

CHAPTER 13**SHELLFISH****Authority**

N.J.S.A. 24:2-1.

Source and Effective Date

R.2000 d.455, effective October 16, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1c, Chapter 13, Shellfish, expires on April 14, 2006. See: 37 N.J.R. 3767(a).

Chapter Historical Note

Chapter 13, Shellfish, was adopted as R.1974 d.185, effective July 9, 1974. See: 6 N.J.R. 233(b), 6 N.J.R. 310(b).

Subchapter 2, Depuration of Soft-shelled Clams, was adopted as R.1978 d.127, effective May 1, 1978. See: 10 N.J.R. 103(a), 10 N.J.R. 188(d).

Pursuant to Executive Order No. 66(1978), Chapter 13, Shellfish, was readopted as R.1987 d.362, effective September 8, 1987. See: 19 N.J.R. 1143(a), 19 N.J.R. 1642(a).

Subchapter 2, Depuration of Soft-shelled Clams, was repealed and Subchapter 2, Depuration of Hard Shell and Soft Shell Clams, was adopted as new rules by R.1990 d.542, effective November 19, 1990. See: 22 N.J.R. 109(a), 22 N.J.R. 3547(a).

Pursuant to Executive Order No. 66(1978), Chapter 13, Shellfish, was readopted as R.1992 d.384, effective September 8, 1992. See: 24 N.J.R. 2504(a), 24 N.J.R. 3532(a).

Pursuant to Executive Order No. 66(1978), Chapter 13, Shellfish, was readopted as R.1997 d.356, effective August 8, 1997. See: 29 N.J.R. 2608(a), 29 N.J.R. 3855(b).

Pursuant to Executive Order No. 66(1978), Subchapter 2, Depuration of Hard Shell and Soft Shell Clams, was readopted as R.2000 d.455, effective October 16, 2000, and Subchapter 1, Sanitation, Handling, Shipping and Shucking of Shellfish, was repealed and Subchapter 1, Sanitation, Handling, Shipping and Shucking of Shellfish, was adopted as new rules by R.2000 d.455, effective November 6, 2000. See: Source and Effective Date. See, also, section annotations.

CHAPTER TABLE OF CONTENTS**SUBCHAPTER 1. SANITATION, HANDLING, SHIPPING AND SHUCKING OF SHELLFISH**

- 8:13-1.1 Purpose and scope
- 8:13-1.2 Definitions
- 8:13-1.3 Prohibited acts
- 8:13-1.4 Model Ordinance requirements
- 8:13-1.5 Shellfish certificates
- 8:13-1.6 Suspension, revocation or nonrenewal of certification

SUBCHAPTER 2. DEPURATION OF HARD SHELL AND SOFT SHELL CLAMS

- 8:13-2.1 Definitions
- 8:13-2.2 General requirements
- 8:13-2.3 Prohibited acts
- 8:13-2.4 Hard and Soft Shell Clam Depuration Program
- 8:13-2.5 Provisional certificate requirements
- 8:13-2.6 Final certificate requirements
- 8:13-2.7 Certification restrictions, suspensions, and revocations
- 8:13-2.8 Plant location and site specification

- 8:13-2.9 Plant design
- 8:13-2.10 Transportation of clams
- 8:13-2.11 Shellfish storage
- 8:13-2.12 Seawater quality
- 8:13-2.13 Plant depuration equipment
- 8:13-2.14 Clam processing containers
- 8:13-2.15 Water purification system(s)
- 8:13-2.16 Water temperature recording device(s)
- 8:13-2.17 Plant capacity control
- 8:13-2.18 Carryover
- 8:13-2.19 Washing and culling of clams
- 8:13-2.20 Cleaning and sanitizing treatment of equipment
- 8:13-2.21 Bacteriological quality
- 8:13-2.22 Bacteriological sampling
- 8:13-2.23 Recordkeeping
- 8:13-2.24 Harvester allocation tag
- 8:13-2.25 Harvester records
- 8:13-2.26 Shellfish shipping tags
- 8:13-2.27 Depuration plant monitoring/surveillance equipment

SUBCHAPTER 1. SANITATION, HANDLING, SHIPPING AND SHUCKING OF SHELLFISH**8:13-1.1 Purpose and scope**

(a) The purpose of this subchapter is to provide uniform sanitary standards based upon the National Shellfish Sanitation Program Model Ordinance which was developed through a Memorandum of Understanding between the U.S. Food and Drug Administration and the Interstate Shellfish Sanitation Conference. A full text of the current edition of the Model Ordinance incorporated herein by reference is available by contacting the U.S. Food and Drug Administration, Baltimore District Office at 900 Madison Avenue, Baltimore, Maryland 21201. Copies can also be obtained through the Interstate Shellfish Sanitation Conference web page at <http://www.issc.org>.

(b) The scope of this subchapter is to establish the minimum sanitation and recordkeeping requirements for the harvesting, shipping, reshipping of shellstock, and shucking and repacking of raw molluscan shellfish to include clams, oysters, mussels, and whole scallops shipped in both interstate and intrastate commerce.

8:13-1.2 Definitions

In addition to definitions contained in the definition section of the Model Ordinance the following words and terms, when used in this chapter, shall have the following meaning unless the context clearly indicates otherwise.

“DEP” means the New Jersey Department of Environmental Protection.

“Department” means the New Jersey Department of Health and Senior Services.

“FDA” means the U.S. Food and Drug Administration.

“ISSC” means the Interstate Shellfish Sanitation Conference.

“Model Ordinance (M.O.)” means the National Shellfish Sanitation Program’s Model Ordinance published as a Notice of Availability in the Federal Register volume 63 issue/page 38659 through 38660 on July 17, 1998 and contained in the “Guide For The Control Of Molluscan Shellfish” under the purview of the Interstate Shellfish Sanitation Conference and published by the U.S. Department of Health and Human Services; Public Health Services; Food and Drug Administration, 1997 Revision, incorporated herein by reference as amended and supplemented.

“NSSP” means the National Shellfish Sanitation Program.

“Person” means and includes an individual, firm, corporation, association, society, partnership, and their agents or employees.

“Retail” means a retail sale which is defined as any sale to the ultimate consumer or his/her family, or to a person who will not sell the product.

“Wholesale” means any sale to any other person than the ultimate consumer or his or her family.

8:13-1.3 Prohibited acts

(a) No person shall sell, offer for sale or have in his or her possession with intent to sell without a permit from the DEP any shellfish which have been taken from a place classified as “Prohibited” or otherwise closed to harvesting by the DEP pursuant to N.J.A.C. 7:12 (N.J.S.A. 58:24-1) or from a place condemned by authorities having supervision at the point of origin of the shellfish without permission from such authorities and/or the DEP.

(b) No person shall engage in the wholesale handling of shellfish, operate or conduct an establishment for the shucking, repacking or wet storage of shellfish without a certificate issued by the Department, except that shellstock harvested by a harvester in accordance with the provisions of these rules may be transported and sold to a certified dealer.

(c) No person shall receive or accept any shipment of shellfish for shucking, repacking, shipping or sale unless the New Jersey dealer holds a current certificate issued pursuant to N.J.A.C. 8:13-1.5 and holds a current license issued pursuant to N.J.S.A. 24:15-13. Shellfish originating from out-of-State sources shall be received from states or countries that have received the endorsement of the FDA and the dealer shall be listed in the current Interstate Certified Shellfish Shippers List published by the FDA.

(d) No retailer may repack or shuck shellfish without a certificate from the Department unless it is done on order from the consumer.

8:13-1.4 Model Ordinance requirements

Persons engaged in the handling, shucking, repacking, depuration, wet storage, and shipping of shellfish shall comply with the provisions of the Model Ordinance, except Chapter I, Chapter II, Chapter III, Chapter IV, Chapter V, Chapter VI, Chapter VIII @ .01 and .02C, and Chapter XV which are not being adopted and incorporated herein by reference.

8:13-1.5 Shellfish certificates

(a) Any person desiring to engage or continue to engage in the wholesale handling, shipping, shucking, repacking, wet storage, or depurating of shellfish shall make application in writing on forms supplied by the Department, entitled “Application for Certification to Handle Oysters, Clams or Mussels.” Applicants shall provide all identifying information required on the form including name, mailing address, and telephone number of the owner of the business, the location address of the establishment, trade name, name and address of corporate officers, name and county of registered agent if applicable, the type and source of shellfish to be handled, the type of operations to be carried out, and whether shellfish will be sold in interstate commerce.

(b) Upon receipt of such applications and upon approval of the facilities and sanitary condition of the establishment or area, and compliance by the applicant with other provisions of the law and regulations, a certificate shall be issued for such operation by the Department.

(c) All shellfish certificates shall expire on June 30 of each year. A renewal application entitled “Application for Certification to Handle Oysters, Clams or Mussels” shall be completed on forms supplied by the Department with the information required in (a) above and returned to the Department no later than June 30 of the application year. In no case shall a shellfish firm operate without a valid certificate issued by the Department. The certification shall not be transferable with respect to persons or locations. If the certificate operator has ceased operations, the discontinuance of operations statement shall be completed and returned to the Department.

(d) Current certificates shall be kept on file and open to inspection by representatives of the State or local health department.

8:13-1.6 Suspension, revocation or nonrenewal of certification

(a) Upon evidence duly ascertained by the Department or any local board of health that the holder of the certificate has, or is currently, violating any rule, regulation or statute applicable to wholesale shellfish operations, the Department shall, upon hearing and proof of allegation, suspend, revoke or refuse to renew any such certificate. The hearing shall be conducted pursuant to the provisions of the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

(b) When in its determination that the protection of the public health warrants such action, the Department may suspend any certification pending hearing. In no case shall a shellfish facility operate as such while suspended. Upon written request, the certificate holder will be granted an expedited hearing conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and the Uniform Administrative Procedure Rules, N.J.A.C. 1.1.

(c) A certificate to operate a shellfish facility shall not be renewed or restored until the Department determines that all requirements of this subchapter and any other applicable rules and regulations have been satisfied.

SUBCHAPTER 2. DEPURATION OF HARD SHELL AND SOFT SHELL CLAMS

8:13-2.1 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

“Certified depuration plant operator” (DPO) means a person who is responsible for maintaining complete and accurate records of all depuration processes and controls all critical activities of the depuration plant.

“Critical activities” means and includes all the critical parameters for depurating shellfish, including, but not limited to, the allocation of process containers, the procedures for harvesting and landing of shellfish, treatment of process water, HACCP Plan implementation, standard operating procedures for the depuration process, tank and equipment maintenance, process security and surveillance procedures and equipment, sanitation procedures, and required record-keeping.

“Department” means the Department of Health and Senior Services.

“Depuration” or “depurate” means the process of reducing the pathogenic organisms that may be present in shells-tock by using a controlled aquatic environment as the treatment process.

“Depuration plant” means a premises or establishment in which clams obtained from waters officially sanctioned and classified by the Department of Environmental Protection as special restricted or seasonal special restricted are subject to a process of depuration with the proper controls approved by the Department which will render the depurated clams alive, and microbiologically acceptable within the meaning of State rules and regulations.

“Depuration Plant Operations Manual” means a written manual to include all depuration procedures and operations that will be conducted in a depuration plant including identifying individuals responsible for critical control activi-

ties and procedures to be employed by the depuration plan, when operations must be discontinued or when critical control activities are not being met.

“Depuration process” means the procedure and equipment by which shellfish harvested from waters officially sanctioned and classified by the Department of Environmental Protection as Special Restricted or Seasonal Special Restricted are treated at a depuration plant for controlled purification.

“Depuration unit” means a tank or series of tanks supplied by a single process water system.

“DPO” means depuration plant operator.

“Fecal coliform” means that portion of the coliform group which will produce gas from lactose in an EC medium or A-1 multiple tube procedure liquid medium within 24 (+2) hours in a water bath maintained at 112 degrees Fahrenheit (44.5 degrees + 0.2 degrees centigrade).

“Hard shell clams” means the species *Mercenaria mercenaria*.

“Hazard Analysis Critical Control Point (HACCP) Plan” means a plan that meets the criteria as set forth in 21 CFR 123.6.

“Lot” means the number of bushels of clams which have been harvested on a particular day from the same area designated by the Department of Environmental Protection.

“MPN” (most probable number) means a statistical estimate of the number of bacteria per unit volume and is determined from the number of positive results in a series of fermentation tubes.

“Person” means an individual, or a firm, partnership, company, corporation, trustee, association, cooperative, or any public or private entity.

“Process batch” means the number of lots of clams and the identification of each lot used to fill each separate depuration unit. A process batch can be one lot or more but cannot exceed two consecutive days harvest, nor exceed the number of bushels of clams the process tanks are capable of handling.

“Process tank(s)” means the tanks in which the controlled purification process is carried out.

“Process water” means the water in depuration tanks during the time that shellfish are being depurated.

“Sanitize” means an effective bactericidal treatment of clean surfaces of equipment and utensils, to effectively destroy microorganisms, including pathogens.

“Shellfish Resource Recovery Steering Committee” (SRRSC) means designated representatives from the Department of Environmental Protection and the Department of Health and Senior Services who have regulatory responsibilities for resource recovery programs.

"Soft shell clams" means the species *Mya arenaria*.

"Total coliform" means all of the aerobic and facultative anaerobic, gram negative, non spore forming, red shaped bacilli which ferment lactose broth with gas formation within 48 hours at 95 degrees Fahrenheit (35 + 0.5 degrees centigrade).

"Treated clams" means shellfish that have been depurated.

"Turbidity" means particles in water which reduce light transmittance as measured by a nephelometer. Units are usually given as Nephelometric turbidity units or as N.T.U.

"Ultraviolet light ("UV")" means that portion of the light spectrum containing the bactericidal wave lengths centered around 254 nanometers.

"Untreated clams" means shellfish that have not been depurated.

"U.S. Standard Bushel" means United States dry measure of four pecks, or 2150.42 cubic inches.

"Zero hour" ("0 hour") means the time at which a depuration unit becomes full with process water and the last container of the last lot of clams is placed into the tanks for depuration.

Amended by R.2000 d.455, effective November 6, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).
Rewrote the section.

8:13-2.2 General requirements

Any person engaged in the depuration of clams shall conform to the rules governing sanitation, handling, shipping and shucking of shellfish promulgated under this chapter, Title 24 of the Revised Statutes, and 21 CFR 123.

Amended by R.2000 d.455, effective November 6, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).
Inserted a CFR reference.

8:13-2.3 Prohibited acts

No person shall distribute or sell, offer for sale or have in his or her possession with the intent to distribute or sell any clams which have been harvested from special restricted waters and have not been depurated for at least 48 hours and which do not meet the bacteriological standards set forth under N.J.A.C. 8:13-2.21. Clams shall be depurated for a minimum of 48 hours, but not longer than 72 hours. Depuration shall be restricted to clams of the species approved by the Department. Only clams harvested from waters approved for this purpose by the Department of Environmental Protection pursuant to N.J.S.A. 58:24-1 et seq. may be depurated. Clams from other sources may not be stored on the premises of the depuration plant. The **depuration plant shall be used for no purpose other than the depuration of clams.**

8:13-2.4 Hard and Soft Shell Clam Depuration Program

(a) Any person(s) wishing to construct and/or operate a soft or hard shell clam depuration plant shall submit to the SRRSC a detailed proposal providing all pertinent information concerning the proposed plant on applications provided by the SRRSC. A detailed set of construction plans shall accompany the application. All depuration plant proposals shall be forwarded to:

Department of Health and Senior Services
Consumer and Environmental Health Services
Shellfish Project
PO Box 369
Trenton, New Jersey 08625-0369

(b) The SRRSC shall only accept proposals for consideration which demonstrate that they will be in conformance with all local requirements, including zoning, building, and fire codes.

(c) The SRRSC will respond in writing to each proposal after all requested information has been submitted. Each response shall state the reason(s) for acceptance or denial of the proposal.

(d) If an applicant does not initiate construction within six months of its approval, the SRRSC reserves the right to withdraw its approval.

(e) The SRRSC shall have the right to limit the number of plant permits issued, based upon Department of Environmental Protection and Department of Health and Senior Services enforcement capabilities.

Amended by R.2000 d.455, effective November 6, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).
Deleted former (e), recodified former (f) as (e).

8:13-2.5 Provisional certificate requirements

(a) Upon approval by the SRRSC to initiate construction of a depuration plant, the issuance of a provisional shellfish certificate to operate a depuration plant on an interim basis until the final verification studies are completed is contingent upon the following:

1. Submission of a completed shellfish certificate application as required under N.J.A.C. 8:13-1.3 and a food/cosmetic license application with the required statutory fee as required under N.J.S.A. 24:15-13;
2. Approval of construction plans;
3. Approval of the depuration system including the clam processing containers as specified under N.J.A.C. 8:13-2.14;
4. Completion of plant construction;
5. Completion of a preoperational inspection conducted by the Department indicating substantial compliance with all of the provisions of this subchapter;

6. Filing the necessary permit applications required under N.J.A.C. 7:12. The Department must receive verification from DEP that the applicant meets the DEP regulatory provisions;

7. A written HACCP plan and depuration plant operations manual, which includes the scheduled depuration process, shall be submitted for approval to the Department prior to issuance of a provisional depuration plant certification. The depuration plant operations manual shall be updated as changes occur in the depuration plant;

8. The plant capacity shall be filed by the firm and approved by the Department utilizing the criteria specified in N.J.A.C. 8:13-2.13 prior to provisional certification approval by the Department;

9. Each plant must have at least one employee designated a certified depuration plant operator. Applicants for DPO shall take a standard examination administered by the Department which demonstrates a comprehensive knowledge of the principles and procedures of the depuration process and the provisions of the rules at N.J.A.C. 8:13-2. Applicants must obtain a passing score of at least 70 in order to receive certification;

10. A plant verification study shall be conducted by the operator prior to receiving provisional certification. This verification study shall demonstrate to the Department that all critical parameters meet the specifications as set forth in this chapter and are adequate to insure sufficient physiological activity of the shellfish for purification to occur at any point in the tank under maximum loading conditions, and plant verification studies must include at least three consecutive process runs which meet all critical activities as well as the end point bacteriological standards set forth under N.J.A.C. 8:13-2.21 for each process batch.

Amended by R.2000 d.455, effective November 6, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).
Rewrote the section.

8:13-2.6 Final certificate requirements

(a) Considering the extremes of environmental conditions and physiological status of bivalves an acceptable process verification study shall be conducted during periods when extreme conditions are known to occur. Only after this additional process verification study is completed indicating that all critical activities have been met, including meeting the bacteriological standards set forth under N.J.A.C. 8:13-2.21, will final certification be considered by the Department.

(b) Final certification will be issued based upon a record of satisfactory compliance with the HACCP Plan and scheduled depuration process which is incorporated in the Depuration Plant Operations Manual and the requirements of (a) above.

(c) The certificate shall expire on June 30 of each year. Certificate renewal is required each year on forms supplied by the Department.

(d) Shellfish certification and food/cosmetic license are not transferable with respect to changes in location and/or ownership.

Amended by R.2000 d.455, effective November 6, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).
Rewrote (a) and (b).

8:13-2.7 Certification restrictions, suspensions, and revocations

(a) Depuration Plant (DP) certification is limited to the depuration and sale of depurated clams.

(b) The certificate issued by the Department pursuant to these rules may be suspended or revoked for any violation of Title 24 of the Revised Statutes or of any rule or regulation of the Department or when bacteriological data shows that the depuration process is not reducing fecal coliform levels to the standards set forth in these rules. Any violation of a special permit to possess shellfish harvested from special restricted waters issued by the Department of Environmental Protection is grounds for suspension or revocation of the certificate issued by the Department.

(c) The Department, when in its judgement has determined that any of the critical activities of the depuration rules are violated, may, before a hearing, suspend the certification pending the hearing. When the certification has been suspended, the person shall have the right to an expedited hearing. In all other cases, the person shall be afforded the opportunity for a hearing in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and N.J.S.A. 52:14F-1 et seq., and the Uniform Administrative Rules of Practice, N.J.A.C. 1:1, prior to the suspension or revocation of the license. When the special permit issued by the Department of Environmental Protection under N.J.A.C. 7:12-9 is suspended or revoked, the shellfish certificate issued by the Department is no longer valid.

Amended by R.2000 d.455, effective November 6, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).

In (a), substituted "Depuration Plant (DP) certification" for "Certification".

8:13-2.8 Plant location and site specification

The depuration plant shall be located in such an area where seawater of proper quality and sufficient quantity is available for the process. The plant shall be located close enough to the harvest site to minimize travel time, to prevent excessive bacterial multiplication, and to reduce stress in the clams. The plant shall be so located that it will not be subject to flooding by high tides.

8:13-2.9 Plant design

The plant shall be designed in such a manner as to prevent cross-contamination of undepurated and depurated clams and in order that a video surveillance system can effectively monitor all critical activities. Washing and culling facilities, with a convenient supply of potable wash water which meets the requirements of N.J.A.C. 7:10 (Safe Drinking Water Act rules), shall be provided for untreated and treated clams. Three separate dry storage areas meeting the requirements of N.J.A.C. 8:13-2.11 shall be provided for undepurated clams, clams depurated pending laboratory approval, and depurated approved clams. The plant shall be provided with potable running water, electricity, and sewage disposal sufficient to meet all the specifications and carry out all the requirements set forth in these rules.

Amended by R.2000 d.455, effective November 6, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).

Substituted "depurated" for "treated" and "undepurated" for "untreated" throughout.

8:13-2.10 Transportation of clams

(a) The vessel(s) or vehicle(s) used in the transportation of clams shall be kept in a clean and sanitary condition. The clams stored and transported in the vessel(s) shall be protected from undue environmental stress such as freezing in winter and overheating in direct sunlight during the summer months. Clams shall be protected from contamination at all times during harvesting and transportation to the depuration plant.

(b) A waterproof serially numbered harvester-allocation tag approved by the Department shall be issued by the DPO and affixed to each harvest container in the plant as part of the daily harvest allocation, as specified in N.J.A.C. 8:13-2.24. The tags shall be accounted for or used that day only.

(c) Only serially numbered "U.S. Standard" bushel size containers shall be used in the harvesting, transportation, and receiving of hard shell and soft shell clams at the depuration plant unless written approval is given to use an alternate standard type of container. All reasonable measures shall be taken to assure that containers of clams received at the plant are filled to a level not to exceed one U.S. standard bushel.

(d) During the unloading procedures from the harvesting vessels at the designated times and locations, the containers of clams shall not be covered and shall be open to view.

(e) Once off-loading commences, the containers of shellfish shall immediately be moved into the plant and the attached harvester allocation tag shall be date and time stamped upon receipt by the DPO on that harvest day.

(f) Overland transportation must be approved by the SRRSC under the provisions of DEP rules N.J.A.C. 7:12-9.

Amended by R.2000 d.455, effective November 6, 2000.

See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).

In (c), substituted "to a level not to exceed one U.S. standard bushel" for "to capacity" at the end; and in (e), substituted "DPO" for "plant".

8:13-2.11 Shellfish storage

(a) Shellfish received from harvesters shall be stored immediately in the undepurated temperature controlled storage unit prior to depuration unless the shellfish are already temperature acclimated as required below and will be depurated upon receipt from the harvesters. This unit shall be cool and protect the shellfish from contamination. When staging the shellfish for depuration, the internal temperature of the shellfish in the controlled storage unit shall be maintained within five degrees Fahrenheit of the process water temperature, but shall not exceed 68 degrees Fahrenheit (20 degrees Celsius).

(b) After removal from the depuration process, shellfish shall be stored in the intermediate refrigerator at temperatures of 45 degrees Fahrenheit (7.2 degrees Celsius) or below pending laboratory analysis.

(c) Shellfish packed in shipping containers and placed in the treated shellstock refrigerator shall be stored at 45 degrees Fahrenheit (7.2 degrees Celsius) or below.

Amended by R.2000 d.455, effective November 6, 2000.

See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).

Rewrote the section.

8:13-2.12 Seawater quality

(a) No seawater shall be used for depuration unless it meets the following requirements:

1. The source seawater meets or is better than the criteria for Special Restricted Waters as specified in the NSSP Model Ordinance then in effect.
2. The source seawater shall be free of toxic chemicals, pesticides, detergents, dye stuffs, radioisotopes and marine toxins in concentrations which exceed established State/Federal rules or regulations, or exist in concentrations deemed hazardous by State or Federal officials.
3. Salinity must be within 20 percent of the harvest area value, at the time of harvest.

(b) The seawater in which the undepurated clams are placed for depuration shall be of sufficient quality to assure optimal physiological activity. The following requirements shall be met either naturally or through treatment of the water:

1. No detectable organisms of the coliform group in the tank influent as measured by a recognized multi-tube MPN per 100 milliliter test for potable water or a test of equivalent sensitivity;
2. The pH shall be between the range of 7.0 to 8.4;

3. The dissolved oxygen levels shall be a minimum of 5.0 mg/liter;

4. Turbidity shall not be more than 20 Nephelometric turbidity units; and

5. Temperature range shall be a minimum of 35 degrees Fahrenheit (2.0 degrees Celsius) to a maximum of 68 degrees Fahrenheit (20 degrees Celsius) for soft shell clams; and a minimum of 50 degrees Fahrenheit (10 degrees Celsius) to a maximum of 68 degrees Fahrenheit (20 degrees Celsius) for hard shell clams unless different maximum and minimum temperature values are documented that provide effective depuration during the scheduled depuration process verification study.

i. Refrigeration units shall be installed of sufficient capacity to cool and maintain processing water 68 degrees Fahrenheit (20 degrees Celsius) or below.

ii. A system shall be established to raise and maintain the water temperature above 35 degrees Fahrenheit (2.0 degrees Celsius) for soft shell clams and 50 degrees Fahrenheit (10 degrees Celsius) for hard shell clams.

Amended by R.2000 d.455, effective November 6, 2000.

See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).

Rewrote the section.

8:13-2.13 Plant depuration equipment

(a) The depuration process shall be designed and constructed to provide sufficient water of adequate quantity and quality throughout the system in a manner which accomplishes effective purification.

(b) Hydraulic seawater system design and material requirements are as follows:

1. The seawater pumping system, including the intake structures, intake pumps, distribution or piping network, valves, filling and flow measuring devices, shall be maintained in good working order at all times and shall be of sufficient size and design to supply the system with process seawater to meet the requirement set forth in (c) below.

2. The distribution piping network shall be constructed in such a manner so that the entire system can be easily cleaned.

3. Accurate flow control devices shall be installed in the process seawater system to assure that the flow requirements are being met and maintained.

4. Electrical hydraulic equipment such as pumps, ultraviolet unit(s) and other electrical components of the seawater circulation system shall be protected from water splash and corrosion.

5. The seawater hydraulic system shall be constructed of materials which are inert, noncorrosive and nontoxic to man or clams.

6. A minimum of five mg/liter of dissolved oxygen shall be maintained throughout the depuration processing system. An aeration system shall be installed if the oxygen level is below five mg/liter. The aeration system shall not produce excessive foaming. Bubble type aeration systems are prohibited. Accurate dissolved oxygen meters to measure the dissolved oxygen of the process water shall be provided.

(c) The process tank(s) in which controlled depuration is carried out shall be constructed of suitable sturdy material which is smooth, free of breaks and open seams. Materials used in process tank construction shall, under use conditions, be corrosion resistant, nontoxic, and nonabsorbent. The tank(s) shall be maintained in good repair and shall be easily accessible for cleaning and inspection. The tank(s) shall be self-draining to facilitate tank cleaning. Tank design shall be approved by the Department prior to installation. Tank design shall insure that:

1. Uniform hydraulic flow is maintained throughout the tank(s);

2. The stacking system for shellfish process containers within the tanks will provide a satisfactory flow of process seawater;

3. Vibrations and tank disturbances are not present;

4. The flow and quality of treated seawater can be easily monitored. The volume flowing through each tank shall be at least one gallon per minute per U.S. bushel of clams;

5. The process tank(s) shall have the capacity to supply at least five cubic feet of seawater per U.S. bushel of clams at the overflow level for soft shell clams and at least eight cubic feet of seawater per U.S. bushel for hard shell clams.

6. The tank(s) shall be protected against chemical, microbiological, or other contamination;

7. A minimum space shall be provided to assure three inches between the bottom of the clam processing containers and the process tanks; and

8. Clam processing containers and the clams in the containers shall be submerged in the process water during the entire depuration process.

Amended by R.2000 d.455, effective November 6, 2000.

See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).

Rewrote the section.

8:13-2.14 Clam processing containers

(a) Clam processing containers used in the process tanks shall be constructed of materials which are noncorrosive, nontoxic, and of suitable shape and size to allow processed seawater to pass easily in all directions; allow for intermediate washing of clams; and be easily cleanable and constructed of materials which can be sanitized. Clam processing

containers shall not be used for any other purpose other than for depuration.

1. The maximum depth of shellfish in the containers shall be three inches (76 mm) for hard shell clams and in increments of 1/2 U.S. bushels.

2. The maximum depth of shellfish in the containers shall be eight inches (20.3 cm) for soft shell clams and in increments of 1/2 U.S. bushels.

Amended by R.2000 d.455, effective November 6, 2000.

See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).

In (a), deleted "container design must be approved by the Department in writing prior to receiving a provisional certificate. Clam processing" following "processing" in the introductory paragraph.

8:13-2.15 Water purification system(s)

(a) An ultraviolet (UV) bacteriological reduction unit shall be installed to provide process seawater meeting a bacteriological quality of no detectable organisms of the coliform group as measured by a recognized multi-tube MPN per 100 milli-liter test for potable water or a test of equivalent sensitivity sampled at the UV unit outlet unless this quality can be met naturally and the water is not recirculated. A recirculating seawater system shall be so designed, installed and operated to assure that the water received UV treatment prior to entering the system.

1. The Department will consider alternate methods of bacteriological reduction if adequate scientific information is presented showing that the equipment will produce process water of the required bacteriological quality; proper testing is conducted; and the practicability of equipment can be demonstrated.

2. Chemicals such as chlorine or similar disinfecting compounds shall not be used to treat the process seawater, unless the compounds in the water are completely inactivated prior to introduction into the distribution system.

(b) The ultraviolet (UV) sterilization unit shall meet the following minimum requirements:

1. The unit shall be designed and operated to deliver at peak load at least one gallon per minute of treated water per U.S. bushel of clams;

2. The unit shall have water flow control device(s) to prevent the water flow exceeding the capacity of the unit regardless of the incoming pressure; and

3. A meter and recording chart shall be attached to the unit which will continuously monitor and record the following:

i. Any changes in ultraviolet transmissivity of the water to be treated; and

ii. Depreciation or reduction in the output of the intensity of the ultraviolet lamps;

4. The recorder chart shall be calibrated in hours and days and the chart shall be marked to indicate "0", "24", "48", and "72" hour intervals for each process batch. Alternate types of recorder units shall be approved by the Department prior to use and shall be capable of providing the required information;

5. The ultraviolet system shall have provisions for in-place cleaning of the interior of the purification chamber and ultraviolet tubes; and

6. The ultraviolet tubes shall be replaced when they reach a point of 60 percent efficiency or 7,500 hours old.

Amended by R.2000 d.455, effective November 6, 2000.

See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).

In (a), rewrote the introductory paragraph.

8:13-2.16 Water temperature recording device(s)

(a) A water temperature recording device(s) shall be installed in a position to accurately record the process water temperature. The device(s) shall be installed to meet the following requirements:

1. The recorder case shall be moisture-proof under normal operating conditions;

2. The temperature recording device(s) shall be graduated with a range between two degrees Fahrenheit and 100 degrees Fahrenheit;

3. The chart shall be graduated with not less than two degrees Fahrenheit divisions, with not more than 40 degrees Fahrenheit per inch of scale, graduated in time scale divisions of not more than one hour;

4. The chart shall have a rotation period to record for 72 hours and indicate a continuous recording for the 48/72 hour depuration process;

5. The recorded elapsed time as indicated by the temperature recorder chart rotation shall be within two percent of true elapsed time; and

6. The chart support shall be provided with a pin or pins to puncture the chart in a manner to prevent improper or false rotation.

(b) Temperature recording device operation is as follows:

1. The temperature recording device shall be activated on the onset of the depuration process (0 hour);

2. Charts shall identify the dates of process batch including lot number(s) and quantity of clams in each lot; and

3. Any unusual occurrences shall be recorded on the chart, such as system breakdown or large temperature deviations.

(c) Alternate types of recorder units will be considered by the Department. Such units must be approved by the Department prior to use.

(d) An accurate indicating thermometer shall be provided to check the temperature recording device.

Amended by R.2000 d.455, effective November 6, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).

8:13-2.17 Plant capacity control

(a) The maximum amount of clams in each tank shall not exceed the flow requirement of one gallon per minute of seawater per bushel of clams nor the physical size limits of the tank and other spacing criteria established in this subchapter.

1. The plant capacity shall be established as set forth in N.J.A.C. 8:13-2.5. Each process tank shall be posted to indicate the maximum tank capacity for that particular process. This posting shall be of size and legibility to allow for viewing by the required surveillance cameras.

2. If the flow rate of the system or individual tanks decrease, the plant operator shall adjust the number of bushels of clams in the tanks not to exceed the flow requirement and repost the new capacities.

3. The DPO shall employ all reasonable means to ensure that all tanks in the system have equal flow. If this cannot be achieved, then the operator shall post each tank with its rated capacity.

4. The DPO shall notify the Department by telephone at the beginning of the next working day if the total capacity of the system changes, either by an increase or decrease in flow capacity, and resubmit in writing the new rated capacity for departmental approval within five days after verbal notification.

5. The DPO will be responsible for allocating the processing containers and harvester allocation tags for harvesters on a daily basis. The allocation of containers and tags shall not exceed the approved capacity specified in the plant's scheduled depuration process.

6. The number of bushels of clams harvested each day shall not exceed the amount which the plant is capable of processing on that day.

Amended by R.2000 d.455, effective November 6, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).

In (a)5, substituted "scheduled depuration process" for "SOP".

8:13-2.18 Carryover

(a) In the event that insufficient clams are harvested to make a full process batch, no more than two consecutive days catch of clams can be combined to make up a process batch.

(b) Processing shall begin within 36 hours of receipt of clams at the depuration plant.

(c) If a plant carries over part of a day's catch, then the next day's harvest cannot exceed the number of bushels which the plant is capable of processing on that day.

(d) If a plant exceeds capacity due to a process failure, the plant shall notify the Department regarding the disposition of these clams by the next working day.

Amended by R.2000 d.455, effective November 6, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).

8:13-2.19 Washing and culling of clams

(a) Appropriate culling procedures will be employed to ensure that broken, cracked, dead, or gaping clams are removed and not placed into the process containers. Before depuration, clams shall be washed with water taken from a source approved by the Department. During the depuration process, the tanks shall be drained whenever necessary and the tank and clams flushed of fecal material, sand, and debris to prevent an accumulation of these materials. After the depuration process is completed, the water shall be drained from the tanks before the clams are removed. Washing facilities shall be designed to prevent cross-contamination of untreated and treated clams.

(b) Final culling of shellfish shall be conducted after the shellfish have been depurated.

(c) Culled shellfish in storage pending disposal shall be appropriately labeled to distinguish them from undepurated and depurated clams and shall be disposed of in a manner approved by the Department.

Amended by R.2000 d.455, effective November 6, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).
Rewrote the section.

8:13-2.20 Cleaning and sanitizing treatment of equipment

(a) Adequate facilities shall be provided for the proper washing, cleaning, and sanitizing treatment. All floors, walls, tanks, equipment and utensils shall be maintained in a clean condition. All clams and seawater contact surfaces shall be cleaned and sanitized, as defined under N.J.A.C. 8:21-13.6(c) and (d), at the frequencies listed as follows:

1. Process tanks and seawater distribution piping shall be drained of seawater after each process and tanks and racks shall be cleaned and sanitized within three hours after a process batch is removed from the system and rinsed of sanitizing residuals before another depuration process begins.

2. The seawater reservoir(s) used to hold incoming process seawater shall be drained and flushed after each process batch and cleaned and sanitized at least once a week.

3. Clam processing containers shall be cleaned and sanitized within three hours after removal of clams.

4. The ultraviolet or quartz tubes and tube chamber of the UV unit(s) shall be cleaned within three hours after each depuration process.

Amended by R.2000 d.455, effective November 6, 2000.

See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).
In (a), rewrote the introductory paragraph.

8:13-2.21 Bacteriological quality

(a) Depurated clams shall meet the following bacteriological quality standard:

1. For soft shell clams a fecal coliform geometric mean value not to exceed 50 organisms/100 grams and not more than 20 percent of the samples shall exceed a 100 fecal coliform value per 100 grams based upon a five sample test. A fecal coliform geometric mean value not to exceed 110 organisms/100 grams and no sample shall exceed 170 organisms/100 grams based upon a three sample test.

2. For hard shell clams a fecal coliform geometric mean value not to exceed 20 organisms/100 grams and not more than 20 percent of the samples shall exceed a 45 fecal coliform value per 100 grams based upon a five sample test. A fecal coliform geometric mean value not to exceed 45 organisms/100 grams and no sample shall exceed 100 organisms/100 grams based upon a three sample test.

(b) The SRRSC reserves the right to establish adjunct bacteriological testing in addition to the fecal coliform standards currently being utilized.

Amended by R.2000 d.455, effective November 6, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).
Rewrote (a).

8:13-2.22 Bacteriological sampling

(a) Bacteriological sampling collection and analysis of depurated clams shall be conducted by a laboratory approved by the designated State of New Jersey shellfish laboratory evaluation officer, who is certified by the United States Food and Drug Administration under the Model Ordinance. The laboratory shall not be affiliated with the depuration plants being regulated under these rules.

(b) The following minimum sampling programs shall be followed:

1. Clams samples are to be taken randomly for each process batch of clams at the following intervals:

i. Zero hour samples shall be collected at a frequency established in writing by the Department. The frequency shall be based on levels of pollution, weather conditions, and seasonal changes with a minimum of two samples per lot when zero hours sampling is deemed necessary.

ii. Five samples per lot at a period of time between 40 and 48 hours. Samples taken prior to 48 hours which do not meet the bacteriological standards shall be resampled to show that the process batch meets the bacteriological standards before being offered for sale and results received by the DPO. Sampling may be reduced to three samples per lot based upon test results *indicating low variability in test results* and approval by the Department.

iii. Five samples per lot at "72" hours if found necessary.

2. A water sample of the ultraviolet (UV) treated water shall be taken directly from the outlet of each UV unit during each process cycle.

(c) All bacteriological sampling results shall be forwarded to the Department's shellfish project in writing within five days of completion.

(d) Clam process batch(es) which do not meet the bacteriological standards set forth after 48 hours of depuration shall be further depurated for an additional 24 hours. Clam process batch(es) which do not meet the bacteriological standard after 72 hours of depuration cannot be further depurated and shall not be used for human food consumption and shall be disposed of in a manner approved by the Department. The certificate holder shall be responsible to notify the Department's shellfish project by telephone immediately upon receipt of bacteriological results which do not meet the standard after 48 or 72 hours of depuration.

(e) No depurated clams shall be packed prior to notification from the approved laboratory of acceptable bacteriological quality unless a procedure has been approved by the Department that distinguishes these clams from those that are ready for shipment.

(f) No depurated clams shall be shipped until laboratory results confirming acceptable bacteriological quality have been received by the plant.

Amended by R.2000 d.455, effective November 6, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).
Rewrote the section.

8:13-2.23 Recordkeeping

(a) Each lot of clams brought to the depuration plant shall be assigned a process batch number. The following records corresponding to the process batch shall be kept on the premises at all times for at least one year and be available for inspection upon request. All records shall be kept in indelible ink and shall indicate the following:

1. The process batch number as well as the harvester allocation tag serial number(s) for each process;
2. The name of each clammer working each day along with the number(s) of his or her serialized harvester allocation tag;
3. The number of clams and bushels each clammer harvests each day;
4. The total number of bushels and clams in each process batch;
5. The number of bushels and number of clams culled in the plant before and after the depuration process;

6. The date and time of "0" hour entry for each process batch;

7. The number of hours the clams are depurated along with the date and time the process is terminated for each process batch;

8. The ultraviolet (UV) unit intensity out-put and process water temperature records;

9. The sales information to include date, number of bushels of soft shell clams, number of hard shell clams, person and address to whom sold shall be recorded at the time of sale and identified to the process batch; and

10. A copy of the harvest depuration record as required in N.J.A.C. 7:12-9 shall be available for review and inspection upon request.

(b) Copies of the records required in (a)1 through 7 above shall be submitted via facsimile machine to the Department shellfish project no later the 12:00 noon of the next working day.

Amended by R.2000 d.455, effective November 6, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).
Rewrote the section.

8:13-2.24 Harvester allocation tag

(a) Each harvest container shall have a Department approved harvester allocation tag affixed to it at the time of issuance to the individual clammer.

1. This tag shall be made of waterproof material and shall be compatible with a time clock which has been approved by the Department.

2. This tag shall, at a minimum, contain the following information:

- i. The harvester name and permit number;
- ii. The date issued;
- iii. The time issued;
- iv. A serialized number;
- v. The DEP harvest area;
- vi. The process date;
- vii. The process "0" hour time; and

viii. The date and time issued along with the date and time the shellfish are received by the plant, both of which shall be date and time stamped on this tag.

3. This tag shall remain affixed on each container from the time allocated through and including harvesting, transporting, holding prior to depurating, during the depuration process, while in the intermediate storage refrigerator awaiting final packaging.

4. This tag shall be retained in an orderly fashion by the plant and shall be available at the plant for a period of time no less than one year.

Amended by R.2000 d.455, effective November 6, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).
Rewrote the section.

8:13-2.25 Harvester records

Upon landing of the shellfish at the approved landing site and time, each harvester shall record the specific DEP designated harvest site on the harvester allocation tag as required in N.J.A.C. 7:12-9.

Amended by R.2000 d.455, effective November 6, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).
Rewrote the section.

8:13-2.26 Shellfish shipping tags

(a) The process batch number which identifies the date of scheduled process and the harvest area shall be stamped on all shellfish shipping tags which shall be affixed to each container of clams sold. Shellfish shipping tags shall be affixed to each shellfish shipping container as it is being packed. The shellfish shipping tags shall meet the following requirements:

1. Shellfish tags shall be at least 2½ inches wide and 5¼ inches long and constructed of a waterproof and tear resistant material;

2. The attachment point shall be reinforced, preferably with a metal and fiber eyelet;

3. Shellfish shipping tags shall be preprinted or stamped in waterproof ink with the shippers name, address, certificate number prefixed with NJ in capital letters, the common name of the shellstock, numerical count, and/or standard measure of the shellstock in the container, and the date shipped. A certification number shall be followed by the letters "DP";

4. The process batch number which identifies the date of the scheduled process and the harvest area(s) shall be stamped on each shellfish shipping tag;

5. The tag shall contain the following statement in bold capital letters "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND KEPT ON FILE FOR 90 DAYS THEREAFTER."; and

6. All shellstock intended for raw consumption shall include a consumer advisory. The following statement, from Section 3-603.11 of the 1997 Food Code issued by the FDA, incorporated herein by reference, or as revised in subsequent editions, or an equivalent statement, shall be included on all shellstock:

"RETAILERS, INFORM YOUR CUSTOMERS"

"Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, poultry, or shellfish reduces the risk of foodborne illness. Individuals with certain health conditions may be higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information."

Amended by R.2000 d.455, effective November 6, 2000.
See: 32 N.J.R. 416(a), 32 N.J.R. 3982(b).
Rewrote the section.

8:13-2.27 Depuration plant monitoring/surveillance equipment

(a) A video surveillance system shall be installed and operated to clearly monitor all critical control activities of the depuration plant and shall be in working order and operating at all times. The plant shall provide two monitors for remote viewing via telephone lines in state offices. This system shall be approved by the SRRSC prior to provisional certification.

(b) A video cassette recorder shall be provided and shall operate to record all surveillance camera sequences.

(c) The plant shall have an audible alarm and a visible alarm in plain view of surveillance cameras which is triggered when the electrical service is interrupted during a process.