

Fiscal Impact Analysis of Proposed Readoption of 15A NCAC 18A Rule Package

Rule Amendments: 15A NCAC 03K .0110, 18A .0301, .0302, .0305, .0401-.0424, .0426-.0430, .0432-.0439, .0501-.0504, .0601-.0621, .0701-.0713, .0801-.0806 (readoption, repeal through readoption, amendment, adoption, and repeal)

Name of Commission: N.C. Marine Fisheries Commission

Agency Contact: Jason Walsh, Fisheries Economics Program Manager
N.C. Division of Marine Fisheries
3441 Arendell Street
Morehead City, NC 28557
Jason.walsh@ncdenr.gov
252-269-9299

Impact Summary: State government: Minimal
Local government: No
Federal government: No
Substantial impact: No

AUTHORITY

<u>N.C. General Statutes</u>	
N.C.G.S. § 113-134.	Rules.
N.C.G.S. § 113-182.	Regulation of fishing and fisheries.
N.C.G.S. § 113-221.2.	Additional rules to establish sanitation requirements for scallops, shellfish, and crustacea; permits and permit fees authorized.
N.C.G.S. § 113-221.4.	Embargo.
N.C.G.S. § 143B-289.52.	Marine Fisheries Commission – powers and duties.

Necessity: General Statute 150B-21.3A requires State agencies to review their existing rules every 10 years to determine which rules are still necessary, and to either readopt or repeal each rule as appropriate. This package of 85 rules in 15A NCAC 03 and 18A (see Appendix I), is proposed for the readoption of one rule with no changes, readoption of 55 rules with amendments, repeal through readoption of 23 rules, amendment of two rules, adoption of three rules, and the repeal of one rule pursuant to this requirement. Proposed changes would help ensure that North Carolina remains in full compliance with national requirements, allow the Division of Marine Fisheries (DMF) to increase clarity of rules for stakeholders, and allow the DMF to efficiently support and enforce rules.

I. Background

The 85 rules in this package all relate to standards for commercial shellfish sanitation and processing procedures. Session Law 2011-145 abolished the Division of Environmental Health and transferred the Shellfish Sanitation and Recreational Water Quality sections to the DMF under a Type I transfer. As a result, N.C.G.S. § 130A-230 was repealed and the authority for

rulemaking for the sanitation requirements for harvesting, processing, and handling of scallops, shellfish, and crustaceans was transferred to the Marine Fisheries Commission (MFC), which is now contained in N.C.G.S. § 113-221.2.

The purpose of the MFC is to manage, restore, develop, cultivate, conserve, protect, and regulate the marine and estuarine resources within its jurisdiction, as described in N.C.G.S. § 113-132, including commercial and recreational fisheries resources (Chapter 143B, Article 7, Part 5D). For the protection of public health, the MFC is also required to adopt rules establishing sanitation requirements for the harvesting, processing, and handling of scallops, shellfish, and crustacea of in-state origin. The rules of the MFC may also regulate scallops, shellfish, and crustacea shipped into North Carolina (N.C.G.S. § 113-221.2). Additionally, the MFC has authority to define conduct as a crime in the N.C. Administrative Code (Chapter 113 of the N.C. General Statutes) and does so for the most egregious infractions that threaten the public health. The associated rules in this package are described in this analysis.

North Carolina is part of the National Shellfish Sanitation Program (NSSP), which is a federal/state cooperative program designed to “promote and improve the sanitation of shellfish (oysters, clams, mussels, and scallops) moving in interstate commerce” as stated in Section I, page 2 of the NSSP Guide for the Control of Molluscan Shellfish ([Guide](#)). DMF employees work together with representatives from other states, the federal government, and industry through the Interstate Shellfish Sanitation Conference to develop guidelines for all state shellfish programs that are summarized in the Guide. North Carolina must meet the minimum standards included in the Guide for N.C. shellfish to be able to be sold through interstate commerce and protect N.C. shellfish consumers within and outside of the State.

II. Proposed Rule Changes

The MFC is proposing 85 rules for either readoption with no changes, readoption with amendments, repeal through readoption, amendment, adoption, or repeal. These 85 rules are rules that introduce unlawful language into rule, are proposed to be newly adopted rules, codify existing practices in rules, incorporate material by reference, add requirements from other rules, are rules proposed to be repealed, are proposed to be readopted with minor language changes, or are proposed to be readopted without any changes. Adopting the below described rule readoptions, repeals through readoption, amendments, adoptions, or repeals would help ensure that North Carolina remains in full compliance with national requirements included in the Guide and would bring organization and clarity to the shellfish sanitation rules in 15A NCAC 18A.

i. Rules that add “unlawful” language to rule:

There are three rules proposed for readoption that propose the addition of "unlawful" language for failing to meet certain requirements for 1) vessels and vehicles used for the commercial harvest and transport of shellfish (15A NCAC 18A .0419), 2) temperature controls of shellfish during harvest (15A NCAC 18A .0420), and 3) temperature controls for storage of shellfish (15A NCAC 18A .0427).

For the first two of these rules, the "unlawful" requirements are currently being implemented and enforced through proclamation authority delegated to the Fisheries Director in 15A NCAC 03K

.0110 for issuance of proclamations for the protection of public health. Similarly, the requirement to not allow dogs or other animals in or on vessels or vehicles engaged in the commercial harvest and transport of shellfish is currently being implemented and enforced via proclamation. Initially, these requirements were implemented via proclamation to address variable conditions, consistent with N.C.G.S. § 113-221.1 and 15A NCAC 03H .0103. Proclamations are available and maintained through the DMF website and announced through an opt-in list serve. Additionally, N.C.G.S. § 113-221.1 states that stakeholders are under a duty to keep themselves informed of current proclamations; the agency's stakeholders are familiar with the proclamation process. Now that the conditions are no longer variable, associated "unlawful" requirements and the requirement about animals are proposed to be added to the rules for clarity.

The "unlawful" language is proposed to be added to these two rules for emphasis and clarity. Failure to meet the shellfish sanitation requirements is considered to pose an imminent threat to public health. The added clarifying language could result in incremental improvements in compliance which would enhance the protection of public health related to the consumption of shellfish. In turn, this could help to bolster consumer confidence in N.C. shellfish. As compared to the regulatory baseline, the proposed changes will not require any procedural changes and should not result in any additional costs.

For the third rule, the requirements for temperature controls for storage of shellfish are already set forth in the rule. Proposed changes add associated "unlawful" requirements, which establishes more protection of public health related to the consumption of shellfish and helps to bolster consumer confidence in N.C. shellfish. Proposed changes to the third rule also clarify that the rule may be superseded by proclamation issued under the authority of 15A NCAC 03K .0110 or further specified in the Hazard Analysis Critical Control Point (HACCP) plan (15A NCAC 18A .0434). Adding the "unlawful" requirements to this rule may produce small costs to stakeholders who are caught violating a rule. Increasing consumer confidence in N.C. shellfish through rule is expected to outweigh any small costs infractions could bring to stakeholders.

ii. Rules proposed for adoption:

The three rules proposed for adoption are consistent with requirements of the Guide and are currently enforced by other MFC rules and compliance with the Guide. Placing the requirements in discrete permanent rules would help to ensure clarity amongst stakeholders and DMF employees. The proposed rule 15A NCAC 18A .0437 is bringing into rule already enforced requirements for a relatively new product of in-shell shellfish. In-shell shellfish is a product that is already shucked and then returned to the half shell. This product is a relatively novel and popular approach to selling shellfish. Currently in-shell product is subject to all other shellfish sanitation rules, but this proposed rule provides clarity to stakeholders that are participating in providing in-shell product to the market. The proposed rule 15A NCAC 18A .0438 provides clarity for when a shellfish dealer is found out of compliance. Currently shellfish dealers can be penalized for not being in compliance through the recertification of their permit. Explaining the steps and requirements in rule for dealers to get into compliance allows for clarity for stakeholders.

Further, the proposed rule provides a clear time schedule that ensures stakeholders have complete timeline information when they are working towards meeting compliance in the case of items that do not pose an immediate threat to consumers. This timeline is currently enforced through the Guide and is being brought into rule for stakeholder clarity. The proposed rule 15A NCAC 18A .0439 brings clear recall procedures into rule and references the FDA Enforcement Policy on Recalls CFR Title 21, Chapter 1, Subchapter A., Part 7-Enforcement Policy. Providing the reference in rule allows for stakeholders to best understand recall procedures and requirements.

The proposed changes to rules 15A NCAC 18A .0437, 15A NCAC 18A .0438, and 15A NCAC 18A .0439 will not require any procedural changes and are not expected to have quantifiable economic impact on stakeholders nor the state of North Carolina. The proposed rules could result in incremental improvements in compliance with shellfish sanitation requirements which would enhance the protection of public health related to the consumption of shellfish. In turn, this could help to bolster consumer confidence in N.C. shellfish.

iii. Rules that codify existing practices:

There is a group of 21 rules proposed for readoption that codify existing practices in rule, consistent with the Guide, enabling North Carolina to remain compliant and continue participating in interstate commerce of shellfish. The proposed changes are not expected to have quantifiable economic impact on stakeholders nor the state of North Carolina because the practices are already occurring and being enforced in accordance with proclamation or the Guide. Due to the improved clarity of the requirements, unquantifiable incremental benefits are possible in terms of enhanced protection of public health and increased consumer confidence in the safety of North Carolina shellfish.

- 15A NCAC 18A .0301 provides updated definitions for sections .0300 through .0800.
- 15A NCAC 18A .0405 explicitly states that if a facility is flooded the shellfish plant shall discontinue operation and clarifies that all contaminated shellfish product shall be destroyed, bringing practice, required by the Guide, into rule for clarity amongst stakeholders.
- 15A NCAC 18A .0406 clarifies language about flooring requirements and ensures stakeholders are aware that floors cannot allow for leakage where shellfish is stored.
- 15A NCAC 18A .0407 clarifies language about the cleanliness of wall and ceiling materials.
- 15A NCAC 18A .0408 specifies the minimum lighting requirements in shellfish plants. The minimum lighting level is 25 foot-candles in packing and shucking rooms and 10 foot-candles throughout the rest of the shellfish plant. These changes help to bring clarity to the rule, which is otherwise vague on minimum lighting requirements. The current requirements, set out by the Guide, state that a “dealer shall provide lighting throughout the facility that is sufficient...” The agency reviewed the requirement and determined the above-described minimums are sufficient and are readily met by current stakeholders. The minimum requirements are not expected to result in increases needed for lighting in existing shellfish plants but allows for clarity for existing and future stakeholders.

- 15A NCAC 18A .0409 provides more details about the hazards that the ventilation requirements are intended to prevent from occurring.
- 15A NCAC 18A .0415 clarifies that the rule applies to the shellfish plant and the area around the plant.
- 15A NCAC 18A .0416 reorganizes and clarifies hygiene requirements for employees while working in the shellfish plant.
- 15A NCAC 18A .0418 clarifies the requirements for where chemicals shall be stored in a shellfish plant.
- 15A NCAC 18A .0422 clarifies the requirements for water that can be used to clean shellstock and points to two other rules where related requirements are set, to ensure regulated stakeholders are informed.
- 15A NCAC 18A .0424 clarifies who can receive shellfish and how that shellfish can be received. More detail is provided in this rule but is not in addition to current practices enforced by the DMF in accordance with the Guide.
- 15A NCAC 18A .0426 clarifies under which circumstances bulk shipments between shellfish dealers are permitted.
- 15A NCAC 18A .0429 points to the rule where requirements are for determining if shellfish is adulterated (15A NCAC 18A .0438). Proposed changes also clarify that the authority of marine fisheries inspectors to seize shellfish under separate statutory authority (N.C.G.S. § 113-137) shall not be affected by requirements for embargo in the rule. The practice of voluntary disposal of adulterated shellfish is also accounted for, which is the most common outcome for adulterated shellfish, consistent with the Guide.
- 15A NCAC 18A .0432 provides clarity on requirements for consumer advisory warnings on public-facing products.
- 15A NCAC 18A .0504 clarifies that reshippers can only buy from shellfish dealers. This requirement is already in place but can only be determined indirectly through a combination of rules with defined terms and applicability rules.
- 15A NCAC 18A .0612 provides clarification that equipment used in the handling of ice shall only be used to handle ice.
- 15A NCAC 18A .0614 clarifies requirements for labeling of shellfish containers. Proposed changes are not in excess of requirements of the Guide and consolidate requirements in one rule for stakeholders.
- 15A NCAC 18A .0615 provides clarification for shellfish cooling requirements. The amendments reflect a change for the temperature for shucked shellfish and in-shell product of 40° F or below to 45° F or below, consistent with a change in the Guide. Proposed changes are not in excess of requirements of the Guide and consolidate requirements in one rule for stakeholders.
- 15A NCAC 18A .0618 provides clarification that the heat shock process shall be listed and posted in a viewable location.
- 15A NCAC 18A .0619 clarifies requirements for labeling and repacking of shellfish. Proposed changes are not in excess of requirements of the Guide and consolidate requirements in one rule for stakeholders.

- 15A NCAC 18A .0620 provides clarification for the amount of time that thawed shellfish can exceed 45° F. Proposed changes are not in excess of requirements of the Guide and consolidate requirements in one rule for stakeholders.

iv. Rules that incorporate material by reference:

There are changes to 12 rules proposed for readoption that bring clarity to the rule by incorporating material in the rule by reference, pursuant to N.C.G.S. § 150B-21.6. The proposed changes are not expected to have quantifiable economic impact on stakeholders nor the state of North Carolina.

Proposed rule changes in 15A NCAC 18A .0301 include a definition for the state shellfish control "authority" from the National Shellfish Sanitation Program (NSSP), "easily cleanable" from the 2017 U.S. Food Code, and "sanitize" from 21 CFR 110.3.

Rules in 15A NCAC 18A .0400 apply to shellfish dealers, depuration facilities, shellstock plants, shucking and packing plants, repacking plants, reshippers, permittees with facilities approved for wet storage, and all other businesses and persons that buy, sell, transport, or ship shellfish. The proposed changes are as follows:

- 15A NCAC 18A .0402 organize and clarify general requirements for operation. Standards for food contact surface equipment are incorporated by reference from the Guide.
- 15A NCAC 18A .0403 organize and clarify supervision and training requirements. Principles of food hygiene and food safety are incorporated by reference from the Code of Federal Regulations.
- 15A NCAC 18A .0413 organize and clarify requirements for the water supply. Standards for the water supply and standards for certification of a laboratory other than the State Laboratory of Public Health for testing a water supply from a private source are incorporated by reference from the N.C. Administrative Code.
- 15A NCAC 18A .0414 organize and clarify requirements for toilet facilities. Standards for disposal of toilet wastes and other sewage are incorporated by reference from the N.C. Administrative Code.
- 15A NCAC 18A .0428 clarify requirements for sampling and testing of shellfish. Standards for poisonous or deleterious substances are incorporated by reference from the Guide.
- 15A NCAC 18A .0430 organize and clarify requirements for bacteriological and contamination standards for shellfish. Standards for contaminants that render shellfish unsafe for human consumption are incorporated by reference from the Guide.
- 15A NCAC 18A .0433 clarify requirements for conducting a hazard analysis to determine food safety hazards. The definition of "reasonably likely to occur" is incorporated by reference from the Code of Federal Regulations.
- 15A NCAC 18A .0434 organize and clarify requirements for a Hazard Analysis Critical Control Point (HACCP) plan. The definition of "reasonably likely to occur" is incorporated by reference from the Code of Federal Regulations. Proposed changes also

incorporate by reference standards for taking corrective action from the Code of Federal Regulations.

The proposed rule changes in 15A NCAC 18A .0610 clarify requirements for equipment sanitation for shucking and packing plants and repacking plants. Standards for sanitizing solutions are incorporated by reference from the Code of Federal Regulations.

The proposed rule changes in 15A NCAC 18A .0701 organize and clarify requirements for operation of depuration facilities; there are no active depuration facilities in North Carolina. Standards for depuration are incorporated by reference from the Guide. Requirements are also added from another rule proposed for repeal (15A NCAC 18A .0704; see next section for description.)

The proposed rule changes in 15A NCAC 18A .0801 organize and clarify requirements for facilities approved for wet storage; there are no active facilities approved for wet storage in North Carolina. Standards for wet storage are incorporated by reference from the Guide.

v. **Rules that move requirements from other rules:** (see also "Repealed rules")

Requirements from six rules are proposed to be moved to eight other rules proposed for re-adoption (one previously discussed) and one rule proposed for adoption (previously discussed) for efficiency and clarity. Aggregating related requirements in fewer rules allows stakeholders to access the requirements more easily and makes the requirements clearer. The proposed changes are not expected to have quantifiable economic impact on stakeholders nor the state of North Carolina.

- 15A NCAC 18A .0410 is proposed to be renamed as "Pest Control", retaining current requirements for the control of flies, and adding requirements from 15A NCAC 18A .0411 for rodents and animals, which is proposed for repeal. A definition of "pests" is proposed to be added to 15A NCAC 18A .0301 (previously discussed).
- 15A NCAC 18A .0434 (HACCP Plan) and 15A NCAC 18A .0435 (Sanitation Monitoring Requirements) are each proposed to add requirements from 15A NCAC 18A .0436 (Monitoring Records), which is proposed for repeal.
- 15A NCAC 18A .0502 (Grading Shellstock and Commingling) is proposed to add requirements for graders from 15A NCAC 18A .0503 (Grader), which is proposed for repeal.
- 15A NCAC 18A .0412 (Plumbing) applies broadly to shellfish dealers, depuration facilities, shellstock plants, shucking and packing plants, repacking plants, reshippers, permittees with facilities approved for wet storage, and all other businesses and persons that buy, sell, transport, or ship shellfish. Amendments are proposed to add requirements for hand washing from 15A NCAC 18A .0604 (Handwashing Facilities), which only applies to shucking and packing plants and repacking plants. As a result, 15A NCAC 18A .0412 is proposed to be renamed as "Plumbing and Hand Washing Facilities" and 15A NCAC 18A .0604 is proposed for repeal. Another rule, 15A NCAC 18A .0416 (Personal Hygiene) currently sets requirements for hand washing and hand washing facilities in the context of an employee's personal hygiene and is also broadly applicable to all shellfish

dealers. These are not new requirements, and it is appropriate for the hand washing requirements to be included in the "Plumbing" and "Personal Hygiene" rules.

- 15A NCAC 18A .0420 (Transporting Shellfish) and 15A NCAC 18A .0421 (Records) are each proposed to add requirements from 15A NCAC 18A .0617 (Shipping), which is proposed for repeal.
- 15A NCAC 18A .0439 (Recall Procedure) is proposed for adoption (previously discussed) to set requirements for conducting recalls of adulterated or misbranded shellfish that applies broadly to shellfish dealers, depuration facilities, shellstock plants, shucking and packing plants, repacking plants, reshippers, permittees with facilities approved for wet storage, and all other businesses and persons that buy, sell, transport, or ship shellfish. This makes moot 15A NCAC 18A .0621 (Recall Procedure), which only applies to shucking and packing plants and repacking plants; this rule is proposed for repeal.

vi. Rules proposed for repeal: (see also "Rules that move requirements from other rules")

There are 23 rules proposed for repeal through readoption and one rule that was previously readopted that is proposed for repeal (15A NCAC 18A .0704). Most of these rules pertain to depuration facilities (12 rules) and wet storage of shellstock (five rules), neither of which are actively occurring nor anticipated to occur in North Carolina. Should this change, amendments to remaining rules (15A NCAC 18A .0701 and .0801) incorporate by reference requirements in the Guide for these practices. Requirements from six rules are proposed to be added to other rules for efficiency and clarity (15A NCAC 18A .0411, .0436, .0503, .0604, .0617, .0621). The remaining rule (15A NCAC 18A .0305) is duplicative of another MFC rule (15A NCAC 03P .0102). No economic impacts are expected from the proposed repeals of these rules.

vii. Rules that only contain minor language changes:

There is a group of 15 rules proposed for readoption that make small changes to rules to bring clarity and modern language into rule or to make conforming changes across the package of rules. The affected rules are: 15A NCAC 03K .0110, 18A .0302, .0401, .0404, .0417, .0501, .0601, .0602, .0603, .0605, .0606, .0607, .0608, .0609, .0611, .0613, and .0616. The proposed changes are not expected to have quantifiable economic impact on stakeholders nor the state of North Carolina.

viii. Rules proposed for readoption without changes:

The proposed rule 15A NCAC 18A .0423, is proposed for readoption without changes and is not expected to have any economic impact on stakeholders nor the state of North Carolina.

III. Economic Impact Summary

The overarching effect of these proposed rule amendments is to conform rule language with current state proclamations and national requirements so as to remain compliant and continue participating in interstate commerce of shellfish. As compared to the regulatory baseline, the

proposed amendments will not require any procedural changes and should not result in any additional costs to the state. Adding the "unlawful" requirements to the rule for temperature controls for storage of shellfish (15A NCAC 18A .0427) may produce small costs to stakeholders who are caught violating the rule. No other costs to the regulated community are expected. The proposed amendments will help to clarify the shellfish sanitation requirements for the regulated community. The improved clarity could provide a small benefit to DMF in the form of reduced time spent providing technical assistance. The added clarifying language could result in unquantifiable, incremental improvements in compliance with shellfish sanitation requirements which would enhance the protection of public health related to the consumption of shellfish. In turn, this could help to bolster consumer confidence in N.C. shellfish.

1 15A NCAC 03K .0110 is proposed for amendment as follows:

2

3 **15A NCAC 03K .0110 PUBLIC HEALTH AND CONTROL OF OYSTERS, CLAMS, SCALLOPS, AND**
 4 **MUSSELS**

5 (a) The National Shellfish Sanitation Program Guide for Control of Molluscan Shellfish, Section II: Model Ordinance
 6 (Model Ordinance) includes requirements for the sale or distribution of shellfish from approved areas or ~~shellstock~~
 7 shellfish dealers, as defined in 15A NCAC 18A .0301, and to ensure that shellfish have not been adulterated or
 8 ~~mislabeled-misbranded~~ during cultivation, harvesting, processing, storage, or transport. To protect public health, the
 9 Fisheries Director may, by proclamation, impose requirements of the Model Ordinance as set forth in Paragraph (b)
 10 of this Rule on any of the following:

11 (1) the cultivation, distribution, harvesting, processing, sale, storage, or transport ~~of~~ of:

12 (A) oysters;

13 (B) clams;

14 (C) scallops; ~~or~~ and

15 (D) mussels;

16 (2) areas used to store shellfish;

17 (3) means and methods to take shellfish;

18 (4) vessels used to take shellfish; ~~or~~ and

19 (5) shellstock conveyances as defined in 15A NCAC 18A .0301.

20 (b) Proclamations issued under this Rule may impose any of the following requirements:

21 (1) specify time and temperature controls;

22 (2) specify sanitation requirements to prevent a food safety hazard, as defined in 15A NCAC 18A .0301,
 23 or cross-contamination or adulteration of shellfish;

24 (3) specify sanitation control procedures set forth in 21 ~~Code of Federal Regulations (CFR) Part~~ CFR
 25 123.11;

26 (4) specify Hazard Analysis Critical Control Point (HACCP) requirements set forth in 21 ~~CFR~~
 27 Part:CFR:

28 (A) 123.3 Definitions;

29 (B) 123.6 HACCP Plan;

30 (C) 123.7 Corrective Actions;

31 (D) 123.8 Verification;

32 (E) 123.9 Records; and

33 (F) 123.28 Source Controls;

34 (5) specify tagging and labeling requirements;

35 (6) implement the National Shellfish Sanitation Program's training requirements for shellfish harvesters
 36 and certified shellfish dealers;

1 (7) require sales records and collection and submission of information to provide a mechanism for
2 tracing shellfish product back to the water body of origin; and

3 (8) require product recall and specify recall procedures.

4 21 CFR 123.3, 123.6-9, 123.11, and 123.28 are ~~hereby~~ incorporated by reference, including subsequent amendments
5 and editions. A copy of the reference ~~materials—material~~ can be found at ~~http://www.ecfr.gov/cgi-bin/text-~~
6 ~~idx?SID=f4edd666e75f54ccda1d9938f4edd9ab&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl, free of charge.~~
7 <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-123?toc=1>, at no cost.

8 (c) Proclamations issued under this Rule shall suspend appropriate rules or portions of rules under the authority of
9 the Marine Fisheries Commission as specified in the proclamation. The provisions of 15A NCAC 03I .0102
10 terminating suspension of a rule pending the next Marine Fisheries Commission meeting and requiring review by the
11 Marine Fisheries Commission at the next meeting shall not apply to proclamations issued under this Rule.

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13 *History Note: Authority G.S. 113-134; 113-182; 113-201; 113-221.1; 113-221.2; 143B-289.52;*

14 *Eff. April 1, 2014;*

15 *Amended Eff. May 1, 2017;*

16 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,*
17 *2018-2018;*

18 *Amended Eff. April 1, 2024.*

1 15A NCAC 18A .0301 is proposed for readoption with substantive changes as follows:

2
3 **SECTION .0300 – SANITATION OF SHELLFISH - GENERAL**

4
5 **15A NCAC 18A .0301 DEFINITIONS**

6 The following definitions shall apply throughout Sections .0300 ~~to .0900~~ through .0800 of this Subchapter:

- 7 (1) "Adulterated" ~~means the following:~~ means:
- 8 (a) ~~Any any~~ shellfish that have been harvested from ~~prohibited areas;~~ polluted areas as defined
9 in 15A NCAC 03L .0101;
- 10 (b) ~~Any any~~ shellfish that have been shucked, packed, or otherwise processed in a plant ~~which~~
11 that has not been permitted by the Division of Marine Fisheries in accordance with these
12 Rules or by another state shellfish control "authority" as defined in the National Shellfish
13 Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish, Section I: Purposes
14 and Definitions, in accordance with these Rules; This definition is incorporated by reference,
15 including subsequent amendments and editions. A copy of the reference material can be
16 found at [https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-](https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp)
17 program-nssp, at no cost;
- 18 (c) any shellfish that may have been contaminated by flood waters in accordance with Rule .0405
19 of this Subchapter;
- 20 ~~(e)(d)~~ ~~Any any~~ shellfish ~~which that~~ exceed the ~~bacteriological~~ standards in Rule .0430 of this
21 Subchapter; and
- 22 ~~(d)(c)~~ ~~Any any~~ shellfish ~~which are that~~ have been deemed to be an imminent ~~hazard;~~ hazard.
- 23 (2) ~~"Approved area" means an area determined suitable for the harvest of shellfish for direct market~~
24 ~~purposes.~~
- 25 (3) ~~"Bulk shipment" means a shipment of loose shellstock.~~
- 26 (4) ~~"Buy boat or buy truck" means any boat which that~~ complies with Rule .0419 of this Subchapter or
27 truck which complies with Rule .0420 of this Subchapter that is used by a person permitted under these
28 Rules to transport shellstock from one or more harvesters to a facility permitted under these Rules.
- 29 ~~(5)(2)~~ "Certification number" means the unique identification number assigned by the state shellfish control
30 agency to each certified shellfish ~~dealer.~~ dealer for each location. It consists of a ~~one to five digit one-~~
31 ~~to-five-digit~~ number preceded by the ~~two letter~~ two-letter state abbreviation and followed by the ~~two~~
32 ~~letter symbol~~ two-letter abbreviation designating the type of operation certified.
- 33 (3) "Clean" means free from dirt, debris, dust, marks, stains, waste materials, litter, or foreign material.
- 34 ~~(6)(4)~~ "Critical control point" means a point, ~~step~~ step, or procedure in a food process at which control can
35 be applied, and a food safety hazard can as a result be prevented, ~~eliminated~~ eliminated, or reduced to
36 acceptable levels.

- 1 ~~(7)~~(5) "Critical limit" means the maximum or minimum value to which a physical, ~~biological~~ biological, or
2 chemical parameter must be controlled at a critical control point to prevent, ~~eliminate~~ eliminate, or
3 reduce to an acceptable level the occurrence of the identified food safety hazard.
- 4 ~~(8)~~(6) "Depurate" or "Depuration" "depuration" means ~~mechanical purification or the removal of adulteration~~
5 ~~from live shellstock by any artificially controlled means~~ the process of reducing the pathogenic
6 organisms that may be present in shellstock by using a controlled aquatic environment as the treatment
7 process.
- 8 ~~(9)~~(7) "Depuration facility" means ~~the physical structure wherein depuration is accomplished, including all~~
9 ~~the appurtenances necessary to the effective operation thereof~~ any establishment or place where the
10 depuration of shellfish occurs by a shellfish dealer.
- 11 ~~(10)~~(8) "Division" means the Division of ~~Environmental Health or its authorized agent~~ Marine Fisheries.
- 12 (9) "Easily cleanable" has the same meaning as defined in the 2017 U.S. Food Code. This definition is
13 incorporated by reference, not including subsequent amendments and editions. A copy of the
14 reference material can be found at <https://www.fda.gov/food/fda-food-code/food-code-2017>, at no
15 cost.
- 16 (10) "Food contact surface" means the parts of equipment, including auxiliary equipment, that may be in
17 contact with the food being processed, or that may drain into the portion of equipment with which
18 food is in contact.
- 19 (11) "Food safety hazard" means any biological, ~~chemical~~ chemical, or physical property that may cause a
20 food to be unsafe for human consumption.
- 21 (12) "Good repair" means maintained to function as designed and without defect.
- 22 ~~(12)~~(13) "HACCP plan" means a written document that delineates the procedures a shellfish dealer follows to
23 implement food safety controls.
- 24 ~~(13)~~(14) "Hazard analysis critical control point (HACCP)" means a system of inspection, ~~control~~ control, and
25 monitoring measures initiated by a shellfish dealer to identify microbiological, ~~chemical~~ chemical, or
26 physical food safety hazards ~~which that~~ are likely to occur in shellfish products produced by the dealer.
- 27 ~~(14)~~(15) "Heat shock process" means the practice of heating shellstock to facilitate removal of the shellfish
28 meat from the shell.
- 29 ~~(15)~~(16) "Imminent hazard" means ~~a situation which is likely to cause an immediate threat to human life, and~~
30 ~~immediate threat of serious physical injury, an immediate threat of serious physical adverse health~~
31 ~~effects, or a serious risk of irreparable damage to the environment if no immediate action is taken~~ has
32 the same meaning as defined in G.S. 130A-2.
- 33 ~~(14)~~(17) "In-shell product" means non-living, processed shellfish with one or both shells present.
- 34 ~~(16)~~(18) "Misbranded" means ~~the following:~~ as defined in G.S. 106-30 shall include any shellfish that are not
35 labeled in compliance with these Rules.
- 36 (a) — Any shellfish which are not labeled with a valid identification number awarded by regulatory
37 authority of the state or territory of origin of the shellfish; or

~~(b) — Any shellfish which are not labeled as required by these Rules.~~

- (19) "National Shellfish Sanitation Program (NSSP)" means the cooperative federal-state-industry program for the sanitary control of shellfish that is adequate to ensure that the shellfish produced in accordance with the NSSP Guide For The Control Of Molluscan Shellfish will be safe and sanitary.
- (17) ~~"Operating season" means the season of the year during which a shellfish product is processed.~~
- (18) ~~"Person" means an individual, corporation, company, association, partnership, unit of government or other legal entity.~~
- (20) "Pests" means animals or insects, including, but not limited to dogs, cats, birds, rodents, flies, and larvae.
- (21) "Plant" means the establishment or place where shellfish processing occurs by shellfish dealers.
- (22) "Processing" or "processed" means any activity associated with the handling, shucking, freezing, packing, labeling, or storing of shellfish in preparation for distribution. This includes the activities of a shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor.
- (19) ~~"Prohibited area" means an area unsuitable for the harvesting of shellfish for direct market purposes.~~
- (20)(23) "Recall procedure" means the detailed procedure the ~~permitted shellfish~~ dealer will use to retrieve product from the market when it is determined that the product ~~may not be safe for human consumption as determined by the State Health Director~~ is adulterated or misbranded.
- (21) ~~"Relaying or transplanting" means the act of removing shellfish from one growing area or shellfish grounds to another area or ground for any purpose.~~
- (22)(24) "Repacking plant" means ~~a shipper,~~ the establishment or place where a shellfish dealer, other than the original shucker-packer, ~~who~~ repacks shucked shellfish into other containers for delivery to the consumer.
- (23)(25) "Reshipper" means ~~a shipper who ships shucked shellfish in original containers, or shellstock, from permitted shellstock dealers to other dealers or to consumers.~~ person that purchases shellfish from a shellfish dealer and sells the product without repacking or relabeling to another shellfish dealer, wholesaler, or retailer.
- (26) "Responsible individual" means the individual present at a shellfish dealer that is the supervisor at the time of the inspection. If no individual is the supervisor, then any employee is the responsible individual.
- (24) ~~"Sanitary survey" means the evaluation of factors having a bearing on the sanitary quality of a shellfish growing area including sources of pollution, the effects of wind, tides and currents in the distribution and dilution of polluting materials, and the bacteriological quality of water.~~
- (25)(27) "Sanitize" means ~~the a bactericidal treatment by a process which meets the temperature and chemical concentration levels in 15A NCAC 18A .2619,~~ has the same meaning as defined in 21 CFR 110.3, which is incorporated by reference including subsequent amendments and editions. A copy of the reference material can be found at <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-110/subpart-A/section-110.3>, at no cost.

1 ~~(26)~~(28) "SELL BY date" means a date ~~conspicuously~~ placed on a container or tag by which a consumer is
2 informed of the latest date the product will remain suitable for sale.

3 ~~(27)~~(29) "Shellfish" means oysters, mussels, ~~scallops~~ scallops, and all varieties of ~~clams~~. However, ~~clams~~,
4 whether shucked or in the shell, fresh, frozen, whole, or in part. ~~the term~~ The requirements of Sections
5 .0300 through .0800 of this Subchapter shall not ~~include~~ apply to scallops ~~when~~ if the final product is
6 the shucked adductor muscle only.

7 (30) "Shellfish dealer" means a plant to which a Shellfish Dealer Permit and Certificate of Compliance is
8 issued by the Division for the activities of shellstock shipping, shucking or packing, repacking,
9 reshipping, or depuration.

10 ~~(28)~~(31) "Shellstock" means any live molluscan shellfish ~~which that~~ remain in their shells.

11 ~~(29)~~(32) "Shellstock conveyance" means all trucks, vessels, trailers, or other conveyances used to transport
12 shellstock.

13 (30) ~~"Shellstock dealer" means a person who buys, sells, stores, or transports or causes to be transported~~
14 ~~shellstock which was not obtained from a person permitted under these Rules.~~

15 ~~(31)~~(33) "Shellstock plant" means any establishment or place where shellstock are washed, packed, or
16 otherwise prepared for ~~sale~~ sale by a shellfish dealer.

17 ~~(32)~~(34) "Shucking and packing plant" means any establishment or place where shellfish are shucked and
18 packed for ~~sale~~ sale by a shellfish dealer.

19 (35) "Use" means employ, set, operate, or permit to be operated or employed.

20 ~~(33)~~(36) "Wet storage" means the ~~temporary placement~~ storage by a shellfish dealer of shellstock from
21 approved areas, a growing area in the open status and classified as "approved" or "conditionally
22 approved" as defined in Rule .0901 of this Subchapter, in containers or floats in natural bodies of ~~water~~
23 water, or in tanks containing natural or synthetic sea ~~water~~ water at any permitted land-based activity
24 or facility.

25
26 *History Note:* Authority G.S. 130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;

27 Eff. February 1, 1987;

28 Amended Eff. August 1, 2000; August 1, 1998; February 1, 1997; January 4, 1994; September 1,
29 1990; December 1, ~~1987-1987~~;

30 Readopted Eff. April 1, 2024.

1 15A NCAC 18A .0302 is proposed for amendment as follows:

2

3 **15A NCAC 18A .0302 PERMITS**

4 (a) It shall be unlawful to operate any of the following facilities without first obtaining a Shellfish Dealer Permit
5 and Certificate of Compliance from the Division of Marine Fisheries:

- 6 (1) depuration facilities;
7 (2) repacking plants;
8 (3) shellstock plants; and
9 (4) shucking and packing plants.

10 (b) It shall be unlawful to operate as a ~~shellstock~~-shellfish dealer without first obtaining a Shellfish Dealer Permit
11 and Certificate of Compliance from the Division.

12 (c) It shall be unlawful to operate as a reshipper without first obtaining a Shellfish Dealer Permit and Certificate of
13 Compliance from the Division if shellfish are purchased and shipped out of state.

14 (d) Approval for wet storage of shellstock shall be granted only to persons permitted pursuant to this Rule.

15 (e) Application for a permit shall be submitted in writing to the Division. Application forms may be obtained from
16 the Division, P.O. Box 769, 3441 Arendell Street, Morehead City, NC 28557.

17 (f) No permit shall be issued by the Division until an inspection by the Division shows that the facility and
18 equipment comply with all applicable Rules in Sections .0300 through .0800 of this Subchapter. The owner or
19 responsible ~~person~~-individual shall sign the completed inspection sheet to acknowledge receipt of the inspection
20 sheet.

21 (g) All permits shall be posted in a conspicuous place in the facility.

22 (h) All permits shall expire on April 30 of each year and are non-transferrable.

23 (i) Plans and specifications for proposed new construction, expansion of operations, or changes in operating
24 processes shall be submitted to the Division for review and approval prior to beginning construction or making a
25 change.

26 (j) A permit may be revoked or suspended in accordance with 15A NCAC 03O .0504.

27

28 *History Note: Authority G.S. 113-134; 113-182; 113-221.2; 143B-289.52;*

29 *Eff. February 1, 1987;*

30 *Amended Eff. April 1, 1997;*

31 *Readopted Eff. March 15, ~~2023~~, 2023;*

32 *Amended Eff. (Pending legislative review pursuant to S.L. 2019-198).*

1 15A NCAC 18A .0305 is proposed for repeal through readoption as follows:

2

3 **15A NCAC 18A .0305 APPEALS PROCEDURE**

4

5 *History Note: Authority G.S. 130A-230;*

6 *Eff. February 1, 1987;*

7 *Amended Eff. September 1, ~~1990~~1990;*

8 *Repealed Eff. April 1, 2024.*

1 15A NCAC 18A .0401 is proposed for reoption with substantive changes as follows:
2

3 **SECTION .0400 - SANITATION OF SHELLFISH - GENERAL OPERATION STANDARDS**
4

5 ~~Rules .0401—.0431 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18A .0401—~~
6 ~~.0431); has been transferred and recodified from Rules .0901—.0931 of Title 10 Subchapter 10B of the North Carolina~~
7 ~~Administrative Code (T10.10B .0901—.0931), effective April 4, 1990.~~
8

9 **15A NCAC 18A .0401 APPLICABILITY OF RULES**

10 The rules in this Section shall apply to the operation of all facilities and persons permitted in Rule .0302 of this
11 Subchapter, including shellfish dealers, shellstock plants, reshippers, shucking and packing plants, repacking plants,
12 deputation facilities, permittees with facilities approved for wet storage, and all other businesses and persons that buy,
13 sell, transport, or ship shellfish. These ~~Rules do~~ rules shall not apply to persons ~~individuals~~ possessing shellfish for
14 personal use.
15

16 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

17 *Eff. February 1, 1987;*

18 *Amended Eff. April 1, 1997; December 1, ~~1987-1987;~~*

19 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0402 is proposed for readoption with substantive changes as follows:

2
3 **15A NCAC 18A .0402 GENERAL REQUIREMENTS FOR OPERATION**

4 ~~(a) During the operating season the plant shall be used for no purpose other than the handling of shellfish. All unnecessary equipment and materials shall be removed from the plant and the floors kept clear for thorough cleaning.~~

5
6 ~~(b) (a) All floors, walls, shucking benches and stools, shucking blocks, tables, skimmers, blowers, colanders, buckets, or any other equipment or utensils used in the processing operation shall be cleaned and sanitized daily, or more frequently as may be necessary during the day's operation to prevent the introduction of undesirable microbiological organisms and filth into the shellfish product. Shellfish dealers shall provide mechanical refrigeration that is capable of maintaining an ambient temperature of 45°F or less and be sized to handle one day's production. The mechanical refrigeration shall include an automatic temperature regulating control and be equipped with an accurate, operating thermometer in the refrigerated storage area. If the sole means of refrigeration is a portable unit, that unit shall be capable of operating utilizing alternating current electrical power that will allow the unit to be plugged into a power supply during transport and at the certified facility.~~

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15 ~~(e) (b) Ceilings and windows shall also be kept clean. Refrigerators, refrigeration rooms, and ice boxes shall be washed and sanitized. Food contact surfaces shall be easily cleanable, corrosion-resistant, constructed of non-toxic and food-grade materials, and shall be kept in good repair. Shellfish dealers shall only use food contact surface equipment that conforms to standards found in the guidance document within the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish, Section II: Model Ordinance titled "Shellfish Industry Equipment Construction Guide", which is incorporated by reference, including subsequent amendments and editions. A copy of the reference material can be found at <https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp> at no cost.~~

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22
23 ~~(c) Food contact surfaces of equipment, utensils, and containers shall be cleaned at the end of each day or operation and shall be sanitized prior to the start-up of each day's activities. Food contact surfaces shall also be cleaned and sanitized following any interruption during which the surfaces have become contaminated.~~

24
25
26 ~~(d) Non-food contact surfaces such as equipment, floors, walls, ceilings, and windows shall be kept clean and in good repair.~~

27
28 ~~(d) (e) Wheelbarrows, measures, baskets, shovels, and other implements used in the handling of shellstock shall not be used for any other purpose and shall be cleaned and stored in the shellstock room when not in prior to use.~~

29
30 ~~(f) Shellfish dealers shall provide a temperature measuring device accurate to +/- 2°F for use in monitoring product temperatures.~~

31
32
33 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*
34 *Eff. February 1, 1987-1987;*
35 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0403 is proposed for reoption with substantive changes as follows:

2

3 **15A NCAC 18A .0403 SUPERVISION AND TRAINING**

4 (a) The ~~owner shellfish dealer~~ shall personally supervise or shall designate ~~an~~ a responsible individual whose principal
5 duty shall be to supervise and be responsible for compliance with the ~~Rules~~ rules of this Subchapter. No unauthorized
6 ~~persons~~ individuals shall be allowed in any processing area of the plant during periods of operation. For the purpose
7 of this Rule, "unauthorized individual" shall mean an individual that is not designated and trained by the shellfish
8 dealer or responsible individual to perform specific processing tasks in the facility.

9 (b) The shellfish dealer shall ensure that all employees that manufacture, process, pack, or hold food obtain training
10 in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene,
11 in accordance with 21 CFR 117.4, which is incorporated by reference, including subsequent amendments and editions.
12 A copy of the reference material can be found at [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117/subpart-A/section-117.4)
13 117/subpart-A/section-117.4 at no cost. Employees shall complete the training within 30 days following the initial
14 hire date. The shellfish dealer or responsible individual shall maintain a record of the completed training.

15

16 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

17 *Eff. February 1, ~~1987~~1987;*

18 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0404 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0404 CONSTRUCTION**

4 Shellfish plants shall be ~~adequate in size and construction~~ sized and constructed to permit compliance with the
5 operational provisions of Sections .0300 through .0800 of this Subchapter.

6

7 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

8 *Eff. February 1, ~~1987-1987;~~*

9 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0405 is proposed for re adoption with substantive changes as follows:

2

3 **15A NCAC 18A .0405 ~~PLANT LOCATION~~ FACILITY FLOODING**

4 (a) Shellfish plants shall be located so that they will not be subject to flooding by high tides.

5 (b) If the facility floors are flooded, processing shall be discontinued until flood waters have receded and the facility
6 and equipment are cleaned and sanitized.

7 (c) Any shellfish that may have been contaminated by flood waters shall be deemed adulterated and shall be destroyed.

8

9 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 113-221.4; 143B-289.52;~~*

10 *Eff. February 1, ~~1987~~1987;*

11 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0406 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0406 FLOORS**

4 Floors shall be ~~of~~ concrete or other equally impervious material, constructed so that they ~~may be~~ are easily and
5 ~~thoroughly cleaned~~ cleanable, and shall be sloped so that water drains ~~completely and rapidly~~. For new construction,
6 ~~the joints between walls and floors shall be rounded to expedite cleaning~~, completely, and kept in good repair. The
7 junction between floors and walls shall be sealed to render them impervious to water in areas where the floor gets wet
8 and is used to store shellfish, process food, or clean equipment and utensils.

9

10 *History Note:* Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~

11 Eff. February 1, ~~1987~~1987;

12 Readopted Eff. April 1, 2024.

1 15A NCAC 18A .0407 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0407 WALLS AND CEILINGS**

4 ~~Walls to a height of at least two feet above the floor shall be constructed of smooth concrete or other equally~~
5 ~~impervious material. The remainder of the walls and ceilings shall be smooth concrete, cement plaster, or other~~
6 ~~material approved by the Division and shall be painted with a light color washable paint.~~

7 (a) Walls and ceilings in areas where shellfish are stored, handled, processed, or packaged or where food handling
8 equipment or packaging materials are stored shall be constructed of smooth, easily cleanable, non-corrosive,
9 impervious material. The walls and ceilings in these areas shall also be light-colored, such as white in color, so that
10 unclean surfaces can be detected.

11 (b) Doors and windows shall be tightly fitted and kept in good repair so as to keep pests and weather out of the facility.

12

13 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

14 *Eff. February 1, ~~1987-1987;~~*

15 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0408 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0408 LIGHTING**

4 (a) Natural or artificial lighting shall be provided in all parts of the plant. Light bulbs, fixtures, or other glass suspended
5 within the plant shall be safety type or otherwise protected to prevent contamination in case of breakage. Lighting
6 intensities shall be a minimum of 25 ~~foot candles~~ foot-candles on working surfaces in packing and shucking ~~rooms.~~
7 rooms and a minimum of 10 foot-candles measured at a height of 30 inches above the floor throughout the rest of the
8 processing portion of the facility.

9 (b) Light bulbs, fixtures, or other glass within the plant shall be shatterproof or shielded to prevent food contamination
10 in case of breakage.

11

12 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

13 *Eff. February 1, ~~1987~~ 1987;*

14 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0409 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0409 VENTILATION**

4 Ventilation shall be provided to ~~eliminate~~prevent odors and ~~condensation~~condensation from contaminating shellfish,
5 food contact surfaces, or food packaging materials.

6

7 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

8 *Eff. February 1, ~~1987-1987;~~*

9 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0410 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0410 FLY-PEST CONTROL**

4 (a) All ~~outside-exterior~~ openings shall be ~~screened, screened~~ or provided with wind ~~curtains curtains~~, or be provided
5 with other fly control methods approved by the Division, to prevent the entrance of pests. All screens shall be kept in
6 good repair. All ~~outside-exterior~~ doors shall open outward and shall be self-closing.

7 (b) The use and storage of pesticides and rodenticides shall comply with all applicable ~~state-State~~ and federal
8 guidelines, laws and rules.

9 (c) No pets or other animals shall be allowed in those portions of the facility where shellfish, food handling equipment,
10 or packaging materials are stored, handled, processed, or packaged.

11

12 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

13 *Eff. February 1, ~~1987-1987;~~*

14 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0411 is proposed for repeal through readoption as follows:

2

3 **15A NCAC 18A .0411 RODENT AND ANIMAL CONTROL**

4

5 *History Note: Authority G.S. 130A-230;*

6 *Eff. February 1, ~~1987~~1987;*

7 *Repealed Eff. April 1, 2024.*

1 15A NCAC 18A .0412 is proposed for reoption with substantive changes as follows:

2

3 **15A NCAC 18A .0412 PLUMBING AND HAND WASHING FACILITIES**

4 (a) All plumbing shall be in compliance with applicable plumbing codes.

5 (b) Hand washing facilities shall be provided with running water at a minimum temperature of 100°F dispensed from
6 a hot and cold combination faucet.

7 (c) Hand washing facilities shall be provided in or adjacent to each bathroom and in shucking and packing rooms.
8 Hand washing facilities in packing areas shall be located where supervisors can observe employee use.

9 (d) Hand washing facilities shall be separate from three-compartment or other sinks used for cleaning equipment and
10 utensils.

11 (e) Soap, single service towels in protected dispensers, and an easily cleanable waste receptacle shall be available and
12 used at hand washing facilities. Other hand drying devices may be used if approved by the Division of Marine Fisheries
13 based upon being equally effective at drying hands without the potential for recontamination.

14

15 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

16 *Eff. February 1, ~~1987-1987;~~*

17 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0413 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0413 WATER SUPPLY**

4 ~~(a) The water supply shall be from a source approved by the Division.~~

5 ~~(b) The water supply used shall be located, constructed, maintained, and operated in accordance with the Commission~~
6 ~~for Public Health's rules governing water supplies. Copies of 15A NCAC 18A .1700 and 15A NCAC 18C may be~~
7 ~~obtained from the Division.~~

8 (a) The water supply used shall be in accordance with 15A NCAC 18A .1720 through .1728, 15A NCAC 18C, or 02
9 NCAC 09C .0703, which are incorporated by reference, including subsequent amendments.

10 (b) If the water supply is from a private source, samples for bacteriological analysis shall be collected by the Division
11 of Marine Fisheries prior to use and after the water supply has been repaired or disinfected, and submitted for analysis
12 to the State Laboratory of Public Health or other laboratory that is certified in accordance with 10A NCAC 42C .0102,
13 which is incorporated by reference, including subsequent amendments.

14 (c) Cross-connections with unapproved water supplies shall be prohibited. A backflow or back siphonage of a solid,
15 liquid, or gas containment into the water supply shall be precluded by use of an air gap or backflow prevention device
16 in accordance with applicable plumbing codes.

17 (d) Hot and cold running water under pressure shall be provided to food preparation, utensil, and hand washing areas
18 and any other areas in which water is required for cleaning. Running water under pressure shall be provided in
19 sufficient quantity to carry out all food preparation, utensil washing, hand washing, cleaning, and other water-using
20 operations.

21

22 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

23 *Eff. February 1, 1987;*

24 *Amended Eff. September 1, ~~1990~~1990;*

25 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0414 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0414 TOILET FACILITIES**

4 ~~Separate and convenient toilet facilities shall be provided for each sex employed and shall comply with the N.C. State~~
5 ~~Building Code, Volume 2, Plumbing. Floors, walls, and ceilings shall be smooth, easily cleanable and kept clean.~~
6 ~~Fixtures shall be kept clean. All toilet wastes and other sewage shall be disposed of in a public sewer system or in the~~
7 ~~absence of a public sewer system, by an on-site sewage disposal system approved by the Department in accordance~~
8 ~~with G.S. 130A-335.~~

9 (a) Toilets shall be provided in the plant by the owner or responsible individual and shall be kept clean and in good
10 repair.

11 (b) Toilet tissue, in a holder, shall be provided by the owner or responsible individual.

12 (c) Toilet room doors shall not open directly into a processing area and shall be tight-fitting and self-closing.

13 (d) All toilet wastes and other sewage shall be disposed of in accordance with 15A NCAC 18A .1900 or 15A NCAC
14 02H .0200, which are incorporated by reference, including subsequent amendments.

15

16 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

17 *Eff. February 1, 1987;*

18 *Amended Eff. September 1, ~~1990; 1990;~~*

19 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0415 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0415 ~~WASTE DISPOSAL~~PREMISES**

4 ~~Shells, washings, and other wastes shall be disposed of in a sanitary landfill or in a sanitary manner approved by the~~
5 ~~Division.~~

6 (a) The premises shall be maintained free from conditions that may constitute an attractant, breeding place, or
7 harborage for pests such as unmowed weeds or grass, uncontained litter or waste, or unused equipment.

8 (b) To prevent pests and odors, shells and other solid waste shall not be permitted to accumulate on the premises.

9

10 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

11 *Eff. February 1, ~~1987.~~1987;*

12 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0416 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0416 PERSONAL HYGIENE**

4 (a) All employees shall wash their hands thoroughly with soap and running water before beginning work and again
5 after each ~~interruption~~-interruption or if their hands may have become soiled or contaminated. Signs to this effect
6 shall be posted in conspicuous places in the plant by the operator. Hand washing signs shall be posted by the owner or
7 responsible individual at each hand washing facility in a language understood by employees.

8 ~~(b) All persons handling shucked shellfish shall sanitize their hands before beginning work and again after each~~
9 ~~interruption.~~

10 ~~(c)~~(b) All ~~persons~~-individuals employed or engaged in the ~~handling, shucking, or packing~~-packing, or repacking of
11 shellfish shall wear clean, washable outer clothing. Clean plastic or rubber aprons, overalls, and rubber gloves shall
12 be considered satisfactory.

13 (c) All individuals employed or engaged in the shucking, packing, or repacking of shellfish shall wear hair restraints
14 and have clean fingernails free from nail polish and that are short enough to not extend past the fingertips. Employees
15 shall not wear jewelry other than easily cleanable rings. The use of absorbent wraps or absorbent finger cots shall not
16 be permitted.

17 (d) Employees shall not eat, drink, use electronic cigarettes or vaping products, or use tobacco in any form in the
18 rooms where shellfish are stored, processed, or handled.

19 ~~(e) All persons~~-An individual known to be a carrier of any disease ~~which that~~ can be transmitted through the handling
20 of shellfish or who ~~have~~-has an infected wound or open lesion on any exposed portion of ~~their bodies~~-the body shall
21 be prohibited from handling ~~shellfish~~-shellfish or coming into contact with food contact surfaces.

22

23 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

24 *Eff. February 1, ~~1987~~-1987;*

25 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0417 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0417 ~~LOCKER~~EMPLOYEES' PERSONAL ARTICLES**

4 ~~A separate room or locker shall be provided for storing employees' street clothing, aprons, gloves, and personal~~
5 ~~articles. Employees' street clothing, aprons, gloves, food, drink, and personal articles shall be stored in a room or~~
6 ~~locker separate from any area where shellfish are shucked or packed or any area that is used for the cleaning or storage~~
7 ~~of utensils.~~

8

9 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

10 *Eff. February 1, ~~1987~~1987;*

11 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0418 is proposed for reoption with substantive changes as follows:

2

3 **15A NCAC 18A .0418 SUPPLY STORAGE**

4 ~~(a) Storage room shall be provided for storing shipping containers, tags, and other supplies. Shipping containers,~~
5 boxes, and other supplies shall be stored in a storage room or area. The storage room or area shall be kept clean.

6 (b) Pesticides, rodenticides, chemical agents, sanitizers, and other toxic substances shall be stored separate from
7 processing areas or food contact surfaces. Each of the following categories of toxic substances shall be stored separate
8 from one another:

9 (1) pesticides and rodenticides;

10 (2) detergents, sanitizers, and cleaning agents; and

11 (3) caustic acids, polishes, and other chemicals.

12 (c) Cleaning compounds, sanitizers, and other toxic substances shall be labeled and used in accordance with the
13 manufacturer's label directions.

14

15 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

16 *Eff. February 1, ~~1987-1987;~~*

17 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0419 is proposed for reoption with substantive changes as follows:

2

3 **15A NCAC 18A .0419 HARVEST ~~BOATS~~VESSELS AND VEHICLES**

4 ~~All boats used in the harvesting and handling of shellstock shall be kept clean and repaired such that the shellstock~~
5 ~~thereon shall not be subject to adulteration by bilge water, by leakage of water from prohibited areas, or by other~~
6 ~~means. Decks, holds, or bins used for shellstock on boats shall not be washed with water from prohibited areas. Human~~
7 ~~wastes shall not be discharged into shellfish waters.~~

8 (a) It shall be unlawful to use vessels or vehicles that are engaged in the commercial harvest, handling, or transport
9 of shellstock in such a manner that allows contact of shellstock with bilge water, standing water, or other sources of
10 contamination in the vessel or vehicle.

11 (b) It shall be unlawful to allow dogs or other animals on or inside vessels or vehicles that are engaged in the
12 commercial harvest or transport of shellstock.

13 (c) It shall be unlawful to discharge human waste overboard from vessels or vehicles used in the harvesting of
14 shellstock.

15

16 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

17 *Eff. February 1, ~~1987-1987;~~*

18 *Readopted Eff. (Pending legislative review pursuant to S.L. 2019-198).*

1 15A NCAC 18A .0420 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0420 TRANSPORTING SHELLSTOCKSHELLFISH**

4 (a) All ~~shellstock shellfish~~ storage areas in trucks, ~~buy boats, buy trucks, vessels,~~ trailers, and other conveyances used
5 for transporting ~~shellstock shellfish~~ shall be enclosed, tightly constructed, ~~painted with a light color washable paint,~~
6 kept clean, and shall be subject to inspection by the ~~Division.~~ Division of Marine Fisheries.

7 (b) ~~Shellstock shall be shipped under temperature and sanitary conditions in accordance with these Rules which will~~
8 ~~keep them alive and clean and will prevent adulteration or deterioration. All shellstock shall be kept under mechanical~~
9 ~~refrigeration at a temperature of 45°F (7.1°C) or below. All conveyances used to transport shellstock shall be equipped~~
10 ~~with an operating thermometer. It shall be unlawful to transport shellstock and in-shell product unless shipped under~~
11 ~~mechanical refrigeration and the shipping conveyance is pre-chilled and maintained at an ambient temperature of 45°F~~
12 ~~or below. The storage area of the shipping conveyance shall be equipped with an accurate, operating thermometer.~~

13 (c) ~~Buy boats and buy trucks shall be kept clean with water from a source approved by the Division under Rule .0413~~
14 ~~of this Subchapter. Buy boats and buy trucks shall provide storage space for clean shipping containers, identification~~
15 ~~tags, and records. It shall be unlawful to transport shucked shellfish unless maintained under temperature control of~~
16 ~~45°F or below.~~

17

18 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

19 *Eff. February 1, 1987;*

20 *Amended Eff. May 1, ~~1994-1994;~~*

21 *Readopted Eff. (Pending legislative review pursuant to S.L. 2019-198).*

1 15A NCAC 18A .0421 is proposed for readoption with substantive changes as follows:

2
3 **15A NCAC 18A .0421 ~~DAILY RECORD~~RECORDS**

4 (a) All ~~permitted persons shellfish dealers~~ who conduct any business of buying, selling, or shipping shellfish shall
5 keep an accurate, daily record ~~which that~~ shall show the names ~~and addresses~~ of all persons from whom shellfish are
6 received, ~~the address of any shellfish dealer from whom shellfish are received,~~ the location of the source of shellfish,
7 and the names and addresses of all persons to whom shellfish are sold or ~~shipped,~~ shipped with the exception of retail
8 sales. These records ~~shall be recorded and~~ shall be kept on file for a minimum of one year, ~~year for fresh shellfish,~~
9 and a minimum of two years for frozen shellfish. All records shall be open to inspection by the Division of Marine
10 Fisheries at the dealer facility at any time during business hours.

11 (b) All shellfish dealers who receive shellstock from licensed harvesters shall record the following information at the
12 time of receipt:

- 13 (1) harvester name;
14 (2) harvest area;
15 (3) time of the start of harvest;
16 (4) quantity and type of shellfish received;
17 (5) time shellfish were received; and
18 (6) time shellfish were mechanically refrigerated.

19 (c) Each shellfish shipment shipped by a shellfish dealer shall be accompanied by a shipping document that includes:

- 20 (1) name, address, and certification number of shipping dealer;
21 (2) name and address of major consignee;
22 (3) type and quantity of shellfish product;
23 (4) date and time of shipment;
24 (5) documentation that shipping conveyance is pre-chilled at 45°F or below prior to shipment; and
25 (6) temperature of shellstock recorded by shipping dealer at time of shipment.

26 (d) A dealer receiving a shellfish shipment from another shellfish dealer shall record the temperature of the shipping
27 conveyance and the temperature of the shellfish product received. These records shall be kept on file for a minimum
28 of one year for fresh shellfish, and a minimum of two years for frozen shellfish. All records shall be open to inspection
29 by the Division at the dealer facility at any time during business hours.

30 (e) Within 72 hours of any purchase or sale of shellfish, each purchase or sale shall be entered into a permanently
31 bound ledger book, computer record, or any other method that permanently records the information and is organized
32 so that it can be reviewed by the Division.

33
34 *History Note:* Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~

35 Eff. February 1, 1987;

36 Amended Eff. August 1, ~~1998-1998;~~

37 Readopted Eff. April 1, 2024.

1 15A NCAC 18A .0422 is proposed for reoption with substantive changes as follows:

2

3 **15A NCAC 18A .0422 SHELLSTOCK CLEANING**

4 No person shall offer for sale any shellstock ~~which~~ that have not been washed free of ~~bottom harvest area~~ sediments
5 and detritus. Water used for shellstock washing shall be obtained from a water source in accordance with Rule .0413
6 of this Section or from a growing area in the open status and classified as "approved" or "conditionally approved" as
7 defined in Rule .0901 of this Subchapter.

8

9 *History Note:* Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~

10 Eff. February 1, ~~1987-1987;~~

11 Readopted Eff. April 1, 2024.

1 15A NCAC 18A .0423 is proposed for readoption without substantive changes as follows:

2

3 **15A NCAC 18A .0423 SALE OF LIVE SHELLSTOCK**

4 Only live shellstock shall be offered for sale.

5

6 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

7 *Eff. February 1, ~~1987-1987;~~*

8 *Readopted Eff. April 1, 2024.*

9

1 15A NCAC 18A .0424 is proposed for reoption with substantive changes as follows:

2

3 **15A NCAC 18A .0424 SHELLFISH RECEIVING**

4 No ~~person shellfish dealer~~ shall receive or ~~accept~~-accept:

5 (1) any ~~shellfish~~ shellstock from:

6 (a) a licensed shellfish harvester ~~unless~~-unless:

7 (i) the container or package bears the harvest tag or label required by these Rules, as
8 required in Rule 15A NCAC 03K .0109 and in accordance with the HACCP plan;

9 and

10 (ii) the shellstock was harvested from a growing area in the open status and classified
11 as "approved" or "conditionally approved" as defined in Rule .0901 of this
12 Subchapter and as indicated on the harvest tag; or

13 (b) another shellfish dealer unless the container or package bears the tag as required in Rule
14 .0425 of this Section or, in the case of a bulk shipment, Rule .0426 of this Section; and

15 (2) any shellfish from another shellfish dealer unless:

16 (a) it is accompanied by the documentation required in Rule .0421(c) of this Section; and

17 (b) the shellfish temperature and other critical limits are in compliance with the HACCP plan.

18

19 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

20 *Eff. February 1, 1987;*

21 *Amended Eff. April 1, ~~1997~~.1997;*

22 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0426 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0426 BULK SHIPMENTS BETWEEN SHELLFISH DEALERS**

4 (a) For the purpose of this Rule:

5 (1) "bulk shipment" shall mean a shipment of a shellstock lot between shellfish dealers.

6 (2) "shellstock lot" shall mean a single type of bulk shellstock or containers of shellstock of no more
7 than one day's harvest from a single growing area harvested by one or more harvesters.

8 ~~(b) Shipment in bulk~~ Bulk shipments shall not be made except ~~where~~ if the shipment is from only one consignor to
9 one consignee and accompanied by the uniform shipping tag-consignee, both of which shall be shellfish dealers.

10 (c) When a shellstock lot is shipped, if multiple containers are used they shall be on a wrapped pallet, in a tote, in a
11 net bailer, or other container and the unit shall be tagged with a single tag in accordance with Rule .0425 of this
12 Section. The single tag shall also include a statement that "All shellstock containers in this lot have the same harvest
13 date and area of harvest" and shall include the number of individual containers in the unit.

14 (d) The shellfish dealer shall provide a transaction record that accompanies the bulk shipment that contains the same
15 information required on a dealer's tag in Rule .0425 of this Section and additionally states the name of the consignee,
16 which shall be a shellfish dealer.

17 (e) Bulk shipments shall be kept above the floor using pallets to prevent the shellstock from becoming contaminated,
18 unless the shipping conveyance has a channeled floor.

19

20 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

21 *Eff. February 1, ~~1987~~1987;*

22 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0427 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0427 SHELLSTOCK ~~SHELLFISH~~ STORAGE**

4 ~~Shellstock held in wet or dry storage must be kept so that they will not become adulterated. All shellstock held in dry~~
5 ~~storage shall be kept under mechanical refrigeration at a temperature of 45°F (7.1°C) or below. All refrigerated~~
6 ~~shellstock storage areas shall be equipped with an operating thermometer.~~

7 (a) It shall be unlawful to fail to keep shellstock and in-shell product under mechanical refrigeration at a temperature
8 of 45°F or below unless otherwise required by proclamation issued under the authority of Rule 15A NCAC 03K .0110
9 or otherwise specified in the HACCP plan.

10 (b) Refrigerated storage areas shall be equipped with an accurate, operating thermometer.

11 (c) It shall be unlawful to fail to keep shucked shellfish under temperature control at a temperature of 45°F or below.

12

13 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

14 *Eff. February 1, 1987;*

15 *Amended Eff. May 1, 1994; December 1, ~~1987, 1987;~~*

16 *Readopted Eff. (Pending legislative review pursuant to S.L. 2019-198).*

1 15A NCAC 18A .0428 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0428 SAMPLING AND TESTING**

4 Samples of shellfish may be taken and ~~bacteriologically~~ examined for any public health reason under the authority of
5 the Marine Fisheries Commission by agents of the Division of Marine Fisheries at any time or place. This may include
6 bacteriological examination or analysis for poisonous or deleterious substances as listed in the latest approved edition
7 of the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish, Section IV:
8 Guidance Documents, Chapter II: Growing Areas; Action Levels, Tolerances and Guidance Levels for Poisonous or
9 Deleterious Substances in Seafood, which is incorporated by reference, including subsequent amendments and
10 editions. A copy of the reference material can be found at [https://www.fda.gov/food/federalstate-food-](https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp)
11 programs/national-shellfish-sanitation-program-nssp, at no cost. Samples of shellfish shall be furnished, upon ~~request,~~
12 request of the Division, by operators of plants, trucks, carriers, stores, restaurants, and other places where shellfish are
13 sold.

14

15 *History Note:* Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~

16 Eff. February 1, 1987-1987;

17 Readopted Eff. April 1, 2024.

1 15A NCAC 18A .0429 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0429 ~~STOPSALE~~ EMBARGO OR DISPOSAL OF SHELLFISH**

4 (a) When it has been determined by the Division of Marine Fisheries that shellfish have not been grown, harvested,
5 stored, treated, transported, handled, shucked, ~~packed~~ packed, or offered for sale in compliance with ~~15A NCAC 18A~~
6 Sections .0300 through .0900 of this Subchapter, those shellfish shall ~~may~~ be deemed ~~adulterated~~ adulterated in
7 accordance with Rule .0438 of this Section, except as required in Rules .0405 and .0430 of this Section.

8 (b) Shellfish or shellfish products processed or prepared for sale to the public determined to be adulterated or
9 misbranded shall be subject to ~~stopsale or disposal by the Division. The Division may temporarily or permanently~~
10 ~~issue an order to stop sale or condemn, destroy, or otherwise dispose of all shellfish or shellfish containers found to~~
11 ~~be adulterated or misbranded.~~ embargo or disposal by the Division in accordance with G.S. 113-221.4. The authority
12 of marine fisheries inspectors to seize shellfish or shellfish products pursuant to G.S. 113-137 shall not be affected by
13 this Rule.

14 ~~(c) All shellfish shall be disposed of in a manner prescribed by the Division or by a court of appropriate jurisdiction.~~

15 (c) If voluntary disposal of adulterated or misbranded shellfish or shellfish products is alternatively chosen by the
16 shellfish dealer, responsible individual, or other person or facility specified in Rule .0401 of this Section, the product
17 disposal shall be observed by a Division employee.

18

19 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 113-221.4; 143B-289.52;~~*
20 *Eff. February 1, ~~1987~~ 1987;*
21 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0430 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0430 BACTERIOLOGICAL AND CONTAMINATION STANDARDS**

4 Shellfish shucked or in the shell and intended or offered for sale ~~in North Carolina that exceed an Escherichia coli~~
5 ~~Most Probable Number of 230 per 100 grams of sample or a total bacteria count of more than 500,000 per gram or~~
6 ~~contain pathogenic organisms in sufficient numbers to be hazardous to the public health shall be deemed adulterated~~
7 ~~by the Division. Shellfish contaminated by any other substance which renders it unsafe for human consumption shall~~
8 ~~be deemed adulterated by the Division.~~ shall be deemed adulterated by the Division of Marine Fisheries if:

9 (1) the concentration of Escherichia coli exceeds a Most Probable Number (MPN), as defined in Rule

10 .0901 of this Subchapter, of 230 per 100 grams of sample;

11 (2) the total bacteria count, as determined by a standard plate count, exceeds 500,000 colony-forming
12 units, as defined in Rule .0901 of this Subchapter; or

13 (3) the shellfish contain any contaminant that renders it unsafe for human consumption in accordance
14 with the latest approved edition of the National Shellfish Sanitation Program (NSSP) Guide for the
15 Control of Molluscan Shellfish, Section IV: Guidance Documents, Chapter II: Growing Areas;
16 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in
17 Seafood, which is incorporated by reference, including subsequent amendments and editions. A
18 copy of the reference material can be found at [https://www.fda.gov/food/federalstate-food-](https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp)
19 programs/national-shellfish-sanitation-program-nssp, at no cost.

20

21 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

22 *Eff. February 1, ~~1987-1987;~~*

23 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0432 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0432 PUBLIC DISPLAY OF CONSUMER ADVISORY**

4 All ~~facilities and persons~~ shellfish dealers permitted ~~in~~ by Rule .0302 of this Subchapter and all other businesses and
5 persons that sell or serve raw shellfish shall post one of the following consumer advisories or an equivalent statement
6 in a conspicuous place where it may be readily observed by the public ~~the following consumer advisory:~~ in the area
7 where raw shellfish is sold or served:

8 (1) "Consumer Advisory

9 Eating raw or undercooked oysters, ~~clams-clams,~~ whole scallops, or mussels
10 may cause severe illness. People with the following conditions are at
11 especially high risk: liver disease, alcoholism, diabetes, cancer, stomach or
12 blood disorder, or weakened immune system. Ask your doctor if you are
13 unsure of your risk. If you eat shellfish and become sick, see a doctor
14 ~~immediately."~~ immediately."; or

15 (2) "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs
16 may increase your risk of foodborne illness, especially if you have certain
17 medical conditions."

18 Nothing in this Rule is intended to supersede regulation of restaurants or other establishments subject to 15A
19 NCAC 18A Section .2600 or the U.S. Food Code.

20

21 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

22 *Temporary Adoption Eff. October 12, 1998; February 1, 1998;*

23 *Eff. April 1, ~~1999-1999;~~*

24 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0433 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0433 HAZARD ANALYSIS**

4 Each shellfish dealer shall conduct a hazard analysis to determine the food safety hazards that are reasonably likely to
5 occur for each kind of shellfish product processed by that dealer and to identify the preventative measures that the
6 dealer can apply to control those hazards. For the purpose of this Rule, "reasonably likely to occur" shall mean a food
7 safety hazard for which a processor would establish controls because experience, illness data, scientific reports, or
8 other information provide a basis to conclude that there is a reasonable possibility that it will occur in the absence of
9 those controls, as defined in 21 CFR 123.6, which is incorporated by reference, including subsequent amendments
10 and editions. A copy of the reference material can be found at [https://www.ecfr.gov/current/title-21/chapter-
11 1/subchapter-B/part-123](https://www.ecfr.gov/current/title-21/chapter-1/subchapter-B/part-123), at no cost.

12

13 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

14 *Eff. August 1, ~~2000; 2000;~~*

15 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0434 is proposed for readoption with substantive changes as follows:

2
3 **15A NCAC 18A .0434 HACCP PLAN**

4 (a) Each shellfish dealer shall have and implement a written HACCP Plan—plan specific to each kind of shellfish
5 product processed. The owner or authorized designee—individual shall sign the plan when implemented and after any
6 modification—implemented, which shall signify that the plan has been accepted for implementation by the dealer. The
7 HACCP plan shall also be signed by the owner or authorized individual after any modification or verification of the
8 plan as required by this Rule. The plan shall be reviewed and updated, if necessary, at least annually.—The plan shall,
9 at a minimum:

- 10 (1) ~~List—list~~ the food safety hazards that are reasonably likely to occur;
- 11 (2) ~~List—list~~ the critical control points for each of the food safety hazards;
- 12 (3) ~~List—list~~ the critical limits that must be met for each of the critical control points;
- 13 (4) ~~List—list~~ the procedures, and frequency thereof, that will be used to monitor each of the critical
14 control points to ensure compliance with the critical limits;
- 15 (5) ~~List—list~~ any corrective action plans to be followed in response to deviations from critical limits at
16 critical control points;
- 17 (6) ~~Provide—provide~~ a record keeping system that documents critical control point monitoring; and
- 18 (7) ~~List—list~~ the verification procedures, and frequency thereof, that the dealer will use.

19 For the purpose of this Rule, "reasonably likely to occur" shall mean a food safety hazard for which a processor would
20 establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude
21 that there is a reasonable possibility that it will occur in the absence of those controls, as defined in 21 CFR 123.6,
22 which is incorporated by reference, including subsequent amendments and editions. A copy of the reference material
23 can be found at <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-123>, at no cost.

24 (b) With the exception of a shellfish dealer that has not been permitted for interstate commerce, the following
25 functions shall be performed by an individual who has successfully completed training in the application of HACCP
26 principles to shellfish processing:

- 27 (1) developing a HACCP plan;
- 28 (2) reassessing and modifying the HACCP plan; and
- 29 (3) performing the record review specified in Paragraph (d) of this Rule.

30 (c) If a deviation from a critical limit occurs, the shellfish dealer shall take corrective action in accordance with 21
31 CFR 123.7, which is incorporated by reference, including subsequent amendments and editions. A copy of the
32 reference material can be found at [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-123/subpart-](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-123/subpart-A/section-123.7#p-123.7(b))
33 A/section-123.7#p-123.7(b), at no cost.

34 (d) At least annually, each shellfish dealer shall verify that the HACCP plan is being implemented to control food
35 safety hazards. Verification procedures shall include:

- 36 (1) a reassessment of the plan when a change occurs that could affect the hazard analysis, and a review
37 of any consumer complaints that have been received; and

1 (2) a review, including signing and dating by the trained individual or responsible individual, of the
2 records that document the monitoring of critical control points, the taking of corrective actions, and
3 the calibrating of any process-monitoring instruments. This review shall occur within one week of
4 the day that the records are made.

5 (e) All records required by this Rule shall be retained at the dealer facility for at least one year after the date they were
6 prepared in the case of refrigerated products, and at least two years after the date they were prepared in the case of
7 frozen products and shall include:

8 (1) the name and location of the dealer;

9 (2) the date and time of the activity that the record reflects;

10 (3) the signature or initials of the individual performing the operation; and

11 (4) the identity of the product and the production code, if any.

12

13 History Note: Authority G.S. ~~130A-230~~; 113-134; 113-182; 113-221.2; 113-221.4; 143B-289.52;

14 Eff. August 1, ~~2000~~-2000;

15 Readopted Eff. April 1, 2024.

1 15A NCAC 18A .0435 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0435 SANITATION MONITORING REQUIREMENTS**

4 (a) Each shellfish dealer shall monitor, at a minimum, monitor the following sanitation ~~items~~items when the plant is
5 operational:

- 6 (1) ~~Safety~~safety of water;
- 7 (2) ~~Condition~~condition and cleanliness of food contact surfaces;
- 8 (3) ~~Prevention~~prevention of cross-contamination~~;cross-contamination~~;
- 9 (4) ~~Maintenance~~maintenance of hand washing, hand ~~sanitizing~~sanitizing, and toilet facilities;
- 10 (5) ~~Protection~~protection of shellfish, shellfish packaging ~~materials~~materials, and food contact surfaces
11 from adulteration~~;becoming adulterated~~;
- 12 (6) ~~Proper~~proper labeling, ~~storage~~storage, and use of toxic compounds;
- 13 (7) ~~Control~~control of employees with adverse health conditions; and
- 14 (8) ~~Exclusion~~exclusion of pests from the facility.

15 (b) Monitoring records of these sanitation items shall be recorded at least daily and shall include the date and time of
16 the activity that the record reflects, and the signature or initials of the individual performing the operation. The records
17 shall be reviewed and signed by the owner or designated individual within one week of recording.

18

19 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*
20 *Eff. August 1, ~~2000~~2000;*
21 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0436 is proposed for repeal through readoption as follows:

2

3 **15A NCAC 18A .0436 MONITORING RECORDS**

4

5 *History Note: Authority G.S. 130A-230;*

6 *Eff. August 1, ~~2002~~2002;*

7 *Repealed Eff. April 1, 2024.*

1 15A NCAC 18A .0437 is proposed for adoption as follows:

2
3 **15A NCAC 18A .0437 IN-SHELL PRODUCT**

4 (a) In-shell product shall be kept under mechanical refrigeration at a temperature of 45°F or below.

5 (b) In-shell product shall be tagged or labeled to contain the following indelible and legible information listed in
6 sequential order:

7 (1) the shellfish dealer's name, address, and certification number assigned by the shellfish control
8 agency in the state of the shellfish dealer's location;

9 (2) the original shipper's certification number, except if the in-shell product is deperated, the original
10 shipper's certification number is not required;

11 (3) a "SELL BY DATE" that indicates the shelf-life or the words "BEST IF USED BY" followed by a
12 date when the product would be expected to reach the end of its shelf-life. The date shall include
13 month, day, and year;

14 (4) if the in-shell product is deperated, the deperation cycle number or lot number;

15 (5) the most precise identification of the harvest location as is practicable, including the initials of the
16 state of harvest, and the state or local shellfish control authority's designation of the growing area
17 by indexing, administrative, or geographic designation. If the authority in another state has not
18 indexed growing areas, then a geographical or administrative designation shall be used (e.g., Long
19 Bay, shellfish lease or franchise number, or lot number);

20 (6) the type and quantity of in-shell product; and

21 (7) the following statement in bold type on each tag or label: "THIS TAG IS REQUIRED TO BE
22 ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT
23 ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS." "RETAILERS: DATE WHEN
24 LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT
25 DATE) _____." OR "THIS LABEL IS REQUIRED TO BE ATTACHED UNTIL
26 CONTAINER IS EMPTY OR IS RELABELED AND THEREAFTER KEPT ON FILE, IN
27 CHRONOLOGICAL ORDER, FOR 90 DAYS." "RETAILERS: DATE WHEN LAST
28 SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE) _____."

29 (c) In-shell product shall include one of the following consumer advisories, or equivalent statement:

30 (1) "Consumer Advisory

31 Eating raw or undercooked oysters, clams, whole scallops, or mussels may cause severe illness.
32 People with the following conditions are at especially high risk: liver disease, alcoholism, diabetes,
33 cancer, stomach or blood disorder, or weakened immune system. Ask your doctor if you are unsure
34 of your risk. If you eat shellfish and become sick, see a doctor immediately."

35 (2) "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk
36 of foodborne illness, especially if you have certain medical conditions."

37 (d) The statement "Keep Refrigerated" or an equivalent statement shall be included on the tag or label.

1 (e) If in-shell product for retail sale is packed in individual containers of five pounds or less and shipped in a master
2 container that includes a tag in compliance with Paragraph (b) of this Rule, the individual containers of five pounds
3 or less shall not require tags as specified in Paragraph (b) of this Rule if a lot code number is included on each container
4 that allows traceback of the in-shell product to the master container. A consumer advisory shall be included on each
5 retail package in accordance with Paragraph (c) of this Rule.

6
7 History Note: Authority G.S. 113-134; 113-182; 113-221.2; 143B-289.52;

8 Adopted Eff. April 1, 2024.

1 15A NCAC 18A .0438 is proposed for adoption as follows:

2
3 **15A NCAC 18A .0438 INSPECTIONS AND COMPLIANCE SCHEDULE**

4 (a) If a critical deficiency is detected during an inspection of a shellfish dealer by a Division of Marine Fisheries
5 inspector:

6 (1) the deficiency shall be corrected by the shellfish dealer during that inspection; or

7 (2) the shellfish dealer shall immediately cease production affected by the deficiency.

8 If the shellfish dealer fails to correct the deficiency during the inspection, the Division shall initiate the suspension or
9 revocation process for the Shellfish Dealer Permit and Certificate of Compliance as set forth in 15A NCAC 03O .0504.

10 For the purpose of this Rule, "critical deficiency" shall mean a condition or practice that results in the production of a
11 shellfish product that is adulterated or presents a threat to the health or safety of the consumer.

12 (b) Shellfish products affected by a critical deficiency shall be controlled to prevent adulterated product from reaching
13 consumers. The Division shall:

14 (1) embargo or destroy adulterated shellfish in accordance with 15A NCAC 18A .0429;

15 (2) initiate a recall of adulterated shellfish; and

16 (3) notify enforcement officials for the United States Food and Drug Administration, as well as shellfish
17 control authorities in states that are known to have received adulterated shellfish.

18 (c) If a key or other deficiency is detected during an inspection of a shellfish dealer by a Division inspector, a
19 compliance schedule shall be issued by the Division inspector that provides a time frame by which the deficiency shall
20 be corrected by the shellfish dealer. For the purpose of this Rule, "key or other deficiency" shall mean a deficiency
21 other than a critical deficiency.

22 (d) If a shellfish dealer fails to meet the compliance schedule, the Division shall proceed with one of the following
23 options:

24 (1) revise the existing compliance schedule;

25 (2) initiate the suspension or revocation process for the Shellfish Dealer Permit and Certificate of
26 Compliance as set forth in 15A NCAC 03O .0504; or

27 (3) seek other administrative remedies.

28 (e) Nothing in this Rule shall be construed to limit or make null any option for remedy in accordance with Rule 15A
29 NCAC 03O .0504 or other available administrative remedy.

30
31 History Note: Authority G.S. 113-134; 113-182; 113-221.2; 113-221.4; 143B-289.52;

32 Adopted Eff. April 1, 2024.

1 15A NCAC 18A .0439 is proposed for adoption as follows:

2

3 **15A NCAC 18A .0439 RECALL PROCEDURE**

4 Each shellfish dealer shall adopt and adhere to a written procedure for conducting recalls of adulterated or misbranded
5 shellfish products. This written procedure shall be based on, and complementary to, the FDA Enforcement Policy on
6 Recalls, CFR Title 21, Chapter 1, Subchapter A., Part 7-Enforcement Policy. This procedure shall include shellfish
7 dealers notifying the Division of Marine Fisheries and any consignee receiving affected product when a recall begins,
8 as well as removal or correction of the affected product.

9

10 *History Note:* Authority G.S. 113-134; 113-182; 113-221.2; 143B-289.52;

11 Adopted Eff. April 1, 2024.

1 15A NCAC 18A .0501 is proposed for readoption with substantive changes as follows:

2

3

SECTION .0500 - OPERATION OF SHELLSTOCK PLANTS AND RESHIPPERS

4

5 ~~Rules .0501—.0504 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18A~~
6 ~~.0501—.0504); has been transferred and recodified from Rules .1001—.1004 of Title 10 Subchapter 10B of the North~~
7 ~~Carolina Administrative Code (T10.10B .1001—.1004), effective April 4, 1990.~~

8

9 **15A NCAC 18A .0501 ~~GENERAL REQUIREMENTS~~ FOR SHELLSTOCK PLANTS AND RESHIPPERS**

10 The rules in Section .0400 and the Rules of this Section shall apply for the operation of shellstock plants and reshippers.

11

12 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

13 *Eff. February 1, ~~1987-1987;~~*

14 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0502 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0502 GRADING SHELLSTOCK AND COMMINGLING**

4 (a) For the purpose of this Rule:

5 (1) "commingling" shall mean the act of combining different lots of shellfish harvested on different
6 days in the same growing area or combining different lots of shellstock harvested from different
7 growing areas.

8 (2) "lot" shall mean clams from one day's harvest, from a single growing area, harvested by one or more
9 harvesters.

10 ~~(a)(b)~~ The grading of shellstock by a shellfish dealer shall be conducted only in a permitted shellstock plant.

11 ~~(b)(c)~~ A ~~separate~~ grading room or area separate from other processing operations shall be required for the grading of
12 shellstock.

13 (d) The grader used to grade shellstock, and any other accessories or tables used in the grading operation, shall be
14 constructed to be easily cleanable and shall be kept in good repair.

15 (e) Shellfish dealers shall not commingle any shellfish, except for clams with prior approval of a commingling plan
16 by the Division of Marine Fisheries. A commingling plan shall be approved by the Division based on limiting the
17 dates of harvest and growing areas and maintaining lot identity so that each individual lot of shellfish can be traced
18 back to its harvest source.

19

20 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

21 *Eff. February 1, ~~1987~~1987;*

22 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0503 is proposed for repeal through readoption as follows:

2

3 **15A NCAC 18A .0503 GRADER**

4

5 *History Note: Authority G.S. 130A-230;*

6 *Eff. February 1, ~~1987~~1987;*

7 *Repealed Eff. April 1, 2024.*

1 15A NCAC 18A .0504 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0504 RESHIPPERS**

4 ~~(a) Reshippers shall meet all applicable requirements for shellstock plants. When shucked shellfish are reshipped,~~
5 ~~they shall be obtained from a permitted shipper. The shucked shellfish shall be received in approved shipping~~
6 ~~containers at a temperature of 40°F (4°C) or below. The temperature of the shellfish shall not exceed 40°F (4°C)~~
7 ~~during the holding and shipping periods.~~

8 ~~(b) Reshippers shall keep adequate and accurate records indicating the source from which shellfish were purchased,~~
9 ~~the date purchased, the name of the waters from which the shellfish were harvested, and the names and addresses of~~
10 ~~persons to whom the shellfish were sold for a period of one year.~~

11 Reshippers shall only purchase shellfish from other shellfish dealers and sell the product to other shellfish dealers,
12 wholesalers, or retailers without repacking or relabeling.

13

14 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

15 *Eff. February 1, 1987;*

16 *Amended Eff. September 1, ~~1990~~1990;*

17 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0601 is proposed for re adoption with substantive changes as follows:

2

3 **SECTION .0600 - OPERATION OF SHELLFISH SHUCKING AND PACKING PLANTS AND**
 4 **REPACKING PLANTS**

5

6 ~~Rules .0601—.0619 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18A~~
 7 ~~.0601—.0619); has been transferred and recodified from Rules .1101—.1119 of Title 10 Subchapter 10B of the North~~
 8 ~~Carolina Administrative Code (T10.10B .1101—.1119), effective April 4, 1990.~~

9

10 **15A NCAC 18A .0601 ~~GENERAL REQUIREMENTS~~ FOR SHUCKING AND PACKING PLANTS AND**
 11 **REPACKING PLANTS**

12 The rules in Section .0400 and the Rules of this Section shall apply for the operation of shucking and packing plants
 13 and repacking plants.

14

15 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

16 *Eff. February 1, ~~1987-1987;~~*

17 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0602 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0602 SEPARATION OF OPERATIONS**

4 A shucking and packing plant shall provide separate ~~rooms~~ areas for shellstock storage, shucking, heat shock, and
5 general storage. A ~~separate packing area with delivery shelf~~ that is separate from other processing areas and with a
6 delivery window or shelf as set forth in Rule .0605 of this Section shall be required.

7

8 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

9 *Eff. February 1, ~~1987-1987;~~*

10 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0603 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0603 HOT WATER SYSTEM**

4 An automatically regulated hot water system shall be provided ~~which~~that has ~~sufficient~~ capacity to furnish water at a
5 temperature of at least 130°F (~~54°C~~) during all hours of shucking and packing plant operation.

6

7 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

8 *Eff. February 1, ~~1987-1987;~~*

9 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0604 is proposed for repeal through readoption as follows:

2

3 ~~15A NCAC 18A .0604 — HANDWASHING FACILITIES~~

4

5 *History Note: Authority G.S. 130A-230;*

6 *Eff. February 1, ~~1987~~1987;*

7 *Repealed Eff. April 1, 2024.*

1 15A NCAC 18A .0605 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0605 DELIVERY WINDOW OR SHELF**

4 (a) A delivery window or a non-corrosive shelf shall be installed in the partition between the shucking room area and
5 packing area. No shuckers or unauthorized personnel shall be allowed in the packing room or area. The
6 If a delivery window is used it shall be equipped with a shelf completely covered with smooth, non-corrosive metal or other
7 impervious material approved by the Division for such purpose, and shall be sloped to drain towards the shucking
8 room area.

9 (b) No shuckers or individuals that are not designated as packers by the owner or responsible individual shall be
10 allowed in the packing area.

11

12 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

13 *Eff. February 1, ~~1987~~1987;*

14 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0606 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0606 NON-FOOD CONTACT SURFACES**

4 All non-food contact surfaces of equipment such as cabinets and shelving shall be ~~non-absorbent, impervious~~ and
5 constructed to be easily ~~cleaned~~ cleanable.

6

7 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

8 *Eff. February 1, ~~1987-1987;~~*

9 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0607 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0607 SHUCKING BENCHES**

4 Shucking benches, tables, and contiguous walls to a height of at least two feet above the bench top, shall be of smooth
5 concrete, non-corrosive metal, or other durable ~~non-absorbent~~ impervious material, free from cracks and pits, and ~~so~~
6 constructed so that drainage is complete and rapid and is directed away from the stored shellfish. Shucking blocks
7 shall be solid, one-piece construction, removable, and easily cleanable. The stands, ~~stalls~~ stalls, and stools shall be of
8 smooth material and shall be painted with a ~~light-colored~~ light-colored washable paint, such as white in color,
9 so that unclean surfaces can be detected.

10

11 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

12 *Eff. February 1, ~~1987~~ 1987;*

13 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0608 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0608 EQUIPMENT CONSTRUCTION**

4 (a) All pails, skimmers, measures, tanks, tubs, blowers, paddles, and other equipment, ~~which that~~ come into contact
5 with shucked shellfish or with ice used for direct cooling of shellfish, shall be made of smooth, non-corrosive,
6 impervious materials and constructed so as to be easily cleanable and shall be kept clean and in good repair.

7 (b) All equipment, including external and internal blower lines and hoses below a point two inches above the overflow
8 level of the tank and blower drain valves, shall be constructed as to be easily ~~cleanable;~~ cleanable and there shall be
9 no V-type threads in the food-product zone of the blower.

10 (c) The blower and skimmer drain shall not be directly connected with the sewer. There shall be an air ~~gap,~~ approved
11 ~~by the Division,~~ gap between the blower and skimmer outlets. A floor drain shall be provided.

12 (d) Air-pump intakes shall be located in a place protected from dirt and other contamination, and shall be equipped
13 with filters.

14

15 *History Note: Authority G.S. ~~130A-230;~~ 113-134; 113-182; 113-221.2; 143B-289.52;*

16 *Eff. February 1, 1987;*

17 *Amended Eff. September 1, ~~1990;~~ 1990;*

18 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0609 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0609 SANITIZING EQUIPMENT**

4 Washing and sanitizing facilities, including a three-compartment wash sink of adequate size to wash the largest
5 utensils used in the ~~plant-shucking and packing plant~~, shall be provided in a section of the plant ~~convenient to so that~~
6 it can service the work areas. The sink shall be kept in good repair. Permanent hot and cold water connections, with
7 combination supply faucets, shall be installed so that all vats may receive hot and cold water. Either steam, hot water,
8 or a sanitizing solution shall be used to sanitize utensils and equipment.

9

10 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

11 *Eff. February 1, 1987;*

12 *Amended Eff. December 1, ~~1987-1987;~~*

13 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0610 is proposed for readoption with substantive changes as follows:

2
3 **15A NCAC 18A .0610 EQUIPMENT SANITATION**

4 All utensils and tools, such as opening knives, shucking pails, measures, skimmers, colanders, tanks, tubs, paddles,
5 and containers ~~which that~~ come in contact with ~~the~~ shellfish shall be thoroughly cleaned and then ~~sanitized~~:sanitized
6 by:

- 7 (1) ~~by~~ steam in a steam chamber or box equipped with an indicating thermometer located in the coldest
8 zone, by exposure to a temperature of 170°F (~~76°C~~) for at least 15 minutes, or to a temperature of
9 200°F (~~93°C~~) for at least five minutes;
- 10 (2) ~~by~~ immersion in hot water at a temperature of 170°F (~~76°C~~) for at least two ~~minutes (a thermometer~~
11 ~~is required)~~:minutes;
- 12 (3) ~~by~~ immersion for at least one minute in, or exposure for at least one minute ~~to,~~ to a constant flow ~~of~~
13 of a solution containing not less than 100 parts per million chlorine residual. Utensils and equipment
14 ~~which have to that must~~ be washed in place ~~will shall~~ require washing, rinsing, and sanitizing; or
- 15 (4) ~~by a bactericidal treatment method which will provide equivalent sanitization to that provided by~~
16 ~~the methods authorized in (1), (2), or (3), as determined by the Division. If the bactericidal~~
17 ~~immersion or spray treatment is employed, testing kits shall be used to ensure that minimum solution~~
18 ~~strengths are maintained throughout the cleaning process.~~other equivalent products and procedures
19 approved in 21 CFR 178.1010, which is incorporated by reference, including subsequent
20 amendments and editions. A copy of the reference material can be found at
21 [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-178/subpart-B/section-](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-178/subpart-B/section-178.1010)
22 178.1010, at no cost.

23 A testing method or equipment shall be available and used to test chemical sanitizers to ensure minimum prescribed
24 strengths.

25
26 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*
27 *Eff. February 1, ~~1987-1987;~~*
28 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0611 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0611 EQUIPMENT STORAGE**

4 Equipment and utensils ~~which that~~ have been cleaned and ~~given bactericidal treatment~~ sanitized shall be stored in a
5 manner to protect against prevent contamination.

6

7 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

8 *Eff. February 1, ~~1987-1987;~~*

9 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0612 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0612 ICE**

4 (a) Ice shall be obtained from a water supply approved by the Division of Marine Fisheries pursuant to Rule .0413 of
5 this Subchapter and shall be stored and handled in a ~~sanitary manner~~ manner to prevent contamination and keep the
6 ice clean.

7 (b) All equipment used in the handling of ice shall be used for no other purpose and shall be cleaned and sanitized at
8 least once each day the facility is in operation.

9

10 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

11 *Eff. February 1, ~~1987~~1987;*

12 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0613 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0613 SHELLFISH SHUCKING**

4 (a) Shellfish shall be shucked in a manner ~~that they are not subject to adulteration to prevent contamination.~~ Shellstock
5 shall be ~~reasonably~~ free of ~~mud when excessive sediment prior to being~~ shucked. Only live shellstock shall be shucked.

6 (b) Shucking of shellstock shall only be permitted on ~~approved~~ shucking tables or ~~benches.~~ benches in accordance
7 with Rules .0402 and .0607 of this Subchapter. Floors ~~used by shuckers~~ shall not be used for the storage of shellfish
8 or the retention of shucking pails or other food contact containers.

9 (c) When shellstock are stored in the shucking room, protection shall be provided for the storage space to prevent
10 ~~possible adulteration the shellstock from becoming adulterated~~ from wash water wastes and from the feet of the
11 employees.

12 (d) Shucking pails shall be placed so as to exclude the drippings from shells and from the hands of shuckers. The
13 pails shall be rinsed with running tap water before each filling.

14 (e) Shucked ~~shellfish, when washed, shellfish~~ shall be ~~thoroughly~~ washed on a skimmer or a container approved by
15 the Division of Marine Fisheries with cold running water from a source ~~approved by the Division under in accordance~~
16 with Rule .0413 of this Subchapter.

17 (f) The return of excess shucked shellfish from the packing room shall not be allowed. All shucked shellfish shall be
18 packed before ~~leaving it leaves~~ the packing room.

19 (g) If blowers are used for cleansing, the total time that shellfish are in contact with water after leaving the shucker,
20 including the time of washing, rinsing, and any other contact with ~~water-water,~~ shall not be more than 30 minutes. In
21 computing the time of contact with water, the length of time that shellfish are in contact with water that is ~~agitated,~~
22 agitated shall be calculated at twice ~~its the actual length-~~ length of time that the shellfish are in contact with the water.
23 Before packing into containers for shipment or delivery for consumption, the shellfish shall be ~~drained and packed~~
24 drained. Shellfish shall be packed without any added substance.

25 (h) ~~Pre-cooling of shucked shellfish shall be done in equipment which meets National Sanitation Foundation standards~~
26 ~~or the equivalent.~~

27

28 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

29 *Eff. February 1, 1987;*

30 *Amended Eff. September 1, ~~1990.~~1990;*

31 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0614 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0614 CONTAINERS**

4 (a) Containers used for transporting shucked shellfish shall be made from ~~food safe materials approved by the United~~
5 ~~States Food and Drug Administration,~~food-safe materials. These containers shall not be reused for packing shellfish.

6 (b) ~~Shucked shellfish shall be packed and shipped in containers, sealed so that tampering can be detected. Each~~
7 ~~individual container shall have permanently recorded container, so as to be conspicuous, the shuckerpacker's,~~
8 ~~repacker's, or distributor's name and address, and the shuckerpacker's or repacker's certification number.~~The shucker-
9 packer's or repacker's name and address and certification number shall be permanently and visibly recorded on the
10 label of each container used for shucked shellfish.

11 (c) Any container of shucked shellfish ~~which that~~ has a capacity of 64 fluid ounces or more shall ~~be dated as of the~~
12 ~~date shucked~~include the words "DATE SHUCKED" followed by the date shucked permanently recorded on both the
13 lid and sidewall or bottom.bottom of the container. The date shall consist of either the abbreviation for the month and
14 number of the day of the month or the Julian format (YDDD), the last digit of the four-digit year and the three-digit
15 number corresponding to the day of the year.

16 (d) Any container of shucked shellfish ~~which that~~ has a capacity of less than 64 fluid ounces shall ~~indicate a SELL~~
17 ~~BY date~~include the words "SELL BY" or "BEST IF USED BY" followed by a date when the product will reach the
18 end of its projected shelf life. The date shall consist of the abbreviation for the month and number of the day of the
19 month.

20 (e) For fresh frozen shellfish, the year shall be added to the date for non-Julian format. If fresh frozen, the container
21 shall be labeled as frozen in equal size type immediately adjacent to the type of shellfish. If a frozen container of
22 shucked shellfish is thawed and repacked, the container shall be labeled as previously frozen.

23 (f) Each container of shucked shellfish shall include a consumer advisory. The following statement, or an equivalent
24 statement, shall be included on all containers: "Consuming raw or undercooked meats, poultry, seafood, shellfish, or
25 eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

26 ~~(d)(g)~~ No person shall use containers bearing a certification number other than the number assigned to ~~him~~him or
27 her.

28

29 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

30 *Eff. February 1, 1987;*

31 *Amended Eff. August 1, 1998; February 1, 1997; December 1, ~~1987-1987;~~*

32 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0615 is proposed for reoption with substantive changes as follows:

2

3 **15A NCAC 18A .0615 SHELLFISH COOLING**

4 ~~Shucked shellfish shall be cooled to an internal temperature of 45°F (7°C) or less within two hours after delivery to~~
5 ~~the packing room. Storage temperatures shall be 40° F (4° C) or below. No ice or other foreign substance shall be~~
6 ~~allowed to come into contact with the shellfish after processing has been completed.~~

7 (a) For shellstock that has not been refrigerated prior to processing, shucked meats and in-shell product shall be chilled
8 to an internal temperature of 45°F or less within three hours of shucking or processing.

9 (b) For shellstock that has been refrigerated prior to processing, shucked meats and in-shell product shall be chilled
10 to an internal temperature of 45°F or less within four hours after removal from refrigeration.

11 (c) If heat shock is used, once shellstock is shucked, the shucked shellfish meats shall be cooled to an internal
12 temperature of 45°F or less within two hours from the time of heat shock.

13 (d) Shucked and packed shellfish shall be stored in covered containers at an ambient temperature of 45°F or less or
14 covered in ice.

15

16 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

17 *Eff. February 1, 1987;*

18 *Amended Eff. April 1, ~~1997-1997;~~*

19 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0616 is proposed for reoption with substantive changes as follows:

2

3 **15A NCAC 18A .0616 SHELLFISH FREEZING**

4 (a) If shellfish are to be frozen, they shall be frozen within three days of shucking and ~~packing and the shucked date~~
5 ~~shall be preceded by the letter (F),~~ packing. Containers of frozen shellfish shall be labeled in accordance with Rule
6 .0614 of this Section.

7 (b) A temperature of ~~0° F (-18° C)~~ 0° F or less shall be maintained in the frozen storage rooms.

8

9 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

10 *Eff. February 1, 1987;*

11 *Amended Eff. April 1, 1997; December 1, ~~1987-1987;~~*

12 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0617 is proposed for repeal through readoption as follows:

2

3 **15A NCAC 18A .0617 SHIPPING**

4

5 *History Note: Authority G.S. 130A-230;*

6 *Eff. February 1, 1987;*

7 *Amended Eff. April 1, ~~1997-1997~~;*

8 *Repealed Eff. April 1, 2024.*

1 15A NCAC 18A .0618 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0618 HEAT SHOCK METHOD OF PREPARATION OF SHELLFISH**

4 (a) ~~Facilities.~~—If a shucking and packing plant uses the heat shock process, it shall be done in a separate room adjacent
5 to the shellstock storage room and the shucking room.

6 (b) ~~Tank construction.~~—The heat shock tank shall be constructed of smooth, non-corrosive metal, designed to drain
7 ~~quickly and completely and to be easily and thoroughly cleaned.~~ cleanable.

8 (c) ~~Booster heaters.~~—All heat shock tanks shall be equipped with booster heaters that are thermostatically controlled.

9 (d) ~~Shellstock washing.~~—All shellstock subjected to the heat shock process shall be ~~thoroughly~~ washed with flowing
10 potable water immediately prior to the heat shock operation.

11 (e) ~~Water temperature.~~—During the heat shock process the water shall be maintained at not less than 140°F (60°C) or
12 more than ~~150°F (65°C).~~ 150°F. An accurate thermometer shall be available and used to determine the temperature
13 during the heat shock process. ~~The heat shock tanks shall be drained and cleaned at the end of each day's operation.~~

14 (f) ~~Alternatives to heat shock method.~~—Nothing in ~~these Rules~~ this Rule shall be construed to prohibit any other
15 process ~~which that~~ has been found by the Division of Marine Fisheries to be equally effective.

16 (g) ~~Water requirements.~~—At least eight gallons of heat shock water shall be maintained in the tank for each ~~one half~~
17 one-half bushel of shellstock being treated. All water used in the heat shock process shall be from a source approved
18 by the Division ~~under in accordance with~~ Rule .0413 of this Subchapter.

19 (h) ~~Cooling.~~—Immediately after the heat shock process, all treated shellstock shall be subjected to a cool-down with
20 flowing potable ~~tap~~ water. All ~~heat shocked~~ heat-shocked shellstock shall be handled in a manner to prevent
21 ~~adulteration of the product.~~ the product from becoming adulterated. Shellfish ~~which that~~ have been subjected to the
22 heat shock process shall be cooled to an internal temperature of 45°F (7°C) or below within two hours after this process
23 and shall be placed in storage at ~~40°F (4°C)~~ 45°F or below.

24 (i) ~~Cleaning.~~—At the close of each day's operation, the heat shock tank shall be completely emptied of all water, mud,
25 and detritus, and ~~thoroughly~~ cleaned and then rinsed with flowing potable water.

26 (j) ~~Sanitizing.~~—All heat shock tanks shall be sanitized immediately before starting each day's operation.

27 (k) The procedure for the heat shock process shall be posted in a location that can be viewed by employees to help
28 ensure the correct procedure can be followed.

29

30 *History Note:* Authority G.S. 130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;

31 Eff. February 1, 1987;

32 Amended Eff. August 1, 2002; August 1, 1998; February 1, 1997; September 1, 1990-1990;

33 Readopted Eff. April 1, 2024.

1 15A NCAC 18A .0619 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0619 REPACKING OF SHELLFISH**

4 (a) If repacking is practiced, it shall be ~~done strictly conducted~~ in accordance with all the requirements ~~stipulated~~ for
5 shucking and packing plants in the Rules of this Section except ~~those for requirements~~ related to shucking.

6 (b) The shucked shellfish to be repacked shall be received at the repacking plant ~~in approved shipping containers~~ at a
7 temperature of ~~32°-40°F (0°-4°C)~~ 45°F or less.

8 (c) Shellfish shall not be repacked more than one time.

9 (d) The temperature of the shellfish shall not exceed an internal temperature of 45°F (7°C) ~~for more than two hours~~
10 during the repacking process.

11 ~~Containers with a capacity of 64 fluid ounces or less in which shucked shellfish are repacked shall indicate a SELL~~
12 ~~BY date preceded by the letter R. Containers with a capacity above 64 fluid ounces in which shucked shellfish are~~
13 ~~repacked shall be dated to show the original shucking date and repacking date, which will be preceded by the letter~~
14 ~~(R).~~ Containers of repacked shellfish shall be repacked and labeled in accordance with Rule .0614 of this Section,
15 except that the original date of shucking shall be added to the new repacked container or the original date of shucking
16 shall be used in establishing the "SELL BY" or "BEST IF USED BY" date.

17 (f) Repackers shall keep ~~accurate~~ records indicating the source from which shellfish were purchased, the date packed,
18 the date of purchase, ~~the area within the state or territory from which the shellfish were harvested,~~ and the names and
19 addresses of ~~persons~~ shellfish dealers to whom ~~the~~ shellfish were sold.

20

21 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

22 *Eff. February 1, 1987;*

23 *Amended Eff. December 1, ~~1987~~1987;*

24 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0620 is proposed for readoption with substantive changes as follows:

2

3 **15A NCAC 18A .0620 SHELLFISH THAWING AND REPACKING**

4 (a) Frozen shellfish shall be thawed ~~under temperatures not to exceed 45° F (7° C)~~ at a temperature of 45°F or less.

5 (b) Shellfish held for thawing shall be separated from other shellfish.

6 (c) Thawed shellfish shall not exceed ~~45° F (7° C)~~ 45°F for more than two hours during the repacking process.

7 (d) Containers of repacked, thawed shellfish shall be labeled as required in Rule .0619 of this Section and shall also
8 be labeled as "PREVIOUSLY FROZEN", or equivalent.

9 (e) Thawed ~~shellfish, which shellfish that~~ shellfish that remain in original containers, containers shall be labeled as required in Rule
10 .0614 of this Section and shall also be labeled as "PREVIOUSLY FROZEN", or equivalent.

11

12 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

13 *Eff. April 1, ~~1997-1997;~~*

14 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0621 is proposed for repeal through readoption as follows:

2

3 **15A NCAC 18A .0621 RECALL PROCEDURE**

4

5 *History Note: Authority G.S. 130A-230;*

6 *Eff. August 1, ~~1998~~1998;*

7 *Repealed Eff. April 1, 2024.*

1 15A NCAC 18A .0701 is proposed for readoption with substantive changes as follows:

2
3 **SECTION .0700 - OPERATION OF DEPURATION (MECHANICAL PURIFICATION) FACILITIES**

4
5 ~~Rules .0701—.0713 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18A~~
6 ~~.0701—.0713); has been transferred and recodified from Rules .1201—.1213 of Title 10 Subchapter 10B of the North~~
7 ~~Carolina Administrative Code (T10.10B .1201—.1213), effective April 4, 1990.~~

8
9 **15A NCAC 18A .0701 ~~GENERAL REQUIREMENTS~~ FOR DEPURATION**

10 ~~(a) The Rules in Section .0400 shall apply for the operation of depuration facilities.~~ In addition to and to the extent
11 not inconsistent with other applicable provisions of North Carolina Marine Fisheries Commission rules, requirements
12 for depuration shall be in accordance with the 2019 Revision of the National Shellfish Sanitation Program (NSSP)
13 Guide for the Control of Molluscan Shellfish chapter titled "Depuration", which is incorporated by reference, not
14 including subsequent amendments and editions. A copy of the reference material is available online at:
15 <https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp>, at no cost.

16 (b) All laboratory analyses used to evaluate the effectiveness of the depuration process shall be performed by a
17 laboratory found by a Food and Drug Administration (FDA) Shellfish Laboratory Evaluation Officer or by an FDA-
18 certified State Shellfish Laboratory Evaluation Officer to conform or provisionally conform to the requirements
19 established under the National Shellfish Sanitation Program (NSSP).

20 (c) If there is an immediate or ongoing critical need for a method for the analysis of depuration process water and
21 shellfish that are used to evaluate the effectiveness of the depuration process and no method approved for use within
22 the NSSP exists, the following may be used:

- 23 (1) a validated Association of Analytical Communities, Bacteriological Analysis Manual, or
24 Environmental Protection Agency method; or
25 (2) an Emergency Use Method as set forth in the latest approved edition of the NSSP Guide for the
26 Control of Molluscan Shellfish.

27
28 *History Note:* Authority G.S. 130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;
29 Eff. February 1, 1987-1987;
30 Readopted Eff. April 1, 2024.

1 15A NCAC 18A .0702 - .0703 are proposed for repeal through readoption as follows:

2

3 **15A NCAC 18A .0702 FACILITY SUPERVISION**

4 **15A NCAC 18A .0703 FACILITY DESIGN AND SANITATION**

5

6 *History Note: Authority G.S. 130A-230;*

7 *Eff. February 1, ~~1987~~1987;*

8 *Repealed Eff. April 1, 2024.*

1 15A NCAC 18A .0704 is proposed for repeal as follows:

2

3 **15A NCAC 18A .0704 LABORATORY PROCEDURES**

4

5 *History Note: Authority G.S. 113-134; 113-182; 113-221.2; 143B-289.52;*

6 *Eff. February 1, 1987;*

7 *Amended Eff. September 1, 1991; September 1, 1990;*

8 *Readopted Eff. May 1, ~~2021-2021~~;*

9 *Repealed Eff. April 1, 2024.*

1 15A NCAC 18A .0705 - .0713 are proposed for repeal through readoption as follows:

2

3 **15A NCAC 18A .0705 FACILITY OPERATIONS**

4 **15A NCAC 18A .0706 SHELLFISH SAMPLING PROCEDURES**

5 **15A NCAC 18A .0707 DEPURATION PROCESS WATER CONTROL - SAMPLING PROCEDURES**

6 **15A NCAC 18A .0708 DEPURATION TREATMENT PROCESS WATER - STANDARDS**

7 **15A NCAC 18A .0709 DEPURATION - SHELLFISH MEAT STANDARDS**

8 **15A NCAC 18A .0710 ULTRAVIOLET UNIT**

9 **15A NCAC 18A .0711 SHELLSTOCK STORAGE**

10 **15A NCAC 18A .0712 DEPURATION - TAGGING AND RELEASE OF SHELLFISH**

11 **15A NCAC 18A .0713 DEPURATION - RECORDS**

12

13 *History Note: Authority G.S. 130A-230;*

14 *Eff. February 1, 1987;*

15 *Amended Eff. September 1, 1990(Rules .0705, .0706); December 1, ~~1987-1987~~(Rule .0705);*

16 *Repealed Eff. April 1, 2024.*

1 15A NCAC 18A .0801 is proposed for readoption with substantive changes as follows:

2
3 **SECTION .0800 - WET STORAGE OF SHELLSTOCK**

4
5 ~~Rules .0801—.0806 of Title 15A Subchapter 10B of the North Carolina Administrative Code (T15A.10B~~
6 ~~.0801—.0806); has been transferred and recodified from Rules .1301—.1306 of Title 10 Subchapter 10B of the North~~
7 ~~Carolina Administrative Code (T10.10B .1301—.1306), effective April 4, 1990.~~

8
9 **15A NCAC 18A .0801 ~~GENERAL REQUIREMENTS~~ GENERAL REQUIREMENTS FOR WET STORAGE OF SHELLSTOCK**

10 ~~The rules in Section .0400 shall apply for wet storage of shellstock.~~ (a) In addition to and to the extent not inconsistent
11 with other applicable provisions of North Carolina Marine Fisheries Commission Rules, requirements for wet storage
12 shall be in accordance with the 2019 Revision of the National Shellfish Sanitation Program (NSSP) Guide for the
13 Control of Molluscan Shellfish (hereinafter referred to as "Model Ordinance") chapter titled "Wet Storage in Approved
14 and Conditionally Approved Growing Areas", which is incorporated by reference except as provided in Paragraph (b)
15 of this Rule, not including subsequent amendments and editions. A copy of the reference material is available online
16 at: <https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp>, at no cost.

17 (b) Amendments and exceptions to the Model Ordinance chapter titled "Wet Storage in Approved and Conditionally
18 Approved Growing Areas" incorporated by reference include:

19 (1) Section @.01, .04, C(1)(a) is amended to read: "Except for a water source in accordance with Rule
20 .0413 of this Subchapter, the quality of the surface source water prior to treatment shall meet, at a
21 minimum, the bacteriological standards for the conditionally approved classification in the open
22 status. Water classified as prohibited or restricted shall not be used as source water."

23 (2) the following sections are not incorporated by reference and shall not apply: Sections @.01, .04,
24 C(2)(a)(ii), @.01, .04, C(2)(b), @.01, .04, C(2)(c), and @.01, .04, C(2)(d).

25
26 *History Note:* Authority G.S. 130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;
27 Eff. February 1, 1987-1987;
28 Readopted Eff. April 1, 2024.

1 15A NCAC 18A .0802 - .0806 are proposed for repeal through readoption as follows:

2

3 **15A NCAC 18A .0802 PLANT DESIGN: SANITATION: AND WET STORAGE**

4 **15A NCAC 18A .0803 WET STORAGE WATER**

5 **15A NCAC 18A .0804 SHELLSTOCK CLEANING**

6 **15A NCAC 18A .0805 WET STORAGE TANKS**

7 **15A NCAC 18A .0806 SHELLSTOCK CONTAINERS**

8

9 *History Note: Authority G.S. 130A-230;*

10 *Eff. February 1, ~~1987~~1987;*

11 *Repealed Eff. April 1, 2024.*