:

7 Delaware Code §§1902(a)

5. OTHER REGULATIONS THAT MAY BE AFFECTED BY THE PROPOSAL:

None

6. NOTICE OF PUBLIC COMMENT:

The hearing record on the proposed changes to 7402 Shellfish Sanitation Regulations will be open December 1, 2018. Individuals may submit written comments regarding the proposed changes via e-mail to Lisa.Vest@state.de.us or via the USPS to Lisa Vest, Hearing Officer, DNREC, 89 Kings Highway, Dover, DE 19901 (302) 739-9042. Public comments will be accepted through close of business Friday, February 1st 2019. A public hearing on the proposed amendment will be held on January 17, 2019 beginning at 6:00 pm in the DNREC Auditorium, located at the Richardson & Robbins Building, 89 Kings Highway, Dover, DE 19901.

7. PREPARED BY:

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7402 Shellfish Sanitation Regulations

1.0 Introduction

International standards for shellfish (molluscan bivalves only) growing area water quality, as well as shellfish growing, harvesting, handling, and processing, are maintained by the Interstate Shellfish Sanitation Conference (ISSC), administrative body of the National Shellfish Sanitation Program (NSSP). Adherence to these standards is a voluntary, cooperative effort by NSSP member states and foreign countries. Member states and countries allow shipment of shellfish into their jurisdictions only from other member states and countries that adhere to ISSC standards and practices. Delaware is an ISSC member, along with 27 other states, the District of Columbia, and nine foreign countries. The NSSP evolved from public health principles and program controls formulated at the original conference on shellfish sanitation called by the Surgeon General of the United States Public Health Service in 1925. Adherence to ISSC standards is administered under the auspices of the U.S. Food and Drug Administration.

The purpose of these Regulations is to ensure that the shellfish harvested for any purpose from Delaware waters, and shellfish shipped to Delaware from beyond its borders, are fit for human consumption - to *protect the public health and safety*. This "*strategic theme*" of Delaware's Shellfish Program is proscribed in the *Environmental Partnership Agreement between Delaware's Department of Natural Resources and Environmental Control and the U.S. Environmental Protection Agency, Region III*. Under this Agreement, key environmental problems and priorities are identified, and key goals established to address them. By protecting the health and safety of shellfish consumers, these Regulations also serve to promote and enhance Delaware's multi-million-dollar shellfish industry, protect the interests of recreational shellfish harvesters, keep as much shellfish ground open to harvesting as environmental conditions allow, and to broadly advocate clean water.

Consumer Warning: Certain people may be at risk of serious illness or death as a result of consuming raw molluscan shellfish, including those with liver disease (from hepatitis, cirrhosis, alcoholism, or cancer), Iron Overload Disease (hemochromatosis), diabetes, those with stomach disorders, including; but not limited to those with low stomach acid, those with immune system disorders, or those with any illness or medical treatment that weakens the body's immune system. Physicians recommend that those at risk not eat any clams, mussels, oysters, or scallops, and furthermore recommend that shellfish, if consumed by the at-risk population, be thoroughly cooked.

2.0 Definitions

NOTE: Those definitions primarily relating to the "Policy To Determine Shellfish Growing Area Classification In And Around Wet Slip Basins And Artificial Lagoons" are contained in Appendix 11.

Approved HACCP Plan (see HACCP): An operational plan mandated by Federal law, effective as of December 18, 1997, and defined in the Federal Register in the "Procedures For the Safe and Sanitary Processing and Importation Of Fish and Fishery Products; Final Rule." which includes Part 123: "Fish and Fishery Products Hazards and Controls Guide," and which is approved by DNREC.

Approved HACCP Training Course: A course approved by DNREC in the instruction of HACCP concepts and operational specifications, mandated by Federal law, effective as of December 18, 1997, and defined in the Federal Register in the "Procedures For the Safe and Sanitary Processing and Importation Of Fish and Fishery Products; Final Rule." which includes Part 123: "Fish and Fishery Products Hazards and Controls Guide."

Approved Depuration Process: The process of reducing bacteria and virus levels to acceptable levels in live shellfish by subjecting them to a strictly controlled aquatic environment, as performed only by a certified depuration processor.

Approved Relaying Operation: The harvesting of shellfish from waters classified as other-than-Approved; however not Prohibited, and their subsequent transference to natural bottom, or in approved containers, to Approved shellfish growing areas; however only with written permission of DNREC.

Approved Source of Shellfish: Shellfish meeting all criteria in these Regulations, including the following:

Shellfish which have been handled by certified interstate Shellfish Dealer/Processors whose names appear on the *Interstate Shellfish Shippers Certified List*; OR shellfish harvested from Delaware waters which have been handled by certified Delaware Intrastate Shellfish Dealer/Processors, and which are available for retail sale to the final customer only in Delaware.¹

Shellfish from Approved waters; OR shellfish from waters classified as other-than-Approved when shellfish harvesting is allowed on a seasonal/conditional basis; OR shellfish subjected to an approved depuration or relay process.

Back Flow/Back Siphonage: Water intended as a potable source; however carrying, or potentially carrying poisonous and/or deleterious substances, because this water flows in the opposite direction of the intended flow due to negative pressure in the potable water supply system.

Business: A shellfish-related business, entity, person, or persons.

Buy Boat/Buy Truck: A boat/truck which is used for the purchasing/shipment of shellfish in the capacity of a certified shellfish dealer/processor.

Certification: The issuance of a numbered license or permit to operate as an intrastate or interstate shellfish dealer/processor.

Certification Number: A number assigned to each certified shellfish dealer/processor by DNREC. The number shall be preceded by the letters "DE" to indicate Delaware, and followed by a two letter symbols designating the type of operation.

Certified Shellfish Dealer/Processor: A person, persons, or business (including buildings, trucks, boats, and other equipment) which engage in one or more of the following: the sale, shucking, packing, repacking, shipping, reshipping, depurating, freezing, or other handling of shellfish on an interstate and/or intrastate basis, as follows:

Interstate Shellfish Dealer/Processor: A certified shellfish dealer/processor permitted to engage in the shellfish trade across state and international borders.

Intrastate Shellfish Dealer/Processor: A certified shellfish dealer/processor permitted to engage in the shellfish trade only within Delaware. This certification is not recognized outside of Delaware.

Commingling: The act of combining different lots of shucked or unshucked shellfish.

Cross Connection: A potable water supply line constructed to allow either back siphonage, or the attachment of a supply line extension which would allow back siphonage.

DNREC: The Delaware Department of Natural Resources and Environmental Control.

Depuration Plant: A plant certified by the State Shellfish Control Authority as a depuration processor.

Depuration Processor (DP): A shellfish dealer/processor which receives or harvests shellstock from approved sources; OR shellfish from waters classified as Seasonally Approved, Conditionally Approved, or Restricted, and which subjects this shellfish to an approved depuration process thereby rendering the shellfish as approved and fit for human consumption; however only as approved by DNREC.

Depuration Process Specifications: The controlled conditions (physical and operational specifications) by which shellfish are subjected to a strictly controlled aquatic environment as a means of reducing the levels of bacteria and viruses in live shellfish to acceptable levels, as approved by DNREC.

Depuration Unit: A tank, trough, or similar vessel in which live shellfish are stored temporarily, and subjected to depuration.

Dry storage: The storage of shellstock out of water.

EPA: The United States Environmental Protection Agency.

FDA: The United States Food and Drug Administration.

Food Contact Surface: Those surfaces of equipment and utensils which normally come in contact with food, and those surfaces from which food may drain, drip, or splash back onto surfaces normally in contact with food.

Food-Product Zone: The parts of food equipment, including ancillary structures, such as blower pipes and drain valves, which may contact the food being processed, or may drain into the portion of equipment with which food is in contact.

HACCP (Hazard Analysis Critical Control Points): A method of conducting sanitation assessments of shellfish/seafood dealer/processors, mandated by Federal law, effective as of December 18, 1997, and defined in the Federal Register as the "Procedures For the Safe and Sanitary Processing and Importation Of Fish and Fishery Products; Final Rule." which includes Part 123: "Fish and Fishery Products Hazards and Controls Guide."

1. Sales made to the final consumer are not required to be made by certified shellfish dealer/processors. However, all shellfish must at some time be handled by a certified shellfish dealer/processor prior to being sold/transferred to the final consumer.

Harvester Tag: A tag required to be affixed by a commercial shellfish harvester to an individual unit of shellfish, and meeting specifications contained in Appendix-10.

Harvest Lot: Shellfish harvested from one shellfish growing area during a single harvesting operation by a single shellfish harvester (for example: a harvester's daily take from a single growing area).

Internal Temperature: The actual temperature of shucked shellfish in the container (not necessarily the air temperature of the refrigerator in which the product may be stored).

Intrastate Shellfish Retailer: A shellfish dealer/processor which sells shellfish only in Delaware.

Marine Head: A toilet or other human waste catchment device with retention and/or discharge capability. A marine head may or may not be an MSD. MSD is the term for a Coast Guard approved marine head. See Appendix-11 for a more detailed definition.

Maximum Seed Size: The maximum size that seed can be grown in waters classified as Prohibited before being transported to waters classified as Approved, Seasonally Approved or Conditionally Approved.

National Shellfish Sanitation Program (NSSP): The cooperative State-FDA-Industry Program for certification of foreign and domestic interstate shellfish dealer/processors as described in the "NSSP Model Ordinance."

Person: A person as defined in Title 1, Chapter 3, Section 302, **Delaware Annotated Code.**

Poisonous or Deleterious Substance: A toxic compound occurring naturally, or which is artificially introduced.

Polluted Waters: Waters which contain human pathogenic organisms and/or indicator organisms and/or other poisonous/deleterious substances at actual or theoretical levels which are determined to render the shellfish growing in the waters unfit for human consumption.

Process Lot: A harvest lot or lots from the same shellfish growing area which are subject to processing.

Process Water: The water in depuration tanks when shellfish are present.

Relay Lot: All shellfish harvested from a single shellfish growing area and transported to another shellfish growing area for natural biological purification.

Relay Operator: A person/business permitted/certified to engage in relaying.

Repacker (RP): A shellfish dealer/processor, other than the original certified shucker-packer, which repacks and ships shucked shellfish into containers other than the original container.

Sanitary Survey: The collection of valid dilution formula loading factors, all elements of a wet slip basin classification survey, and the evaluation of all other actual and potential pollution sources and environmental factors having a bearing on shellfish growing area water quality.

Seed- Juvenile shellfish used in aquaculture operations.

Sewage: Human body wastes and/or other wastes from toilets and other receptacles intended to receive and discharge and/or retain such wastes.

Shellfish: All edible species of oysters, clams, mussels and scallops* either shucked or in the shell, fresh or frozen, whole or in part. The term "shellfish" may be used interchangeably with "shellstock" unless otherwise specified in these Regulations. Some of the common bivalves included in this definition are:

Common Name	Scientific Name
Cockle	Clinocardium nuttalli
	Cardium corbis (Pacific)
Geoduck	Panope generosa
Freshwater clam	Rangia cuneata
Soft shell clam	Mya arenaria
Hard or quahog clam	Mercenaria mercenaria
	Mercenaria campechiensis
Surf clam	Spisula solidissima
Mahogany clam or Ocean quahog	Arctica islandica
Gaper or Horse clam	Tresus nuttalli
	Tresus capax
Razor clam	Solen resaceus
	Ensis directus (Atlantic)
	Solen viridis
	Tagelus plebeius
	Siliqua patula (Pacific)

Bent-nose clam	Macoma nasuta
Pismo clam	Tivela stultorum
Butter clam	Saxidomus giganteus
Calico clam	Macrocallista maculata
Sunray venus	Macrocallista nimbosa
Pacific littleneck clam	Protothaca tenerrima
	Protothaca staminea
Manilla clam	Tapes semidecussata
Pacific (Japanese) oyster	Crassostrea gigas
Eastern oyster	Crassostrea virginica
Olympia or yaquina oyster	Ostrea lurida
European oyster	Ostrea edulis
Blue or bay mussel	Mytilus edulis
Ribbed mussel	Geukensia demissa
California sea mussel	Mytilus californianus
Green lipped mussel	Perna canaliculus

*Scallops are excluded if the final product is the shucked adductor muscle only.

Shellfish Growing Areas (Waters): Naturally-occurring subaqueous or intertidal areas which support or could support live shellfish.

Shellfish Growing Area Classification: A designation which reflects the suitability of an area for shellfish harvesting relating to the fitness of the shellfish therein for human consumption. The following are the classifications that Delaware may use:

Approved" Shellfish Growing Area: An area approved for the harvesting of shellfish for any human food purposes with no seasonal restrictions or conditions.

Seasonally Approved" Shellfish Growing Area: An area where the harvesting of shellfish is allowed conditionally, as per a specified season.

Conditionally Approved" Shellfish Growing Area: An area where the harvesting of shellfish is allowed based on one or more specified conditions.

Prohibited" Shellfish Growing Area: An area where the taking of shellfish is prohibited, except for scientific research purposes with written permission of DNREC.

Shellfish Handler: Any person, persons, or business engaged in the growing, harvesting, buying, treating, packing, selling, shipping or other processing of shellfish.

Shellfish Handling: Any manual, mechanical, chemical manipulation or alteration of shellfish relating to its growing, harvesting, buying, treating, packing, selling, shipping, or other processing.

Shellfish Harvester (Catcher, Taker, Tonger, etc.): A person who removes shellfish from any waters by any means for any purpose.

Shellfish Harvesting (Catching, Taking, Toning, Raking, etc.): The removal of shellfish by any means from a shellfish growing area for any purpose.

Shellfish Processing: The process undertaken when shellfish are shipped, reshipped, shucked, frozen, packed, repacked, depurated, or otherwise handled.

Shellstock: Shellfish in the shell.

Shellstock-Shipper (SS): A shellfish dealer/processor which grows, and/or harvests, and/or buys, and sells/ships shellstock.

Shellstock Shipper Tag: A tag required to be affixed by a shellstock shipper, repacker, or shucker-packer, to an individual unit of shellfish (as defined in these Regulations), and meeting specifications contained in Appendix 10.

Shucked Shellfish: Shellfish, whole or in part, from which one or both shells have been removed.

Shucker-Packer (SP): A shellfish dealer/processor which shucks and packs shellfish, and may also act as a SS or RS.

State Shellfish Control Authority (SSCA): The State agency or agencies having legal authority to classify shellfish growing areas and issue permits for the interstate shipment of shellfish in accordance with the provisions of the "NSSP Model Ordinance." Foreign shellfish control authorities having effective agreements with the FDA are considered State Shellfish Control Authorities for the purposes of these Regulations. DNREC is the State Shellfish Control Authority for Delaware.

Transaction Record: Forms used to document each purchase or sale of shellfish at the wholesale level.

Wet Storage: The temporary storage of shellfish intended for marketing in containers or floats in natural bodies of water or in tanks containing natural or synthetic seawater.

Wet Slip: A place in the water where a boat may be docked or otherwise moored to a fixed or floating structure, including but not limited to a dock, pier, mooring or anchorage.

Wet Slip Basin: A natural waterway and/or artificial lagoon and/or demarcated portions thereof containing more than ten wet slips.

3.0 General Regulations, Water Quality and Classification, Harvesting, Tracking, Permitting, Handling and Shipping:

3.1 General Regulation Specifications:

3.1.1 **DNREC Authority:** These Regulations are adopted under authority of Title 7 of the **Delaware Annotated Code**. These Regulations shall be applied and enforced by DNREC in accordance with the specifications contained herein, and based on the interpretation of satisfactory compliance contained in the latest editions of the "NSSP Model Ordinance." Any person who neglects or fails to comply with any provision of these Regulations shall be subject to penalty.

3.1.1.1 These Regulations shall supersede and replace the Regulations Governing the Production, Handling, Processing, Transportation, and Sale Of Shellfish, and shall apply throughout the State of Delaware.

3.1.2 **Unconstitutionality Clause:** Should any section, paragraph, sentence, clause, or phrase of these regulations be declared unconstitutional or invalid for any reason the remainder of said regulations shall not be affected thereby.

3.1.3 **Seizure of Shellfish:** Shellfish which are determined to be adulterated, or which can not be identified as to source or place or origin, shall be seized, confiscated, and destroyed by DNREC. DNREC shall possess the authority to seize, confiscate, and destroy shellfish in the event of significant non-compliance with these regulations which could result in an eminent health hazard, as determined by DNREC.

3.1.4 **Certification/Permitting/Sanitary Control:** Not all persons/businesses handling shellfish shall necessarily be required to be permitted/certified by DNREC. However, persons/businesses which handle shellfish shall be permitted/certified by DNREC as per these regulations; and all persons or businesses which handle shellfish shall be under the sanitary control of DNREC. Certification, permits or written permission shall be non-transferable.

3.1.5 **Emergency Closure of Shellfish Growing Areas:** Emergency closure of shellfish growing areas to shellfish harvesting may be implemented by DNREC in response to the introduction of contaminants into shellfish growing waters, or in response to events which could affect the introduction of contaminants into shellfish growing waters, including; but not limited to: storms, flooding, sewage treatment plant failures, spills, boat wastes, or toxin-producing phytoplankton blooms (see Appendix 8).

3.1.6 **HACCP (Hazard Analysis Critical Control Point):** HACCP shall take effect on December 18, 1996. DNREC shall regulate under HACCP only those shellfish dealer/processors which are listed in the Interstate Certified Shellfish Shippers List, and which fall under HACCP as defined in Section 123.3 (k) (1) of the Federal law mandating HACCP, as interpreted by DNREC, and shall regulate only the portion or portions of said operation / physical facility which is/are utilized in the receipt, handling, processing, and shipping, of said shellfish, as defined herein.

3.2 Shellfish Growing Area Water Quality, Classification, and Harvesting:

3.2.1 Shellfish Growing Area Water Quality and Classification:

3.2.1.1 DNREC shall determine the size, configuration and classification of shellfish growing areas in Delaware.

3.2.1.2 DNREC shall determine the validity of all information which may have a bearing on the determination of the size, configuration, and classification of shellfish growing areas in Delaware.

3.2.1.3 DNREC shall classify Delaware's shellfish growing areas on the basis of the following:

3.2.1.3.1 Theoretical pollution loading including; but not limited to areas determined to be impacted by wet slip basins, as per the specifications contained in Appendix 11, thereby constituting an administrative closure;

3.2.1.3.2 Sanitary survey data constituting the documented presence of actual and potential point-source and non-point pollution sources; and

3.2.1.3.3 Bacteriological monitoring of shellfish growing waters and/or shellfish tissue (see Appendix 4).

- 3.2.1.4 Delaware's shellfish growing waters shall be classified as Approved, Prohibited, Seasonally Approved, Conditionally Approved, or Restricted.
- 3.2.1.5 Conformance with bacteriological shellfish water quality standards shall be based on a geometric average of the most recent 30 samples per sample station.
- 3.2.1.6 Seasonally Approved and Conditionally Approved shellfish growing areas shall meet the following bacteriological standards on a seasonal and/or conditional basis depending upon the specifications of the classification/condition(s); and Approved shellfish growing areas shall meet the following bacteriological standards at all times:

- 3.2.1.6.1 Total coliform mean MPN levels in shellfish growing waters shall not exceed 70 per 100 ml and not more than 10% of the samples shall exceed an MPN of 230 per 100 ml for a 5-tube decimal dilution test, or an MPN of 330 per 100 ml for a 3-tube decimal dilution test.

AND/OR

- 3.2.1.6.2 Fecal coliform mean MPN levels in shellfish growing waters shall not exceed 14 per 100 ml and not more than 10% of the samples shall exceed an MPN of 43 per 100 ml for a 5-tube decimal dilution test, or an MPN of 49 per 100 ml for a 3-tube decimal dilution test.
- 3.2.1.7 The standard for the Restricted classification of growing areas for purposes of relay or depuration of the shellfish therein shall be a total coliform mean MPN level in said growing waters of 700 per 100 ml. and not more than 10% of the samples shall exceed an MPN of 3,300 per 100 ml. using a 3-tube decimal dilution test. This standard shall apply, and shall be applied, relating to any and all restrictions based on the effects by point or non-point sources of pollution, and/or other conditions as set forth in the latest edition of the NSSP Model Ordinance.

3.2.2 Shellfish Harvesting and Tagging:

- 3.2.2.1 Shellfish harvesting shall not be allowed in the following areas:

- 3.2.2.1.1 Shellfish growing areas classified as Prohibited, unless for scientific research purposes, and only with written permission of DNREC; or in accordance with 3.2.2.2.4.
 - 3.2.2.1.2 Shellfish growing areas classified as Seasonally Approved or Conditionally Approved in accordance with conditions stipulated in Appendix 3.
 - 3.2.2.1.3 Shellfish growing areas not classified, and for which there are insufficient data supporting a harvest.

- 3.2.2.2 Shellfish may be harvested from the following areas under the conditions listed herein and/or in the Appendices:

- 3.2.2.2.1 In shellfish growing areas classified as Approved;
 - 3.2.2.2.2 Shellfish growing areas classified as Seasonally Approved in accordance with conditions stipulated in Appendix 3;
 - 3.2.2.2.3 Shellfish growing areas classified as Restricted.
 - 3.2.2.2.4 Seed may be grown in waters classified as Prohibited and transported to a lease in a shellfish growing area classified as Approved, Conditionally Approved or Seasonally Approved as long as the seed is removed from waters classified as Prohibited before the maximum seed size is exceeded.

- 3.2.2.2.4.1 The maximum seed size for oysters is 25 mm and the maximum seed size for clams is 15 mm.

- 3.2.2.2.4.2 Oysters or clams that are cultured in aquaculture operations in waters classified as Prohibited and exceed the maximum seed size shall be determined to be adulterated and shall be seized, confiscated, and destroyed by DNREC.

- 3.2.2.3 Harvesters shall place tags on individual units of shellstock, recognizing that individual bags or a bulk landing of shellstock may constitute an individual unit of shellstock. All harvester tags shall meet the requirements specified in Appendix 10.

3.3 Permitting of Shellfish Dealer/Processors:

3.3.1 Permit Issuance Parameters:

- 3.3.1.1 Applications for permits to operate as shellfish dealer/processors shall be made on permit applications provided by DNREC. The following shellfish handlers shall be required to be permitted/certified by DNREC in order to engage in the procurement and sale of shellfish:
 - 3.3.1.1.1 All interstate shellfish dealer/processors;
 - 3.3.1.1.2 Intrastate shellfish dealer/processors;
 - 3.3.1.1.3 Shellfish wholesalers;

- 3.3.1.1.4 Shellfish retailers which procure shellfish from non-certified sources;
- 3.3.1.1.5 Shellfish harvesters, engaged in:
 - 3.3.1.1.5.1 Selling/shipping shellfish directly to non-certified shellfish retailers or to final consumers;
 - 3.3.1.1.5.2 Owners of "buy boats" and "buy trucks;" and
 - 3.3.1.1.5.3 Harvesting of shellfish for delivery to a depuration plant and/or for relaying.²

²Persons harvesting shellfish from waters classified as other-than-Approved for delivery to a depuration plant and persons engaged in relaying shall submit operational specifications for said activities to DNREC prior to commencing operations, and shall have received a permit or written permission from DNREC to harvest shellfish from waters classified as other-than-Approved prior to commencing such operations. Additional permits may be required by the DNREC Division of Fish and Wildlife.

- 3.3.1.2 Shellfish retailers shall not be required to be permitted/certified unless shellfish are procured from a non-certified source.²
- 3.3.1.3 Shellfish handlers requiring a permit/certification shall not operate until and unless a permit/certification has been issued by DNREC. Such permits shall expire on the 31st day of March of each year. Permits shall not be transferable. No permit will be issued unless an application is made in writing upon forms supplied by DNREC. Prior to the physical and/or operational alteration of an existing facility and/or prior to initial commencement of shellfish processing operations shellfish dealer/processors shall:
 - 3.3.1.3.1 Submit construction and operational specs. to DNREC;
 - 3.3.1.3.2 Receive approval of the plans and operational specifications from DNREC;
 - 3.3.1.3.3 Submit to an inspection of their plant/operation by DNREC; and
 - 3.3.1.3.4 Shall be found to be in satisfactory compliance with these Regulations, at the discretion of DNREC.
- 3.3.1.4 DNREC shall have the authority to immediately revoke shellfish dealer/processor permits based on the existence of an eminent health hazard and/or significant and/or chronic non-compliance with these Regulations.
 - 3.3.1.4.1 Delaware Shellfish Dealer/Processors shall be considered to be certified only if a current numbered license or permit to operate as an intrastate or interstate shellfish dealer/processor has been issued by DNREC, and the operation is in significant compliance with these regulations, as determined by DNREC.
- 3.3.2 Permit Specifications and Inspection Frequency:
 - 3.3.2.1 The permits listed below shall be issued as interstate shellfish dealer/processor permits, OR intrastate shellfish dealer/processor permits; EXCEPT intrastate shellfish retailer permits which are issued as intrastate permits only. This includes all wholesalers, which shall also apply to harvesters which engage in the activities defined below and elsewhere in these Regulations:
 - 3.3.2.1.1 Shellstock Shipper (SS) permit: Such permits may be issued to shellfish dealer/processors which ship shellfish. Said shellfish may be grown and/or harvested by the shipper in accordance with these Regulations and/or procured from another source. Shellstock shippers may procure shellfish directly from licensed Delaware shellfish harvesters, and may sell shellfish to other certified shellfish dealer/processors in and outside of Delaware and to the final consumer. Shellstock shippers shall not act as shucker-packers, repackers, or depuration-processors. Minimum Inspection Frequency: Twice/year.
 - 3.3.2.1.2 Shucker-Packer (SP) permits: Such permits may be issued to shellfish dealer/processors which shuck and pack shellfish. Shucker-packers may act as shellstock-shippers and repackers. Shucker-packers shall not act as depuration-processors. Minimum Inspection Frequency: Once/month when operating, and at least four times per year, total, unless the facility is open less than four months per year.
 - 3.3.2.1.3 Repackers (RP) permit: Such permits may be issued to shellfish dealer/processors other than the original certified shucker-packer which repack and ship shucked shellfish into other

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containers. Such permit-holders must generally meet more requirements than shellstock-shippers; however, not generally the equipment requirements of a shucker-packer. Repackers may act as shellstock-shippers. Repackers shall not act as shucker-packers or depuration-processors. Minimum Inspection Frequency: Once/month when operating, and at least four times per year, total, unless the facility is open less than four months per year.

3.3.2.1.4 Depuration Processor (DP) permit: Such permits shall be issued to shellfish dealer/processers which receive or harvest shellstock from approved sources, or as per criteria listed in the depuration portions of Section IV of these Regulations, and which subjects said shellfish to an approved depuration process, thereby rendering the shellfish as approved and fit for human consumption. A depuration-processor may act as a shellstock-shipper, or repacker. Minimum Inspection Frequency: Once/month when operating, and at least four times per year, total, unless the facility is open less than four months per year. twice/year.

3.3.2.1.5 Intrastate Shellfish Retailer permit: Such permits may be issued to persons/businesses located in Delaware, which may include vehicles registered only in Delaware and/or permanent structures from which shellfish are sold only to the final consumer. The intention of this permit is to provide sanitary control of shellfish not necessarily procured from a certified shellfish dealer/processor. Minimum Inspection Frequency: twice/year.

3.4 Shellfish Handling and Shipping Parameters:

3.4.1 Importation/Exportation:

3.4.1.1 Only shellfish from approved sources shall be imported into Delaware.

3.4.1.2 Only shellfish which have been handled by certified interstate shellfish dealer/processers shall be exported from Delaware.

3.4.1.3 Intrastate Delaware shellfish dealer/processers shall not sell/ship shellfish out of Delaware; and shellfish handled by intrastate Delaware shellfish dealer/processers shall not be made available for sale outside of Delaware.

3.4.1.4 Shellfish requiring depuration or relaying shall be sold/shipped only within Delaware to certified depuration-processors, or shall be shipped out of Delaware only under the provisions of interstate memoranda of agreement (MOAs) relating to a specific harvest/depuration or harvest/relaying operation by persons permitted to harvest shellfish under these restrictions, as established in writing by DNREC and the cooperating state. All other handling of shellfish from Prohibited waters and from Seasonally Approved or Conditionally Approved waters when the direct harvest of said shellfish is prohibited by these Regulations is prohibited.

3.4.2 Marketing to the Final Consumer:³

3.4.2.1 Only shellfish from approved sources shall be sold/transferred in Delaware to the final consumer.

3.4.2.2 Certified interstate and intrastate shellfish dealer/processers may sell/transfer shellfish directly to the final consumer.

3.4.2.3 Certified interstate and intrastate shellfish dealer/processers may sell/transfer shellfish directly to non-certified shellfish retailers.

3.4.3 Sale/Shipping Between Shellfish Dealer/Processors.

3.4.3.1 Certified intrastate shellfish dealer/processers may sell/transfer shellfish to other intrastate shellfish dealer/processers.

3.4.3.2 Certified interstate shellfish dealer/processers may sell/transfer shellfish to other certified interstate shellfish dealer/processers or to Delaware intrastate shellfish dealer/processers.

3.4.3.3 Certified interstate and intrastate shellfish dealer/processers shall not sell/transfer shellfish to commercial establishments which are in critical or significant violation of these regulations at the discretion of DNREC.

4.0 HACCP and Sanitation: Harvesting, Handling, Processing, Depuration, and Relaying

3. Sales made to the final consumer are not required to be made by certified shellfish dealer/processers. However, all shellfish must at some time be handled by a certified shellfish dealer/processor prior to being sold/transferred to the final consumer.

- 4.1 HACCP (Hazard Analysis Critical Control Points): All HACCP specifications are contained in Appendix 12 of these Regulations, and consists of the "Fish and Fishery Products Hazards and Controls Guide, and the accompanying "Training Guide."
 - 4.1.1 The HACCP method of doing sanitation assessments shall take effect on December 18, 1997. Until then, all portions of these Regulations shall be in effect. As of December 18, 1997, all portions of these Regulations superseded by HACCP shall no longer be in effect. However, the remainder of these Regulations shall not be affected thereby.
 - 4.1.2 After December 18, 1996, a representative person from each Delaware shellfish dealer/processor businesses/operation, and which shall include only those shellfish dealer/processors which are listed in the Interstate Certified Shellfish Shippers List, and which fall under HACCP as defined in Section 123.3 (k) (1) of the Federal law mandating HACCP, as interpreted by DNREC, shall be required to:
 - 4.1.2.1 Complete an Approved HACCP Training Course; and
 - 4.1.2.2 Develop and implement an Approved HACCP Plan. DNREC may provide guidance in developing this Plan, and may draft the Plan if the person/business is unable for any reason to do so without assistance.
- 4.2 General Sanitation:
 - 4.2.1 Sanitary Control: All persons/businesses which handle shellfish shall be required to comply with any or all of Section IV of these Regulations.
 - 4.2.2 Sampling: Representatives of DNREC may secure reasonable samples of shellfish for laboratory and sanitary examination.
 - 4.2.3 Adulterated Product: Shellfish shall not be adulterated. Shellfish shall be considered to be adulterated if they contain poisonous or deleterious substances, and/or based on the following criteria:
 - 4.2.3.1 Only processes approved by DNREC may be used in the handling of shellfish.
 - 4.2.3.2 Only shellfish additives approved by DNREC shall be used in shellfish at concentrations approved by DNREC.
 - 4.2.3.3 In addition to other labeling and tagging requirements, shellfish shall be labeled with all required information regarding additives.
 - 4.2.3.4 Shellfish shall meet the bacteriological standards indicated in Appendices 6 and 7.
- 4.3 Harvesting of Shellfish:
 - 4.3.1 Harvesting For Depuration Or Relay Purposes: Shellfish may be harvested for depuration or relay purposes from waters classified as other-than-Approved; however not from Prohibited waters, and only with written permission of DNREC. Shellfish containing poisonous or deleterious substances shall meet FDA tolerance levels prior to sale to the final consumer.
 - 4.3.2 Waste Disposal:
 - 4.3.2.1 All buy boats shall have a non-receiving-waters-discharge-capable marine head (Type III without a Y-valve) on board.
 - 4.3.2.2 No body excretions shall be discharged overboard from a boat used in harvesting shellfish, or from "buy" boats while in areas from which shellfish are harvested.
 - 4.3.2.3 No other poisonous or deleterious substance shall be discharged overboard.
 - 4.3.2.4 All shellfish harvest vessels shall have at a minimum a bucket with a tight-fitting lid designated exclusively for retention of bodily excretions.
 - 4.3.3 Shellstock Contact Surfaces:
 - 4.3.3.1 Boat decks, storage bins, and other surfaces that contact shellstock shall be constructed of cleanable material(s). Wood which is smooth and cleanable, without cracks and crevices, and is well maintained, shall be considered a suitable shellstock contact surface.
 - 4.3.3.2 Shellstock contact surfaces shall be kept clean with potable water, or with Approved shellfish growing water, and shall be thoroughly cleaned before they contact the shellstock.

NOTE: Shellstock in this case shall mean only live shellfish still in the shell.
 - 4.3.4 Contamination and Temperature Control: NOTE: Shellstock in this case shall mean only live shellfish still in the shell.
 - 4.3.4.1 Dogs, cats or other animals are not permitted on vessels or in vehicles on which shellstock is held.
 - 4.3.4.2 Shellstock shall be covered when ever possible and as soon after harvest as possible to prevent contamination of the shellstock by bird excrement or other contaminants and to reduce exposure to the sun which may cause spoilage.

- 4.3.4.3 DNREC shall have the authority to require shellfish harvesters to provide adequate temperature controls for shellstock during any phase of handling based on ambient air temperature and time of exposure.
- 4.3.4.4 Shellstock shall not come in contact with bilge water or any other polluted water. Shellstock shall be stored after harvest in a location that will prevent the shellfish from contacting bilge water or waters classified as other-than-Approved.
- 4.3.4.5 Shellstock shall be washed reasonably free of bottom sediments and detritus as soon after harvesting as is practical with Approved shellfish growing area water or potable water. The primary responsibility for washing is with the harvester.
- 4.3.4.6 Sacks or other containers used for storing shellstock shall be clean and fabricated from safe materials. Such sacks/containers shall have only been used for the conveyance of shellfish, and shall not have been used for the conveyance of other food products since their fabrication.
- 4.3.5 Records: Harvesters shall place tags on individual units of shellstock, recognizing that individual bags or a bulk landing of shellstock may constitute an individual unit of shellstock. All harvester tags shall meet the requirements specified in Appendix 10.
- 4.4 Post Harvest Handling, Packing, Shipping, and Shucking of Shellfish:
 - 4.4.1 Plant Location/Flooding: Plants in which shellfish are shucked and packed shall be located so they will not be subject to regular flooding. If plant floors become flooded shucking shall be discontinued until after waters have receded, and the building is cleaned.
 - 4.4.2 Plant Arrangement:
 - 4.4.2.1 The handling of shellfish shall be separated by time and/or distance/partitions from other operations which could cause contamination of the shellfish.
 - 4.4.2.2 Packing rooms shall be of sufficient size to permit sanitary handling of the product, and thorough cleaning.
 - 4.4.2.3 A separate room, rooms, or lockers shall be provided for storing employees' street clothing, aprons, gloves, and personal articles.
 - 4.4.2.4 Plants/trucks/conveyances shall be used in a manner which is consistent with plant arrangement requirements, and which provide sanitary protection of the shellfish.
 - 4.4.3 Vectors:
 - 4.4.3.1 Plants/trucks/conveyances shall be constructed so that reasonable barriers to entry are provided for insects, rodents, and other vermin.
 - 4.4.3.2 Extermination efforts shall be required when deemed necessary.
 - 4.4.3.3 Plant premises shall be maintained so that no undue harborage or food is provided for vermin.
 - 4.4.3.4 No domestic animals or fowl shall be permitted in the interior of shellfish processing plants, except guard dogs may be allowed in non-processing portions of plants with no further restrictions, and may be allowed in processing portions of the plant interior when plants are not in use unless the dog's behavior results in chronic unsanitary conditions.
 - 4.4.4 Non-Food Contact Surfaces:
 - 4.4.4.1 Truck floors, storage bins, and other surfaces that contact shellstock shall be constructed of cleanable material(s), shall be kept clean with potable water or Approved shellfish growing water, and shall be thoroughly cleaned before they contact the shellstock.
 - 4.4.4.2 Hardwood in good condition, and smooth and cleanable, shall be considered a suitable shellstock contact surface. NOTE: Shellstock in this case shall mean live shellfish still in the shell.
 - 4.4.4.3 Floors shall be constructed of concrete or other material reasonably impervious to water, shall be graded to drain quickly, shall be free from cracks and uneven surfaces that interfere with proper cleaning or drainage, shall be maintained in good condition, and shall be kept clean.
 - 4.4.4.4 Interior surfaces, including walls, ceilings, refrigeration units, and attached equipment in rooms where shellfish are shucked, packed, or stored, or in which utensils are washed or stored, shall be smooth, washable, light-colored, shall be maintained in good condition, and shall be kept clean.
 - 4.4.4.5 Blow tank air intake filters shall be constructed from approved materials.
 - 4.4.4.6 Surfaces of stands or stalls shall be smooth and cleanable.
 - 4.4.5 General Sanitation:
 - 4.4.5.1 Premises shall be kept clean and free of litter and rubbish. Adequate, covered refuse containers shall be provided throughout the plant. Miscellaneous and unused equipment and articles which are not necessary to plant operations shall not be stored in rooms used for shellstock storage, shucking, packing, or repacking.

- 4.4.5.2 In addition to being maintained in a generally sanitary condition, non-food contact surfaces, including shucking stools, floors, walls, ceilings, and attached equipment in the shellstock storage rooms, packing, and shucking rooms, shall be cleaned as soon as is practicable after the day's operations have ceased.
- 4.4.5.3 Adequate cleaning equipment and solutions shall be provided, used, and stored properly.
- 4.4.5.4 Signs shall be posted in toilet rooms and/or near hand sinks directing employees to wash their hands before starting work and after each interruption.
- 4.4.5.5 Covered refuse containers shall be provided at each hand sink. Soap and paper towels shall be provided at each hand sink.
- 4.4.5.6 Windows and skylights (inside and outside surfaces) shall be maintained, and kept in a clean condition.
- 4.4.6 Lighting: Ample natural and/or artificial light shall be provided in all working and storage rooms. Artificial lighting fixtures shall be shielded.
- 4.4.7 Heating, Cooling and Ventilation: Working rooms shall be ventilated, and shall be heated or cooled when necessary to prevent condensation.
- 4.4.8 Water Supply: All Shucker-Packers, Repackers, and Depuration Processors shall have an adequate potable water supply. Shellstock Shippers shall have a potable water supply or access to Approved shellfish growing waters.
- 4.4.9 Plumbing and Related Facilities:
 - 4.4.9.1 Plumbing shall be installed in compliance with all the *BOCA Southern Plumbing Code* and local plumbing codes.
 - 4.4.9.2 Toilets shall be easily accessible.
 - 4.4.9.3 Sinks with cold running water, and hot running water of at least 100 Degrees-F, shall be provided for employee use after using the lavatory, and shall be located so they are subject to observation by plant personnel responsible for this task.
 - 4.4.9.4 All toilets, toilet rooms, and outhouses, and all surfaces therein, shall be constructed of smooth and cleanable materials, and shall have toilet paper.
 - 4.4.9.5 All toilet rooms and outhouses shall be vented to the outside.
 - 4.4.9.6 A three compartment sink with hot and cold running water available at each compartment shall be provided on the premises for the purpose of washing, rinsing, and sanitizing equipment which contacts the shellfish, such as knives and shucking buckets.
 - 4.4.9.7 At least one hand sink with hot and cold running water shall be provided in the packing room, and one provided in the shucking room.
- 4.4.10 Sewage Disposal: Sewage shall be discharged in accordance with the DNREC "Regulations Governing the Design, Installation and Operation of On-Site Waste water Treatment and Disposal Systems." Sewage disposal facilities shall be so constructed and maintained that wastes will be inaccessible to flies.
- 4.4.11 Food Contact Surfaces:
 - 4.4.11.1 Materials and Construction:
 - 4.4.11.1.1 The tops of shucking benches and tables, and contiguous walls to a height of at least 2 feet above the bench top, shall be of smooth concrete, corrosion-resistant metal, or other durable, non-absorbent material, free from cracks, and so constructed that drainage is complete and rapid, and is directed away from the stored shellfish.
 - 4.4.11.1.2 Equipment and conveyances shall be constructed so shucked shellfish do not become entangled and/or hung up on the equipment during processing operations.
 - 4.4.11.1.3 Shucking blocks shall be smooth and cleanable. Wooden blocks are allowed if smooth and cleanable, and are of solid, one-piece construction, and are easily removable. Shucking blocks of lead and other toxic materials are prohibited.
 - 4.4.11.1.4 Food contact surfaces of refrigeration units, utensils, and other equipment, shall be made of smooth, corrosion-resistant, impervious, nontoxic material which will not readily disintegrate or crack; and utensils and equipment shall be constructed so they are easily cleanable, and shall be kept in good repair.
 - 4.4.11.1.5 Shellstock not shipped in bulk shall be shipped in sacks or other containers approved for storing shellstock, shall be clean, and shall be fabricated from safe materials. NOTE: Shellstock in this case shall mean only live shellfish still in the shell.

- 4.4.11.1.6 Shucked shellfish shall be packed and shipped in clean, single-service containers made of impervious materials, and which possess tamper resistant qualities, or they shall be stored in clean, properly designed, returnable containers, sealed so that tampering can be detected.
- 4.4.11.2 Sanitation and Use:
 - 4.4.11.2.1 All food-contact surfaces, including; but not limited to shucking benches, blocks, and other work surfaces, and utensils which come into contact with shucked shellfish, shall all be used in a sanitary manner, stored in a manner which precludes contamination, and shall be washed and rinsed with potable water, and sanitized as soon as is practicable after the day's operations have ceased.
 - 4.4.11.2.2 Returnable shipping containers shall be thoroughly cleaned as soon after emptying as is practical, and shall be washed and rinsed with potable water, and sanitized on the day they are to be used, and shall be protected against contamination, and handled in a sanitary manner.
 - 4.4.11.2.3 All single-service containers shall be stored and handled in a sanitary manner, and where necessary shall be given bactericidal treatment immediately prior to filling.
 - 4.4.11.2.4 Adequate cleaning equipment, solutions, sanitizers, and test kits shall be provided, used, and stored properly.
 - 4.4.11.2.5 Poisonous and Deleterious Substances: Poisonous and deleterious substances shall be properly used, stored, located, and labeled.
- 4.4.12 Records and Shellstock/Shellfish Labeling:
 - 4.4.12.1 Complete and accurate records of all shellfish received and shipped shall be kept by every shellfish dealer/processor, shall be organized and easily understood pertaining to traceback of shellstock/shellfish to waters of origin, and shall be made accessible to DNREC. Records shall accurately reflect all information required on shellfish tags, as specified in Appendix 10.
 - 4.4.12.2 Shellfish shall not be accepted by shellfish dealer/processers unless the shellfish is identified and accompanied by the information contained in Appendix 10.
 - 4.4.12.3 All shellfish dealer/processers shall retain records of the procurement of and distribution of shellfish/shellstock for a period of at least one year if the product is fresh, and for a period of at least two years if the product is frozen, unless otherwise proscribed by DNREC.
 - 4.4.12.4 Shellfish reshipped or distributed by wholesale dealers shall bear shellfish tags. If the package is reshipped as a unit, remaining unchanged since it was received, the tag shall have sufficient blank space for the reshipper to stamp their reshipper number, state designation, and date of reshipment on the tag.
 - 4.4.12.4.1 Shellstock: All shellfish dealer/processers shall identify each bag, container, or other unit of shellstock with a regulation shellfish tag, as per specifications in Appendix 10.
 - 4.4.12.4.2 Each individual package of fresh or frozen shucked shellfish shall have permanently recorded on the package or label, so as to be easily visible, the shucker-packer's, repacker's, and distributor's name, address, and Interstate Certified Shellstock Shipper's List (ICSSL) certificate number preceded by the abbreviated name of the State. Containers holding 1 gallon or more shall have the identification on the container wall unless the cover becomes an integral part of the container during the sealing process. Packages of frozen shellfish shall show the date or code of packing.
 - 4.4.12.4.3 Each container or unit of shucked shellfish shall be labeled with the information contained in Appendix 10.
- 4.4.13 Shellstock Handling (General):
 - 4.4.13.1 All shellstock shall be protected against contamination at all times, and shall be handled in a sanitary manner, and shall be shipped, delivered, and received in a clean and wholesome condition.
 - 4.4.13.2 Dead shellstock shall be culled as often as is practicable. Only live shellfish shall be shucked. Dead shellstock shall not be made available for human consumption, and shall be disposed of in a sanitary manner. The exception to these requirements shall be Post-Harvest Processed shellfish / shellstock, where killing the animal is an accepted result of said process(es).
 - 4.4.13.3 There shall be no commingling of shellfish.
 - 4.4.13.4 Shellstock shall be washed reasonably free of bottom sediments and detritus as soon after harvesting as is practicable with Approved shellfish growing water or potable water. Although washing shellstock is the primary responsibility of the harvester, it shall also be the responsibility of the person receiving shellstock to ensure that they are washed.

- 4.4.13.5 Flume water shall be maintained reasonably free of sediments, shellfish tissue "fines," and other particulate matter, and shall be changed often enough to preclude excessive accumulation of such matter.
- 4.4.13.6 Shucked shellfish shall not be allowed to become entangled or hung up on equipment for more than 30 minutes during processing operations. Actions shall be taken to dislodge meats from equipment at intervals not to exceed 30 minutes. Such meats may be reintroduced into processing operations. Meats which have become entangled or hung up on equipment for more than 30 minutes shall be dislodged, removed, and discarded.
- 4.4.13.7 Shells from which meats have been removed shall be removed promptly from the shucking room.
- 4.4.14 Temperature Control:
 - 4.4.14.1 Adequate refrigeration shall be required, with thermometers and/or temperature recording devices, as required by DNREC.
 - 4.4.14.2 Shellstock: Shellstock shall be transported in adequately refrigerated trucks if, in the opinion of DNREC, not doing so would subject the product to unacceptable bacterial growth or deterioration due to high ambient outside air temperature and/or an unacceptably long transportation time. Within four hours of receipt/loading of shellstock, said shellstock shall be in an environment capable of achieving and maintaining a product temperature of 45°F or lower.
 - 4.4.14.3 Shucked Shellfish:
 - 4.4.14.3.1 Shucked shellfish shall be cooled to an internal temperature of 45°F or less within 2 hours after packing. Further cooling to a temperature not exceeding 40°F is recommended.
 - 4.4.14.3.2 Shellfish which will not be packed within 1 hour after delivery to the packing room shall be cooled to an internal temperature of 45°F or less within 2 hours, and in all cases shellfish shall be cooled to an internal temperature of 45°F or less within four hours of commencing processing of said shellfish.
 - 4.4.14.3.3 Flume water shall be maintained at 50°F or less during processing operations.
 - 4.4.14.3.4 A temperature of 0°F or less shall be maintained in the frozen-storage rooms.
 - 4.4.14.4 Packing: The temperature of shellfish shall not exceed 50°F during the repacking process. Frozen shellfish shall not be thawed during repacking. Shucked Shellfish Intended For Repacking: Shucked shellfish that is to be repacked by the receiver shall be received at the repacking plant in approved shipping containers at a temperature of 45°F or less. Frozen shellfish which have thawed shall not be repacked or repackaged.
- 4.4.15 Ice: Ice shall be obtained from a source approved by DNREC, and shall be stored and handled in a sanitary manner.
- 4.4.16 Wet Storage:
 - 4.4.16.1 Shellfish in wet storage shall be protected from contamination.
 - 4.4.16.2 Wet storage is prohibited unless written approval is given each year by DNREC. This approval shall include a sketch, drawn to scale, and attached to or drawn on the reverse side of the certificate, showing the approved location of the wet storage area, float, or the water intake for the wet storage tanks, and shall further show all the potential hazards to which the shellfish may be exposed. The approval statement rendered by DNREC shall describe the measures taken to protect the shellfish from the potential hazards. The written approval for wet storage shall expire concurrently with the expiration of the shellfish permit.
- 4.4.17 Supervision and Personnel: Supervision shall be adequate to ensure that personnel adhere to the parameters listed below, shellfish are handled/maintained in a sanitary manner, and the premises are maintained in a sanitary manner.
 - 4.4.17.1 Unauthorized persons shall be excluded from the shellfish processing plant and related operations.
 - 4.4.17.2 Any person known to be infected with any disease in a communicable form, or to be a carrier of any disease which can be transmitted through the handling of shellfish, shall be excluded from handling shellfish. Any person who has an infected wound or open lesion on any exposed portion of his body shall be excluded from shucking or packing shellfish.
 - 4.4.17.3 Personnel shall not eat or use tobacco when engaged in shellfish processing operations. Employees shall not use tobacco in any form in the rooms in which shellfish are shucked or packed.

- 4.4.17.4 Personnel shall maintain their person and outer garments in a clean condition. Any person who handles shucked shellfish shall wear a clean apron or coat.
- 4.4.17.5 Personnel shall wear clean hair restraints when engaged in shucking or packing shellfish.
- 4.4.17.6 Employees shall wash their hands with soap and water before beginning work, and again after each interruption.
- 4.4.17.7 When manual handling of shucked shellfish becomes necessary personnel shall wear sanitized rubber gloves, or shall wash and disinfect their hands immediately prior to such manual handling. Rubber gloves shall be sanitized as often as necessary, and at least twice daily.
- 4.5 Depuration of Shellfish: This Section is specific to depuration, and applies to depuration-processors in addition to other applicable portions of Sections III and IV of these Regulations.
 - 4.5.1 General Requirements: On a case-by-case basis, DNREC shall require any and all means deemed necessary to ensure that shellfish required to be depurated are subjected to the depuration process approved by DNREC for each depuration-processor.
 - 4.5.2 Process Specifications:
 - 4.5.2.1 In addition to routine permitting and certification procedures, depuration process specifications and physical plant specifications shall be approved by DNREC in cooperation with the depuration processor prior to commencing operations. The depuration process specifications shall substantiate that the depuration process will reduce bacteria and viruses to acceptable levels. Sampling protocols and indicator bacteria standards are located in Appendices 5 and 6.
 - 4.5.2.2 Depuration process lots shall consist of shellfish from the same shellfish growing area or bed. A single process lot may consist of more than one harvest lot only if each harvest lot originates from the same shellfish growing area or bed.
 - 4.5.2.3 Shellfish from different process batches shall be packaged separately.
 - 4.5.2.4 Different shellfish species shall not be processed in the same depuration unit unless studies demonstrate that the species are compatible, and that each species is effectively depurated.
 - 4.5.2.5 Shellfish process lots shall not be commingled during washing, culling, depuration, packing, or any other part of the processing operation. Shellfish harvest lots placed in the same depuration unit, and subsequently shipped all at once or in several batches, shall be considered a single process batch. If more than one harvest lot of shellfish are being processed at the same time the identity of each harvest lot shall be maintained throughout the depuration process.
 - 4.5.2.6 Shellfish shall be depurated for at least 48 hours. Longer depuration times may be required by DNREC.
 - 4.5.2.7 The maximum depth of shellfish in depuration vessels shall be 3 inches for hard clams and oysters, and 8 inches for soft clams.
 - 4.5.2.8 Shellfish shall be washed and culled after depuration, and packaged in clean shipping containers fabricated from safe materials.
 - 4.5.2.9 Processing vessels shall be cleaned, sanitized, and rinsed free of the sanitizer before a process lot is processed.
 - 4.5.2.10 Depurated shellfish shall not be repackaged after leaving the depuration plant.
 - 4.5.3 Process Water Specifications: The process water shall meet the following physical, chemical and microbiological parameters:
 - 4.5.3.1 A minimum Dissolved Oxygen concentration of 50% of saturation;
 - 4.5.3.2 No detectable coliform organisms as measured by the standard five-tube MPN for drinking water, or a test of equivalent sensitivity in the tank influent;
 - 4.5.3.3 A salinity within 20% (+ or -) of the harvest area;
 - 4.5.3.4 A minimum temperature of 50°F for oysters and hard clams and 35°F for soft clams and a maximum temperature of 68°F for hard and soft clams; and
 - 4.5.3.5 A minimum flow rate of process water in each depuration unit shall be one gallon per minute for bushel of shellfish. The minimum volume of process water in depuration tanks shall be eight cubic feet of water per bushel of shellfish.
 - 4.5.4 Materials Specifications:
 - 4.5.4.1 Process tanks shall be fabricated from non-toxic, corrosion-resistant, easily-cleanable material. All equipment is to be constructed to be easily cleanable. Shellfish depuration vessels shall be constructed to allow water flow to all shellfish located therein.
 - 4.5.4.2 Separate holding and storage areas shall be provided for depurated and non-depurated shellfish.

4.5.5 Records: In addition to other records required, a record of bacteriological data and other quality assurance related information shall be established and kept for a minimum of two years for each depuration cycle or run. The following shall be maintained for each depuration processor:

- 4.5.5.1 Depuration process specifications for each depuration processor;
- 4.5.5.2 The sanitary survey reports and data for the harvest areas;
- 4.5.5.3 The pre-certification process verification data and reports that are used to establish the operational specifications;
 - 4.5.5.3.1 The periodic analysis of the process data;
 - 4.5.5.3.2 Sanitary inspection reports for the facility;
 - 4.5.5.3.3 An adequate sampling scheme; and
 - 4.5.5.3.4 An evaluation report verifying that the operators records have been reviewed and the process has been evaluated.

4.6 Relaying of Shellfish: This Section is specific to shellfish relaying, and applies to depuration-processors in addition to all portions of Sections III and IV of these Regulations.

4.6.1 Relay Specifications:

- 4.6.1.1 In addition to routine permitting and certification procedures, relay specifications shall be approved by DNREC in cooperation with the relay operator prior to commencing the relay operation. The relay specifications shall substantiate that relaying will reduce bacteria and viruses to acceptable levels.
- 4.6.1.2 Relayed shellfish shall be identified by relay lot. Each relay lot shall be kept separate from other lots to prevent cross-contamination and commingling.
- 4.6.1.3 Shellfish relayed by container shall be washed reasonably free of bottom sediments and detritus, culled, and placed in clean containers made of approved/non-corrosive materials which allow free flow of water to the shellfish. The depth and configuration of shellfish in containers shall allow the shellfish to pump (feed) normally.

4.6.2 Relay Water Specifications: Shellfish shall be held in Approved shellfish growing areas for a sufficient period of time under suitable environmental conditions to assure purification. The bacteriological quality of the shellfish after relaying shall be of the same quality as the same species already in the area in which they were placed. The time required for purification will normally be determined by water temperature, salinity, initial quality, and species of shellfish. This period shall be at least 14 consecutive days when environmental conditions are suitable for purification unless shorter periods are demonstrated to be adequate. Aside from standard shellfish harvest standards, relay area water must meet the following criteria:

- 4.6.2.1 A salinity within 20% (+ or -) of the harvest area; and
- 4.6.2.2 A minimum temperature of 50°F for oysters and hard clams and 35°F for soft clams.

4.6.3 Records: Written operating procedures containing the following shall be maintained by DNREC in cooperation with the relay operator prior to commencing relaying operations, and shall be followed during relaying operations:

- 4.6.3.1 The source and species of shellfish to be harvested;
- 4.6.3.2 The quality of shellfish and/or water quality prior to harvest;
- 4.6.3.3 The quality of shellfish indigenous to the relay area;
- 4.6.3.4 The quality of relayed shellfish after purification;
- 4.6.3.5 The time period during the year the relaying may be conducted;
- 4.6.3.6 The issuance of special harvesting permits to licensed harvester in accordance with Section 4.6;
- 4.6.3.7 The method of transportation to the relay site and the deposition method for the shellfish;
- 4.6.3.8 The method of maintaining adequate separation between lots of relayed shellfish; and
- 4.6.3.9 All specifications relating to container/cage materials and seals if container/cage relaying.

For further information regarding classification of Delaware's shellfish growing areas, please call (302) 739-9939.

This list of ***Prohibited*** shellfish growing areas is recorded at the Delaware Department of Natural Resources and Environmental Control on December 20, 1995. Shellfish harvesting is prohibited in the following areas for any reason at any time:

Delaware River / Bay:

1. The Delaware River north of a line drawn in an east-west direction running concurrently with the New Castle County / Kent County Line from the Western Shore of the Delaware River on the Delaware side of the River east to the New Jersey State Line.
2. Duck Creek, Leipsic River and Simons River and all their tributaries and a contiguous area in the Delaware Bay adjacent to the mouths of these Rivers. This area is identified by the use of signs on the shoreline, and latitudes and longitudes recorded in the *Delaware Fishing Guide*, and/or other maps available to the public.
3. Little Creek and its tributaries and a contiguous area in the Delaware Bay adjacent to the mouth. This area is identified by the use of signs on the shoreline, and latitudes and longitudes recorded in the *Delaware Fishing Guide*, and/or other maps available to the public.
4. St. Jones River and Murderkill River, including their tributaries and a contiguous area in the Delaware Bay adjacent to the mouths of these Rivers. This area is identified by the use of signs on the shoreline, and latitudes and longitudes recorded in the *Delaware Fishing Guide*, and/or other maps available to the public.
5. Mispillion River, Cedar Creek and Slaughter Creek, including their tributaries and a contiguous area in the Delaware Bay adjacent to the mouths of these Rivers. This area is identified by the use of signs on the shoreline, and latitudes and longitudes recorded in the *Delaware Fishing Guide*, and/or other maps available to the public.
6. Broadkill River including its tributaries. This area is marked by signs.
7. An area of Breakwater Harbor and Delaware Bay encompassed within a line running from the northern boundary of Beachplumb Island state-owned lands, in a northeasterly direction for 5000 feet, thence in a southeasterly direction to the west end of the inshore breakwater off of Lewes Beach and running on the inside of this breakwater to a point intersecting a line drawn from the Cape Henlopen Fishing Pier to the breakwater then running along said line to the fishing pier and down the center line of the fishing pier to the beach. This area is identified by the use of signs on the shoreline, and latitudes and longitudes recorded in the *Delaware Fishing Guide*, and/or other maps available to the public.

Rehoboth Bay and Indian River Bay:

8. Lewes-Rehoboth Canal. This area is marked by signs.
9. Rehoboth Bay north of a line drawn in a northeasterly direction between the tip of White Oak Point to the tip of Bald Eagle Point, thence in a southeasterly direction to a point identified as being directly west of the south submarine observation tower at Delaware Seashore State Park and south of the Lewes and Rehoboth Canal mouth, thence in a northeasterly direction to the tip of Thompson Island, thence in an easterly direction to the southern most point of the Rehoboth Bay Marina. This area is marked by signs and buoys.
10. The areas north of a line drawn from the tip of White Oak Point in a southeasterly direction to a point identified as being directly west of the south submarine observation tower at Delaware Seashore State Park and south of the Lewes and Rehoboth Canal mouth, thence in an easterly direction to the south submarine observation tower. This area is marked by signs and buoys.
11. Indian River Inlet and Cedar Islands. The western boundary line begins at Burton's Island, running south to a point west of the marsh which lies south of an unnamed gut south of the South Inlet Marina, thence in an easterly direction to said marsh. The eastern boundary begins one-half mile south of the Inlet running east into the Atlantic Ocean for one-half mile, thence in a northerly direction for one mile, thence in a westerly direction for one-half mile to the beach. The northern boundary (in the vicinity of Cedar Islands in Rehoboth Bay) begins at an unnamed island north of Savages Ditch running in a southeasterly direction to Burton Island. The area is marked by signs and buoys.
12. White Creek and its tributaries extending south of a line drawn in an east-west direction from the East Shore of White Creek to a point on Big Marsh on the West Shore. This area is marked by signs.
13. Indian River-proper and its tributaries and an area adjacent to Indian River-proper bounded by a line 650 feet in length in a north-south direction beginning at the eastern bank of the mouth of Emily Gut thence running from the southern terminus of said line in a westerly direction to Highgrass Point. Vines Creek and Pepper Creek-proper and their tributaries beginning at a point south of Rock Point and running in an easterly direction to Grays Point.
14. Herring Creek and its tributaries extending northwest from a line running from Burton Point in a southerly direction to Long Neck. This area is marked by signs.

15. The southwest corner of Beach Cove. This area is marked by signs.
16. The southeast corner of Beach Cove. This area is marked by signs.
17. The northeast corner of Beach Cove. This area is marked by signs
18. Love Creek - The portion of Love Creek lying in a northwesterly direction from the line formed by a point marked on shore at the southern confluence of Love Creek and Arnell Creek, thence in a southwesterly direction to a point in the marsh identified as being directly south of Boathouse Lane. This area is marked by signs.

17 DE Reg. 650 (12/01/13)

20 DE Reg. 183 (09/01/16)

Little Assawoman Bay:

19. Assawoman Canal. The Canal-proper is not marked. However, the adjacent waters in White Creek in Indian River Bay and Little Assawoman Bay are marked by signs.
20. Miller Creek and its tributaries and the northern reaches of Little Assawoman Bay north of a line running in an east-west direction from Goose Point on the southern bank of Miller Creek at its mouth to an unnamed point on Fenwick Island State Park. This area is marked by signs.
21. Dirickson Creek west of a line running from Bennett Point in a southwesterly direction to Conch Point. This area is marked by signs.
22. Tubbs Cove south of a line running in an east-west direction from the shoreline north of Treasure Beach Campground to Point Of Ridge. This area is marked by signs.
23. The waters adjacent to the Town of Fenwick Island south of a line running from Old Inlet Point in a north-north-easterly direction to an unnamed point on the barrier. This area is marked by signs.

17 DE Reg. 650 (12/01/13)

20 DE Reg. 183 (09/01/16)

Assawoman Bay:

24. That portion of an unnamed bay north of the Delaware / Maryland line adjacent to the Cape Windsor Development. This area is marked by signs.
25. Roy Creek and its tributaries north-west of a line running from an unnamed point on Greys Neck north-east across several unnamed islands to a point south of Route 54. This area is marked by signs.

17 DE Reg. 650 (12/01/13)

20 DE Reg. 183 (09/01/16)

Nanticoke River:

26. Nanticoke River and all its tributaries. This area is marked by signs.

17 DE Reg. 650 (12/01/13)

20 DE Reg. 183 (09/01/16)

Atlantic Ocean:

27. ~~The Atlantic Ocean adjacent to Indian River Inlet encompassed within a line beginning one-half mile south of the Inlet running east into the Atlantic Ocean for one-half mile, thence in a northerly direction for one mile, thence in a westerly direction for one-half mile to the beach, from the northern most point at Cape Henlopen to the Delaware/Maryland State line and due east 3 nautical miles in the State of Delaware's jurisdictional waters. This area is identified by the use of signs on the shoreline, and latitudes and longitudes recorded in the Delaware Fishing Guide, and/or other maps available to the public.~~
28. ~~The Atlantic Ocean within a radius of one-half mile from the South Coastal Sewage Treatment Plant outfall which is located at north latitude 38°31'34" west longitude 75°01'56".~~

17 DE Reg. 650 (12/01/13)

20 DE Reg. 183 (09/01/16)

Applies To All Areas:

- ~~29~~28. All artificial lagoons. Most of these areas are unmarked.
- ~~30~~29. All wet slip basins. Most of these areas are unmarked.
30. Seagrass beds (*Zostera marina* and *Ruppia maritima*)

17 DE Reg. 650 (12/01/13)

APPENDIX 2

This list of **Approved** shellfish growing areas is recorded at the Delaware Department of Natural Resources and Environmental Control into the public record on December 20, 1995. Shellfish harvesting is allowed in the following areas with no seasonal restriction:

1. Delaware River/Bay south of a line drawn in an east-west direction running concurrently with the New Castle County / Kent County Line from the Western Shore of the Delaware River on the Delaware side of the River east to the New Jersey State Line, except the Prohibited areas listed in Appendix 1.
2. Rehoboth Bay with the exception of those areas listed in Appendices 1 and 3.
3. Indian River Bay with the exception of those areas listed in Appendices 1 and 3.
4. Little Assawoman Bay with the exception of those areas listed in Appendix 1.
5. Assawoman Bay with the exception of those areas listed in Appendix 1.
6. ~~The Atlantic Ocean with the exception of those areas listed in Appendix 1.~~

NOTE: Please consult Delaware Fish and Game Laws for size and creel limits prior to harvesting shellfish. For further information regarding classification of Delaware's shellfish growing areas, please call (302) 739-9939.

APPENDIX 3

This list of **Seasonally Approved** shellfish growing areas is recorded at the Delaware Department of Natural Resources and Environmental Control into the public record on December 20, 1995. Shellfish harvesting is allowed in the following areas in accordance with Delaware's fish and game laws from December 1 through April 15:

Rehoboth Bay:

1. The area adjacent to West Bay Trailer Park Marina from a point north of the Marina in a southeasterly direction to a point directly north of the eastern-most point of Sally Cove Marsh and directly east of the middle Marina lagoon, thence in a southwesterly direction to a point south of the Marina. This area is marked by signs and buoys.
2. The area adjacent to the mouth of Herring Creek west of a line running from Burton Point on Angola Neck in a southeasterly direction to Nats Cove Point. This area is marked by signs and buoys.
3. Massey's Ditch and Roman T. Pond south of a line running from Bluff Point in a southeasterly direction to an unnamed point on the north bank of the unnamed island east of Massey's Ditch. This area is marked by signs.

17 DE Reg. 650 (12/01/13)

20 DE Reg. 183 (09/01/16)

Indian River Bay:

4. The area landward of a line running from a point on the south bank of the unnamed island east of Massey's Ditch in a southerly direction to Middle Island, thence in a westerly direction to a point on the Townsend Property east of Emily Gut (the same point marking the beginning of the Prohibited area boundary line). This area is marked by signs and buoys.
5. The area south of an east-west line running from Pasture Point, to Walter Point. This area is marked by signs and buoys.

NOTE: Please consult Delaware Fish and Game Laws for size and creel limits prior to harvesting shellfish.

17 DE Reg. 650 (12/01/13)

20 DE Reg. 183 (09/01/16)

APPENDIX 4

Other-Than-Approved Shellfish Water Bacteriological Standards For Depurated Shellfish

The total coliform mean MPN of the water does not exceed 700 per 100 ml and not more than 10% of the samples exceed an MPN of 2,300 per 100 ml for a 5-tube decimal dilution test (or an MPN of 3,300 per 100 ml for a 3-tube decimal dilution test).

AND/OR

The fecal coliform mean MPN of the water does not exceed 88 per 100 ml and not more than 10% of the samples exceed an MPN of 260 per 100 ml for a 5-tube decimal dilution test (or an MPN of 300 per 100 ml for a 3-tube decimal dilution test).

APPENDIX 5

Depuration Plant Minimum Sampling Schedule

Number of Harvest Areas	Pollution Variability	Incoming Shellfish	Final Product
Single	Low Area	Periodic Single Samples	Single Samples Each Process Lot
Single Area	High	One Sample from Each Harvest Lot	Duplicate Samples Each Harvest Lot in Each Process Batch
Multiple Area	Variable	Periodic Single, Sample Each Area	At Least One Duplicate Sample From Each Harvest Each Week Each Process Batch. Single Samples of Each Batch, Other Times, Same Week

Samples of unprocessed shellfish and partially processed shellfish may be taken midway through the depuration cycle and analyzed for the end-point indicator. Such sample results may be used to predict whether the shellfish are acceptable for release. This approach can be used if an appropriate statistical analysis, performed or approved by DNREC, of the samples collected during the process verification study and other historical sample results demonstrates that this is a viable means of determining that the shellfish have been adequately depurated. Each process batch may be released for market only if the end-point fecal coliform criteria indicated in Appendix 6 are met at 24 or 48 hours.

APPENDIX 6

End-product Standards For Overall Depuration Plant Performance Evaluation

Fecal coliforms per 100 grams

Species	Geometric Mean	Upper 10%
Soft Clam	50	130
Hard Clam	20	70
Surf clam	20	70
Oyster	20	70

End-product Standards For Each Process Batch Of Shellfish

Fecal Coliforms per 100 grams

No. of Samples	Shellfish Species	Geometric Mean Not to Exceed	One Sample May Exceed	No Sample To Exceed
1	S.C.	-	-	170
	O., H.C	-	-	100
2	S.C	125	-	170
	O., H.C.	75	-	100
3	S.C.	110	-	170
	O., H.C.	45	-	100
5	S.C.	50	100	170
	O., H.C.	20	45	100
10	S.C.	50	130	170
	O., H.C.	20	70	100

S.C. = Soft Clam; O. = Oyster; H.C. = Hard Clam

APPENDIX 7

Shellfish Meat Bacteriological Standards

Shellfish Categories II & III Satisfactory Shipping Conditions

Analyze two (2) random samples of shellstock or shucked product for F.C. and A.P.C.

Satisfactory NAI*	Unsatisfactory F.C. (If one or both samples exceed an MPN of 230) Analyze for E. coli (APHA method).	Unsatisfactory A.P.C. If one or both samples exceed a count of 500,000/g) Notify shipper State.
* no action indicated	Satisfactory	Unsatisfactory
**state shellfish regulatory agency	NAI*	(If one or both samples exceed an MPN of 230)

1. Notify dealer, shipper, and shipper state
2. Receiving dealer must notify the SSRA**
of next shipment from same shipper
3. SSRA samples next shipment

Second shipment from same shipper
Determine conditions of shipment

Satisfactory (Analyze five (5) random shellstock and A.P.C.)	Unsatisfactory (Go to PAGE APA-7 for shucked samples for F.C. further guidance)
Satisfactory	Unsatisfactory F.C.
	Unsatisfactory A.P.C.

NAI*	(If any sample exceeds an MPN of 330 or 2 or more out of 5 exceed 230 but are less than or equal to an MPN of 330)	(If any sample exceeds 1,5000,000/g or 3 or more out of 5 exceed 500,000g but are less than or equal to 1,5000,000/g)
	Analyze for E. coli	Shipper state should be notified for investigative and corrective action

Satisfactory	Unsatisfactory
NAI*	(If any sample exceeds an MPN of 330 or 2 or more out of 5 exceed 230 but are less than or equal to 330)

APPENDIX 8

Emergency Closure of Shellfish Growing Areas Notification/Closure/Rescinding of Closure Agenda

Emergency shellfish harvest closure or the rescinding of emergency closure of shellfish growing areas shall be rendered by DNREC, must by law be issued by the Secretary of DNREC, and should entail consultation with the Division of Water Resources Shellfish and Recreational Water Branch Manager, the Division of Air and Waste Management, the Division of Fish and Wildlife, the Division of Parks and Recreation.

APPENDIX 9

Shellfish Process Water Contact Specifications

Shellfish shall not be in contact with fresh or salt water (during processing) after leaving the shucker, including the time of washing, rinsing, and any other contact with fresh or salt water, for more than 30 minutes; unless such shellfish are labeled as to identify water as an ingredient.

APPENDIX 10

Shellfish Harvester and Shipper Tag Specifications

Harvester Tag Specifications

Tags must be at least 2 5/8" by 5 1/4" and made of durable stock, and must carry the following information in indelible lettering / numbering:

- i. Harvester;
- ii. Harvester's name and license number;
- iii. the shellfish dealer/processor to which the shellstock are conveyed;
- iv. the amount of shellstock conveyed;
- v. the species or common name of the shellstock;
- vi. the date of harvest and;
- vii. the shellfish growing area (example: Rehoboth / Indian River Bay, or Delaware Bay), also including DE (State abbreviation).

Shellfish Shipper Tag Specifications

Tags must be at least 2 5/8" by 5 1/4" and made of durable stock, and must carry the following information in indelible lettering/numbering:

- i. Name, address and Certification Number of the Shellfish Dealer/Processor;
- ii. date of harvest;
- iii. depuration cycle number and/or relay lot number, if any;
- iv. The identity of the harvest area, including DE State abbreviation, and harvest area name and/or bed number;
- v. Type and quantity of shellfish; and
- vi. The following statement in bold capitalized type: "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR ONE YEAR."

APPENDIX 11

Policy To Determine Shellfish Growing Area Classification in and Around Wet Slip Basins and Artificial Lagoons

I. Introduction:

In 1988 the ISSC determined that human sewage may be discharged from boats and thereby may pose a human health threat due to consumption of sewage contaminated shellfish. The fecal discharge from one adult person is potentially the pathogenic equivalent to that from hundreds to thousands of people via a sewage treatment plant, depending upon the level of treatment. In 1988 the ISSC adopted the FDA Guideline, "Evaluation of Marinas By State Shellfish Sanitation Control Officials," to be used by the states as a basis for developing and implementing regulations establishing shellfish harvest buffers around wet slip basins associated with marinas and dry stack facilities. This is now NSSP doctrine.

The sewage discharge from boats is unpredictable and not uniformly distributed throughout the water column. Detection of human pathogen indicator bacteria by current methods may not provide sufficient information to properly classify the waters in and around wet slip basins. Therefore, the FDA Guideline requires restrictions on shellfish harvesting in and around wet slip basins based on the theoretical sewage discharge from the basins without regard to levels observed by monitoring.

In addition, precedent exists for the restriction of shellfish harvesting in artificial lagoons based on the poor water quality and/or the concentration of potential pollution sources often found in such lagoons.

Delaware's "Policy to Determine Shellfish Growing Area Classification In and Around Wet Slip Basins and Artificial Lagoons" is based on the FDA Guideline and the precedents established regarding artificial lagoons.

II. Definitions:

- A. **Artificial Lagoon:** A man-made, dead-end waterway, interconnected with another waterway.
- B. **Average Depth:** The average depth of the water at mean low water in a proscribed area.
- C. **Average Number of People Per Boat:** The average number of people occupying each boat during the daily use of the boats in a specific survey area.
- D. **Background:** The ambient biological, chemical and/or physical conditions of a water body.
- E. **Best Management Practices (BMPs):** Initiatives that in theory reduce the theoretical waste discharge of a wet slip basin.
- F. **Charter Boat:** A commercial boat hired to perform services for patrons, typically for a flat fee.
- G. **Commercial Boat:** A boat used primarily as a means of making money.
- H. **Dilution Formula:** The following formula used to calculate the area impacted by wet slip

$$\frac{\text{TWDR} \times 2 \times 10^9 \text{ FC} \times \# \text{ of people/boat} \times \text{wet slip capacity}}{\text{shellfish harvest standard} \times \text{average depth}}$$

- I. **Dilution Formula Loading Factor (Loading Factor):** The following components of the dilution formula are loading factors, as follows:

Theoretical Waste Discharge Rate (TWDR).

Two Billion (2 e9) Fecal Coliform Bacteria (FC) per person per day (this is a constant).

Average number of people per boat.

Wet slip capacity.

- J. **Discharge:** Any actual or theoretical release of fecal material, pathogenic microorganisms, poisonous and deleterious substances. This includes the escape, disposal, spillage, leaking, pumping, emitting, pouring, dumping or emptying of such discharges.
- K. **Dry Stack Facility:** A boating facility which stores boats on dry land, including but not limited to: dry stack facilities; boatels; valet storage; pigeon hole storage; and stackominiums. A dry stack facility may have wet slip capacity.
- L. **Dump Station:** A mechanical and/or gravity fed connection to an approved sewage disposal facility used for the purpose of the disposal of human generated waste, such as the sewage from a porta-pottie.
- M. **Head Boat:** A commercial boat hired to perform services for patrons, typically for a fee per patron.
- N. **Marina:** Any water area with a structure (dock, basin, floating dock, etc.) which is utilized for docking or otherwise mooring vessels and is constructed to provide temporary or permanent docking space for more than ten boats. The definition of marina shall include all related ancillary structures and functions such as docks, piers, boat storage areas, boat ramps, anchorages, breakwaters, channels, moorings, basins, boat repair services, boat sales, sales of supplies normally associated with boating such as fuel, bait, and tackle, boat rentals, and parking areas.
- O. **Marine Head:** A toilet or other human waste catchment device with retention and/or discharge capability. A marine head may or may not be an MSD. MSD is the term for a Coast Guard approved marine head.
 - 1. **Type I MSD:** A device that produces an effluent having a fecal coliform bacteria count not greater than 1,000 per 100 milliliters and no visible floating solids.
 - 2. **Type II MSD:** A device that produces an effluent having a fecal coliform bacteria count not greater than 200 per 100 milliliters and suspended solids not greater than 150 milligrams per liter.
NOTE: A marine head and holding tank capable of being discharged into receiving waters and into a pumpout unit is defined here as a Type II MSD.
 - 3. **Type III MSD:** A device designed for containment of sewage within a holding tank with the capability to discharge only into a pumpout unit (Type III Coast Guard definition without a Y-valve).
 - 4. **Porta-potty:** A portable, self contained sewage retention device that must be removed from the boat and dumped.
- P. **Occupancy Rate:** The percentage of boats in a wet slip basin that are occupied during the course of a day relative to the total number of occupied slips in the wet slip basin at the time of the collection of this information.
- Q. **Overnight Use Boat:** Any boat used for overnight habitation.
- R. **Potential Sewage Discharge Rate:** The percentage of boats in a wet slip basin with marine heads capable of discharging sewage directly into receiving waters (This excludes only Type III MSDs, as Type III MSD is defined in this policy) relative to the total number of boats surveyed in the wet slip basin at the time of the collection of this information.
- S. **Pumpout Facility:** A mechanical device which is temporarily connected to a boat for the purpose of removing sewage from a marine head holding tank to an approved sewage disposal facility.
- T. **Sewage:** Human body wastes and wastes from toilets and other receptacles intended to receive and/or retain human body wastes.
- U. **Shellfish Growing Area Standard:** The median or geometric mean of Fourteen Fecal Coliform Bacteria (FC) per 100 milliliters (ml) (or the equivalent: 3962 FC/cubic foot) of water must be maintained in shellfish growing water in order to harvest and market shellfish from that water.
- V. **Theoretical Waste Discharge:** **Theoretical waste discharge rate** multiplied by **two billion Fecal Coliform bacteria per person per day** multiplied by the **average number of people per boat** multiplied by the **wet slip capacity**.
 (TWDR x 2 e9 FC x # of people/boat x wet slip capacity)
- W. **Theoretical Waste Discharge Rate (TWDR):** The **potential sewage discharge rate** multiplied by the **occupancy rate**.
- X. **Wet Slip:** A place in the water where a boat may be docked or otherwise moored to a fixed or floating structure, including but not limited to a dock, pier, mooring or anchorage.
- Y. **Wet Slip Basin:** A natural waterway and/or artificial lagoon and/or portions thereof containing more than ten wet slips. A wet slip basin may be associated with a marina and/or with a dry stack facility.*
 *An exception shall be made to the >10 boat qualifier if the theoretical waste discharge and/or the potential for waste discharge in the basin is determined by the DNREC to be great enough to require restrictions on shellfish harvesting in or adjacent to and in the basin.

Z. **Wet Slip Basin Classification:** A determination as to the type of wet slip basin. Differentiation as to wet slip basin type based on the parameters listed reflects variation in the theoretical waste discharge. The types of wet slip basins are as follows:

1. **Commercial Wet Slip Basin:** A wet slip basin which has a significant number of commercial boats.
2. **Overnight Use Wet Slip Basin:** A wet slip basin which has a significant number of overnight use boats.
3. **Residential Wet Slip Basin:** A wet slip basin which has primarily non-commercial boats, most of which are less than or equal to 28' and which serves a planned residential community and/or any general residential population(s).

AA. **Wet Slip Basin Classification Survey:** The collection of the verified information required for classification of a wet slip basin.

AB. **Wet Slip Capacity:** The total number of wet slips in a wet slip basin.

AC. **Work Boat:** A boat used primarily for commercial purposes such as the harvesting of marine life for profit, dredging or police work, etc.

III. Policy Specifications:

A. General Policy Specifications:

This policy defines the restrictions on shellfish harvesting in and around wet slip basins associated with marinas and dry stack facilities and also in artificial lagoons.

1. **Artificial Lagoons:** All artificial lagoons, regardless of intended or actual use, shall be classified as "Prohibited" for the harvesting of shellfish.
2. **Wet Slip Basins and Adjacent Areas:**

All wet slip basins located in or adjacent to shellfish growing areas shall be classified as Prohibited for the harvesting of shellfish. DNREC shall classify shellfish growing areas or portions thereof adjacent to wet slip basins as other-than-Approved as determined on a volumetric basis. The size of the shellfish growing area(s), or portions thereof classified on the basis of the presence of wet slip basins, shall correspond to the volume of water required for dilution of the theoretical waste discharge from the wet slip basins as determined by the application of dilution formula loading factors. The area required for dilution shall be determined by performing the dilution formula calculations. Dilution formula loading factors shall be collected during sanitary surveys and/or wet slip basin classification surveys. The size and configuration of the shellfish growing area(s), or portions thereof classified based on the theoretical waste discharge from wet slip basins, shall be reevaluated and if necessary adjusted on a regular basis using the best available information. When reliable mean low water depths are not available actual field measurements shall be taken as a basis for determining available dilution volume. DNREC shall determine cumulative wet slip capacity of individual wet slip basins and/or the sum of more than one wet slip basin irrespective of demarcations that may arbitrarily and/or artificially reduce, eliminate or otherwise alter the theoretical waste discharge(s) of the wet slip basin(s). Therefore, DNREC will establish wet slip basin demarcations based on, but not limited to:

- common ownership and/or management and/or operation;
- sharing common waterways such as an entrance channel; and
- being part of a common development plan.

B. Surveys:

1. **Sanitary Surveys:** A sanitary survey shall be considered valid by definition only if conducted during a time that is reflective of peak use of the facility such as warm season holidays and weekends when the weather is conducive to boating.
2. **Wet Slip Basin Classification Surveys:**

A wet slip basin classification survey may be performed based on written information and/ or by direct observation of the facility. This allows the classification of both proposed and existing wet slip basins. The minimum information required to constitute a valid wet slip basin classification survey of an existing or proposed marina and/or dry stack facility shall be as listed below.

- facility name;
- owner or applicant name, address and phone number;
- specific facility location narrative and drawing showing the location, dimensions and configuration of the facility;
- average depths and areas of the wet slip basin and entry and/or flushing channels;
- a breakdown of the size range and numbers of proposed wet slips, (transient and non-transient) and/or dry stack capacity;

size range and types of boats to be accommodated including the presence of commercial boats and/or overnight use boats;
general population served by the facility; for example, residential population of a single community or general residential population or commercial clients, etc;
types of MSDs to be allowed;
best management practices (BMPs) employed, including, but not limited to those listed in section III. D. Best Management Practices;
available hydrographic information; and
any other information that the owner or applicant wishes to submit.

C. Dilution Formula Loading Factors:

1. Loading Factor Application Parameters:

- a. Loading factors shall never be smaller than the minimum loading factors required by the National Shellfish Sanitation Program.
- b. Loading factors shall be considered valid by definition only if they are reflective of peak use of a wet slip basin, such as the use occurring on warm season holidays and weekends when the weather is conducive to boating, as determined by the DNREC.
- c. All loading factors shall be derived from a representative number of boats as determined by DNREC. All loading factors shall be multiplied by the total wet slip capacity of marinas and dry stack facilities.
- d. Loading factors may be derived from a survey of an individual wet slip basin and applied only to that facility surveyed.
- e. Existing loading factors may be applied to other identically classified wet slip basins.
- f. Written information associated with wet slip basin classification surveys may be assessed and applied based on the criteria listed under "Individual Loading Factors."
- g. Loading factors derived from a sanitary survey may override loading factors derived from wet slip basin classification survey.
- h. Any combination of existing loading factors and wet slip basin classification survey generated or sanitary survey generated loading factors may be applied at the discretion of DNREC, and also irrespective of the classification of the wet slip basin; except loading factors shall never be lower than the minimum required loading factors.

2. Existing Loading Factors:

Loading factors derived from a wet slip basin classification survey shall be no smaller than the following:

- a. **Residential Wet Slip Basin Minimum Loading Factors (Inadequate or No BMPs Employed)**
 - i. 2 billion fecal coliform bacteria per person per day
 - ii. 3.3 people per boat
 - iii. 6.5% theoretical waste discharge rate
- b. **Residential Wet Slip Basin Minimum Loading Factors (Adequate BMPs Employed by Marina)**
 - i. 2 billion fecal coliform bacteria per person per day
 - ii. 3.3 people per boat
 - iii. 4% theoretical waste discharge rate
- c. **Minimum Loading Factors for Wet Slip Basins (Only the Wet Slip Capacity is Known)**
 - i. 2 billion fecal coliform bacteria per person per day
 - ii. 2 people per boat
 - iii. 100% theoretical waste discharge rate

3. Loading Factor Specifications:

a. Average Number of People Per Boat:

Within a specific survey area, the average number of people per boat shall be determined by counting the number of people in all boats surveyed, and dividing this number by the number of boats surveyed.

b. Potential Sewage Discharge Rate:

- i. Boats with no marine head are determined not to be a probable source of sewage, and shall therefore be assigned a 0% potential sewage discharge rate. Boats with type III MSD's (as Type III MSD is defined in this policy) under normal conditions do not discharge sewage into receiving waters and shall therefore be assigned a 0% potential sewage discharge rate. Boats with any other type of marine head are capable of discharging sewage into receiving waters and shall be assigned a 100% potential sewage discharge rate.

ii. An overnight use boat is defined as such due to the increased potential for the discharge of sewage associated with spending extended periods of time on the boat. Therefore, overnight use boats shall be assigned a 100% potential sewage discharge rate unless the installation of a Type III MSD (as Type III MSD is defined in this policy) is proven.

iii. It is possible that any boat with a cabin could carry a marine head. As determined by surveys, the loading factors listed below are reflective of the installation rates for marine heads that are capable of discharging into receiving waters. Unless information to the contrary is determined by direct observation; the following shall apply to a specific survey area or areas as potential sewage discharge rates:

6.5% of all boats < 25'; or the percentage of boats < 25' with cabins, relative to the total number of boats < 25' surveyed, whichever number is greater; and

80% of all boats > 25' or the percentage of boats > 25' with cabins, relative to the total number of boats > 25' surveyed, whichever number is greater

c. Occupancy Rate:

Occupancy rates shall be determined by counting the total number of boats in a wet slip basin that are occupied by a person or persons during the course of a day as a percentage of the total number of wet slips which contain boats sometime during a 24 hour period immediately before or after and inclusive of the time period during which the occupancy rate information was gathered. The aforementioned portion of the 24 hour time period before or after the data collection time period shall be during a time period reflective of peak use of the facility.

d. Theoretical Waste Discharge Rate (TWDR):

The TWDR is determined by multiplying the potential sewage discharge rate by the occupancy rate.

D. Best Management Practices (BMPs):

The TWDR may be adjusted (within the parameters listed in this policy) if BMPs are employed and the marina or dry stack facility only contains boats with Type III MSDs (as Type III MSD is defined in this policy). The following are initiatives that will be given consideration as BMPs by DNREC:

the presence, availability and documented use of pumpout facilities and/or dump stations;

the presence and documented and proven use of dye tablets in MSD holding tanks;

the use of written legal agreements prohibiting the discharge of sewage and which provide substantial penalties for the discharge of sewage;

the use of written legal agreements permitting only boats with Type III MSDs or Type II MSDs with holding tanks capable of being discharged into a pumpout unit;

the use of a harbor master or the equivalent to monitor activities in the marina, such as the illicit discharge of sewage from boats;

the keeping of accurate records; and

the adherence to the seasonal time frame (October 15 through March 15) for the adequate removal boats to allow depuration and the seasonal harvest of shellfish.

NOTE: Other means utilized for the purpose of reducing theoretical waste discharge may be given consideration as BMPs on a case by case basis. Not all BMPs listed are required to be employed to allow the default to the smaller loading factors. The smaller loading factors shall be applied on a case by case basis.

E. Specifications for Shellfish Growing Areas Classified on the Basis of Wet Slip Basins:

1. Shellfish Growing Area Size:

a. Shellfish growing areas or portions thereof classified on the basis of the theoretical waste discharge from wet slip basins shall be no smaller than those required based on the required loading factors.

b. Dilution formula loading factors shall be applied assuming hypothetical zero FC background water. Shellfish growing areas or portions thereof impacted on the basis of the theoretical waste discharge from wet slip basins shall correspond to the volume of water required for dilution of the theoretical waste discharge from wet slip basins to the shellfish growing area standard. The volume of water in wet slip basins is available for dilution and therefore shall be included in the required dilution area.

c. Reclassification of the shellfish growing area or portions thereof beyond a wet slip basin shall not be required if the wet slip basin is large enough for adequate dilution of the theoretical waste discharge produced by the wet slip basin.

d. Reclassification of the shellfish growing area or portions thereof adjacent to a wet slip basin will be required if the volume of water in the wet slip basin is inadequate for dilution of the theoretical waste discharge produced by the wet slip basin.

2. Shellfish Growing Area Configuration:

The boundary lines associated with shellfish growing areas or portions thereof impacted on the basis of the theoretical waste discharge from wet slip basins shall be straight lines established between imaginary points and/or fixed landmarks and marked by buoys and/or signs. These straight lines shall encompass at least the area determined to be impacted based on: the volume of water required for the dilution of the theoretical waste discharge from the wet slip basin(s) to the shellfish growing area standard; and the configuration of the area impacted based on available hydrographic data* and/or by superimposing an arc as measured from the marina entrance channel(s) onto a map, encompassing the area required for dilution. The area determined to be impacted by wet slip basins shall be superimposed over existing shellfish growing areas that are not classified on the basis of the theoretical waste discharge from wet slip basins. However, there shall be no overlap of the required wet slip basin dilution areas regardless of the shellfish growing area classification.

*Only hydrographic data approved by the FDA for use in the determination of the theoretical impact of wet slip basins shall be used when shellfish growing areas specifications are determined.

3. Shellfish Growing Area Classification Adjacent to Wet Slip Basins:

a. The classification of the shellfish growing areas or portions thereof impacted on the basis of the theoretical waste discharge from wet slip basins shall always default to the more restrictive, existing classification or a combination of conditions that provide cumulative required restrictions on shellfish harvesting.

b. Shellfish growing areas or portions thereof adjacent to wet slip basins that are determined to be impacted based on the theoretical waste discharge from wet slip basins may be classified as Seasonally Approved, Conditionally Approved, or Prohibited.

i. Seasonally Approved Classification:

A shellfish growing area or portions thereof (excluding the wet slip basin) impacted by the theoretical waste discharge from a wet slip basin may be classified as "Seasonally Approved" for the harvesting of shellfish, thereby allowing the harvesting of shellfish during a proscribed seasonal time period to correspond historically to the seasonal removal (+ a two-week depuration period), and the subsequent seasonal reintroduction of boats into the basin.

A residential wet slip basin may be declared seasonally vacant by DNREC when all but ten or less boats remain in the wet slip basin, and are to remain out of the basin for the time period (including the depuration period) during which the harvest of shellfish is allowed; OR a residential wet slip basin may be declared seasonally vacant by DNREC if enough dilution volume exists in the basin to accommodate the remaining boats in the basin without requiring additional dilution volume outside of the basin to adequately dilute theoretical loading from the basin.

A wet slip basin not classified as "Residential" may be considered seasonally vacant after an adequate number of boats, as determined by DNREC, are removed from the wet slip basin and are to remain out of the marina for the time period (including the depuration period) during which the harvest of shellfish is allowed.

ii. Conditionally Approved Classification:

DNREC may allow the harvest of shellfish on a seasonal basis in areas determined to be impacted by a wet slip basin, as per pre-established condition(s) which may include seasonal removal of boats from the wet slip basin(s).

iii. Prohibited Classification:

A shellfish growing area or portions thereof determined to be impacted by the theoretical waste discharge from a wet slip basin shall be classified as "Prohibited" if it is determined by the DNREC that a public health threat could result by classifying the area as other than Prohibited.

IV. Examples and Specifications:

Project name: Little Chester Trailer Park & Marina
Applicant information: Recreational Aquatic Profit Entity, Inc.
P.O. Box 666, Washington, D.C. 20002

Project location: Ulva Landing, Indian River Bay

Wet slip basin avg. depth: 5'

Number and size of slips: 102 slips, each slip 18' by 30'

Size and types of boats: Recreational power and sail boats boats to be accommodated:
roughly in the 16' to 25' range

General population served: Private, community residents only

Hydrographic information: None available

BMPs to be employed: One stationary pumpout unit;

Written agreement indicating seasonal removal of boats, as per DNREC Specifications:

Examples 1-A. and 1-B.

Seasonally Approved area size determination is as follows:

TWDR x 2 e9 FC x # of people/boat x wet slip capacity shellfish harvest standard average depth

6.5% x 2 e9 FC x 3.3 people/boat x 102 slips

3962 FC/cubic foot of dilution water

5'

= 2,208,884 sq ft = area required for dilution

102 slips @ 18' x 30' each = 55,080 sq ft = area representing volume in marina at 5' average depth available for dilution

2,208,84 sq ft - 55,080 sq ft = 2,153,804 sq ft = area required for dilution beyond the marina basin

1/2 circle radius = * 2,153,804 sq ft x 2

* Pi

= * 4,307,608 sq ft = * 1,371,154.2 = 1170'

* Pi

Example 1-A. The entire impacted area, as determined by superimposition of an arc based on the theoretical waste discharge from the marina, is within a currently classified Prohibited area. Therefore, no change in shellfish growing area classification for the impacted area is required.

Existing	Existing	Existing
Approved	Approved/Prohibited	Prohibited
Area	Boundary	Area

Proposed 2,153,804 sq ft Superimposed

Seasonally Approved area Arc

(area of 1/2 circle)

Proposed Upland

Marina Basin	102 slips	Land
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Example 1-B. The portion of the Approved shellfish growing area, (in this case 1/2 the total area required for dilution) as determined by superimposition of an arc based on theoretical waste discharge from the marina, is reclassified as Seasonally Approved. NOTE: Rather than actually enforcing a curved boundary, the boundary shall be a straight line encompassing the required 1,076,902 sq ft Seasonally Approved area. Curved lines are not enforceable.

Existing	Existing	Existing
Approved	Approved/Prohibited	Prohibited
Area	Boundary	Area
Proposed	1,076,902 sq ft	Superimposed
Seasonally Approved area	Arc	(1/2 area of 1/2 circle)

Proposed Upland

Marina Basin	102 slips	Land
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Example 2: Two 51 slip Residential Marinas, Inadequate BMPs

Existing	Existing	Existing
Prohibited	Approved/Prohibited	Approved
Area	Boundary	Area
Proposed	2,153,804 sq ft	Seasonally Approved area

(1,076,902 sq ft x 2)

(Each marina basin is 27,540 sq ft)

Proposed

51	Marina	51
slips	Basins slips	

NOTE: There is no overlap of dilution areas. The volume of water represented by the shaded area may not be counted for dilution of the theoretical waste discharge from both marinas.

10 DE Reg. 145 (07/01/06)

20 DE Reg. 183 (09/01/16)

22 DE Reg. 450 (12/01/18) (Prop.)