Rule Impact Analysis for Readoption of 15A NCAC 18A Rule Package Pursuant to G.S. 150B-21.3A

Rule Amendments: 15A NCAC 18A .0134, .0137-.0139, .0144, .0145, .0147-.0149, .0151-.0153, .0156-.0158, .0161, .0162, .0164-.0166, .0168, .0174-.0178, .0181-.0187, .0191

Name of Commission: N.C. Marine Fisheries Commission

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Impact Summary: State government: No

Local government: No Federal government: No Substantial impact: No

Authority:

G.S. 106-129.	Foods deemed to be adulterated.
G.S. 106-130.	Foods deemed misbranded.
G.S. 113-134.	Rules.
G.S. 113-182.	Regulation of fishing and fisheries.
G S 112 221 2	Additional rules to establish conitation requiremen

G.S. 113-221.2. Additional rules to establish sanitation requirements for

scallops, shellfish, and crustacea; permits and permit fees

authorized.

G.S. 113-221.4. Embargo.

North Carolina General Statutes

G.S. 143B-289.52. Marine Fisheries Commission - powers and duties. G.S. 150B-21.3A. Periodic review and expiration of existing rules.

I. 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. The proposed amendments readopt 34 rules in 15A NCAC 18A pursuant to this requirement. These rules all relate to protocols and regulations regarding the proper storage and processing of crustacea meat, as well as the facilities that hold these products.

II. Summary

While all 34 rules proposed for readoption contain substantive changes, upon review none of these changes produce any procedural changes, and therefore no economic costs or benefits to the state are incurred. In short, all proposed changes are either intended to provide heightened clarity to rule language, or to conform rule language around crustacea meat storage, processing, and facility maintenance to that of ongoing practice by North Carolina Division of Marine

Fisheries (NCDMF) staff and licensed seafood processors and dealers. Of particular note, 15A NCAC 18A .0134 defines terms related to shellfish sanitation, and proposes four new definitions in rule. However, it was determined that these new terms simply help clarify ongoing Division practices, and result in no procedural changes as well. As these proposed changes would not affect the operations or material needs of NCDMF or outside stakeholders, there are no incurred economic impacts as well.

These rules have been reviewed to conform to the requirements of G.S. 150B-21.3A, Periodic Review and Expiration of Existing Rules. The proposed readoptions consist of amendments that are of an administrative nature to update the rules. Overall, the proposed readoptions do not result in a significant economic impact to the regulated community, state government, or other parties.

III. Introduction and Purpose of Rule Changes

Session Law 2011-145 abolished the Division of Environmental Health and transferred the Shellfish Sanitation and Recreational Water Quality section to the Division of Marine Fisheries under a Type I transfer. As a result, G.S. 130A-230 was repealed and the authority for rulemaking for the sanitation requirements for harvesting, processing and handling of scallops, shellfish and crustacea was transferred to the Marine Fisheries Commission, which is now contained in G.S. 113-221.2 and G.S. 113-221.4.

The purpose of the Marine Fisheries Commission (MFC) is to manage, restore, develop, cultivate, conserve, protect, and regulate the marine and estuarine resources within its jurisdiction, as described in 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 (G.S. 113-221.2).

Proposed amendments to these rules seek to accomplish two simple goals. Firstly, some proposed amendments update inconsistencies or typographical issues with rule text to increase clarity. The remaining proposed amendments seek to update rule language to conform with the current practices regarding shellfish sanitation, both by NCDMF staff and affected stakeholders. This also remains true for the four new definitions proposed in 15A NCAC 18A .0134 ("Easily Cleanable", "Most Probable Number", "Process Validation Study Report", and "Retort"), which are proposed amendments that would define in rule ongoing practices by the Division. As such, all of these proposed text changes would not generate any procedural changes or economic impacts to the operations outlined in these 34 rules.

IV. Fiscal Impact Analysis

As these 34 rules are being proposed for readoption with no procedural changes, there will be no changes to the economic benefits and costs of the rules. As such, no fiscal impact will be observed from this proposed readoption package.

V. Appendix

Proposed Rules for Readoption

15A NCAC 18A .0134 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0134 DEFINITIONS

The following definitions shall apply throughout to this Section; however, nothing in this Section shall be construed as expanding or restricting the definitions in G.S. 106-129 and G.S. 106-130:

- (1) "Adulterated" as used in G.S. 106-129 means the following:
 - (a) Any any cooked crustacea or crustacea meat that does not comply with these Rules; the Rules in this Section;
 - (b) Any any cooked crustacea or crustacea meat which that exceeds the bacteriological standards in Rule .0182 of this Section;
 - (c) Any any cooked crustacea or crustacea meat which that has been deemed to be an imminent hazard:
- "Code date" means the date conspicuously placed on the container to indicate the date that the product was packed.
- (3) "Cook" means to prepare or treat raw crustacea by heating.
- (4) "Critical control point" means a point, <u>step-step</u>, or procedure in a food process at which <u>a</u> control can be <u>applied</u>, <u>applied</u> and a food safety hazard <u>ean-can</u>, as a <u>result-result</u>, be prevented, <u>eliminated</u> <u>eliminated</u>, or reduced to acceptable levels.
- (5) "Critical limit" means the maximum or minimum value to which a physical, biological biological, or chemical parameter must-shall be controlled at a critical control point to prevent, eliminate eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.
- (6) "Crustacea meat" means the meat of crabs, lobster, shrimp-shrimp, or crayfish.
- (7) "Division" means the Division of Environmental Health or its authorized agent. Marine Fisheries.
- (8) "Easily cleanable" means a surface that is readily accessible and made of such materials, has a finish, and is so fabricated that residues may be effectively removed by normal cleaning methods.
- (8)(9) "Food-contact surface" means the parts of equipment, including auxiliary equipment, which that may be in contact with the food being processed, or which that may drain into the portion of equipment with which food is in contact.
- (9)(10) "Food safety hazard" means any biological, chemical chemical, or physical property that may cause a food to be unsafe for human consumption.
- (10)(11) "Foreign" means any place or location outside the United States.
- (11)(12) "Fresh crustacea" means a live, <u>raw-raw</u>, or frozen raw crab, lobster, <u>shrimp-shrimp</u>, or crayfish <u>which-that</u> shows no decomposition.
- (12)(13) "HACCP plan" means a written document that delineates the formal procedures a dealer follows to implement food safety controls.
- (13)(14) "Hazard analysis critical control point (HACCP)" means a system of inspection, control control, and monitoring measures initiated by a dealer to identify microbiological, chemical chemical, or physical food safety hazards which that are likely to occur in shellfish products produced by the dealer.

- (14)(15) "Imminent hazard" means a situation which that is likely to cause an immediate threat to human life, an immediate threat of serious physical injury, an immediate threat of serious physical adverse health effects, or a serious risk of irreparable damage to the environment if no immediate action is taken.
- (15)(16) "Internal temperature" means the temperature of the product as opposed to the ambient temperature.
- (16)(17) "Misbranded" as used in G.S. 106-130 means any container of cooked crustacea or crustacea meat which that is not labeled in compliance with these Rules. the Rules in this Section.
- (18) "Most probable number (MPN)" means a statistical estimate of the number of bacteria per unit volume and is determined from the number of positive results in a series of fermentation tubes.
- (17)(19) "Operating season" means the season of the year during which a crustacea product is processed.
- (18)(20) "Pasteurization" means the process of heating every particle of crustacea meat in a hermetically-sealed 401 by 301 one pound-container to a temperature of at least 185°F (85°C) 185° F (85°C) and holding it continuously at or above this temperature for at least one minute at the geometric center of a container in properly operated equipment. equipment being operated in compliance with the Process Validation Study Report. The term includes any other process which that has been found equally effective by the Division.
- (19)(21) "Pasteurization date" means a code conspicuously placed on the container to indicate the date that the product was pasteurized.
- (20) "Person" means an individual, corporation, company, association, partnership, unit of government or other legal entity.
- <u>"Process Validation Study Report" means a report of tests that shows a piece of equipment can produce time-temperature results as required by the Rules of this Section, and the procedures required to achieve such results.</u>
- (21)(23) "Processing" means any of the following operations when carried out in conjunction with the cooking of crustacea or crustacea meat: receiving, refrigerating, air-cooling, picking, packing, repacking, thermal processing, or pasteurizing.
- (22)(24) "Repacker" means a facility which that repacks cooked crustacea meat into other containers.
- (23)(25) "Responsible person" means the individual present in a cooked crustacea facility who is the apparent supervisor of the cooked crustacea facility at the time of the inspection. If no individual is the apparent supervisor, then any employee is the responsible person.
- (26) "Retort" means a pressure vessel used to cook raw crustacea.
- (24)(27) "Sanitize" means a bactericidal treatment by a process which meets the temperature and chemical concentration levels in 15A NCAC 18A .2619. to treat food contact surfaces by a process that is effective in:
 - (a) <u>destroying vegetative cells of microorganisms of public health significance;</u>
 - (b) substantially reducing the numbers of other undesirable microorganisms; and
 - (c) not adversely affecting the product or its safety for the consumer.
- (25) "Standardization report" means a report of tests which show that a piece of equipment can produce time/temperature results as required by these Rules.
- (26)(28) "Thermal processing" means the heating of previously cooked crustacea or crustacea meat to a desired temperature for a specified time at the geometric center of a container in properly operated equipment. equipment being operated in compliance with the Process Validation Study Report.
- History Note: Authority G.S. 106-129; 106-130; 130A-230; <u>113-134; 113-182; 113-221.2; 143B-289.52;</u> Eff. October 1, 1992;

Amended Eff. August 1, 2000; August 1, 1998; February 1, 1997; Readopted Eff. April 1, 2022.

15A NCAC 18A .0137 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0137 GENERAL REQUIREMENTS FOR OPERATION

- (a) During the operating season the processing portion of the facility shall be used for no purpose other than the processing of cooked crustacea or crustacea meat.
- (b) Retail sales of cooked crustacea or crustacea meat shall not be made from any processing portion of the facility.
- (c) Accurate records of all purchases and sales of crustacea and crustacea meat shall be maintained for one year. The records shall be available for inspection by the <u>Division. Division of Marine Fisheries.</u>

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

Eff. October 1, 1992;

Amended Eff. April 1, 1997.

Readopted Eff. April 1, 2022.

15A NCAC 18A .0138 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0138 SUPERVISION

- (a) The owner or responsible person shall supervise the processing operation and be responsible for compliance with the rules of this Section. Section, including compliance with personal hygiene requirements as set forth in Rule .0153 of this Section.
- (b) No unauthorized persons shall be allowed in the facility during the periods of operation.
- (c) The owner or responsible person shall observe employees daily to ensure compliance with Rule .0153 of this Section.

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

Eff. October 1, 1992.

15A NCAC 18A .0139 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0139 FACILITY FLOODING

- (a) If the facility floors are flooded, processing shall be discontinued until flood waters have receded and the facility and equipment are cleaned and sanitized.
- (b) Any cooked crustacea or crustacea meat which that may have been contaminated by flood waters shall be deemed adulterated and disposed of in accordance with G.S. 130A 21(c). 113-221.4 and Rule .0181 of this Section.

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

Eff. October 1, 1992;

15A NCAC 18A .0144 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0144 INSECT CONTROL

All outside openings shall be screened, provided with wind <u>curtains</u> or be provided with other methods to eliminate the entrance of insects. All screens shall be kept in good repair. All outside doors shall open outward and shall be self-closing. The use and storage of pesticides shall comply with all applicable State and Federal laws and rules.

History Note: Authority G.S. 130A-230; <u>113-134;</u> <u>113-182;</u> <u>113-221.2;</u> <u>143B-289.52;</u>

Eff. October 1, 1992.

15A NCAC 18A .0145 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0145 RODENT AND ANIMAL CONTROL

Measures shall be taken by the owner or responsible person to keep animals, fowl, rodents, and other vermin out of the facility. The storage and use of rodenticides shall comply with all applicable State and Federal laws and rules.

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

Eff. October 1, 1992.

15A NCAC 18A .0147 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0147 WATER SUPPLY

- (a) The water supply used shall be in accordance with 15A NCAC 18A .1700. 15A NCAC 18A .1720 through .1728.
- (b) A cooked crustacea facility using a non-community water supply shall be listed with the Public Water Supply Section, Division of Environmental Health.
- (e)(b) Water samples for bacteriological analysis shall be collected at least annually by the Division of Marine Fisheries and submitted to the Laboratory Division of the Department or another a laboratory certified by the Department for potable water testing in the State of North Carolina for analysis.

(d)(c) Cross-connections with unapproved water supplies are prohibited. Hot and cold running water under pressure shall be provided to food preparation, utensils utensils, and handwashing areas and any other areas in which water is required for cleaning. Running water under pressure shall be provided in sufficient quantity to carry out all food preparation, utensil washing, hand washing, eleaning cleaning, and other water-using operations.

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

Eff. October 1, 1992;

Amended Eff. April 1, 1997; Readopted Eff. April 1, 2022. 15A NCAC 18A .0148 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0148 ICE

- (a) Ice shall be obtained from a water supply approved by the Division of Marine Fisheries pursuant to Rule .0147 of this Section and shall be stored and handled in accordance with these Rules.in a manner to prevent contamination.
- (b) All equipment used in the handling of ice shall be used for no other purpose and shall be cleaned and sanitized at least once each day the facility is in operation.

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

Eff. October 1, 1992.

15A NCAC 18A .0149 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0149 PLUMBING

- (a) Plumbing fixtures shall be located to facilitate the flow of processing activities and to prevent the splashing of water on food-contact surfaces or cooked crustacea and crustacea meat.
- (b) Fixtures, ducts ducts, and pipes shall not be suspended over working areas.
- (c) Handwash lavatories shall be located so that the supervisor can readily observe that employees wash and sanitize their hands before beginning work and after each interruption.
- (d) Handwash lavatories shall be provided in the following locations:
 - (1) Packing packing room or area. area;
 - (2) Toilet toilet or lounge area. area; and
 - (3) Picking picking room.
- (e) At least one handwash lavatory shall be provided for every 20 employees among the first 100 employees and at least one handwash lavatory shall be provided for every 25 employees in excess of the first 100 employees.
- (f) Additional lavatories required by Paragraph (e) of this Rule shall be located in the picking room.
- (g) A container shall be located near each handwash lavatory in the picking room and packing room or area to sanitize hands in a solution containing at least 100 parts per million (ppm) of available chlorine or other equally effective bactericide. A <u>suitable</u> testing method or equipment <u>approved by the Division of Marine Fisheries</u> shall be available and <u>regularly</u> used to test chemical sanitizers to <u>insure ensure</u> minimum prescribed strengths.
- (h) Soap and single service towels in protected dispensers, or other approved hand drying devices, shall be available near the handwash lavatories.
- (i) All pre-cool rooms, picking rooms, packing rooms or areas, and cooking areas shall be provided with hosebibs hose bibs and wash down hoses. Storage racks shall be provided to keep the hoses elevated off the floor when not in use.
- (j) An automatically regulated hot-water system shall be provided to furnish a sufficient volume of hot water with a temperature of at least 130° F (54.5° C) to carry out all processing operations.
- (k) All handwash lavatories and sinks shall be equipped with mixing faucets.
- (l) A three-compartment sink with drainboards, large enough to wash the largest utensils used in the facility, shall be located in the picking room near the delivery shelf. One three-compartment sink, with drainboards, shall be provided for every 50 employees or fraction thereof.
- (m) The floor drains in coolers shall not be connected directly to a sewer in processing or repacking facilities constructed after October 1, 1992.

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

Eff. October 1, 1992;

15A NCAC 18A .0151 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0151 TOILETS

- (a) Toilets shall be provided by the owner or responsible person in the facility; however, privies may be substituted for toilets when the conditions in Paragraph (d) of this Rule are met. facility.
- (b) Toilet tissue shall be provided provided by the owner or responsible person in a holder.
- (c) Toilet room doors shall not open directly into processing areas of the facility and shall be self-closing.
- (d) Only privies that meet the requirements of Section .1900 of this Subchapter and that were in place at a processing or repacking facility prior to October 1, 1992 may be used at the facility after October 1, 1992.

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

Eff. October 1, 1992.

15A NCAC 18A .0152 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0152 SOLID WASTE

- (a) Cooked crustacea scrap and other putrescible wastes shall be removed from the premises at least daily. Other solid wastes shall be removed from the premises at least weekly.
- (b) Scrap containers shall be removed from the picking room immediately after filling and placed in storage areas approved by the Division. Division of Marine Fisheries.
- (c) Scrap containers shall be non-corrosive and cleaned at least daily.
- (d) Scrap containers shall be cleaned in an area approved by the Division.

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

Eff. October 1, 1992.

15A NCAC 18A .0153 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0153 PERSONAL HYGIENE

- (a) All employees shall wash their hands with soap and running water before beginning work and again after each interruption. Signs to this effect shall be posted in conspicuous places in the facility by the owner. owner or responsible person.
- (b) All persons handling cooked crustacea or crustacea meat shall sanitize their hands before beginning work and again after each interruption.
- (c) All persons employed or engaged in the handling, <u>picking picking</u>, or packing of cooked crustacea or crustacea meat shall wear clean, washable outer clothing.
- (d) Employees shall not eat food, <u>drink nor drink</u>, <u>or</u> use tobacco in any form in the areas where cooked crustacea or crustacea meat are stored, <u>processed processed</u>, or handled.
- (e) Any person known to be a carrier of any disease which can be transmitted through the handling of cooked crustacea or crustacea meat or who has an infected wound or open lesion on any exposed portion of the body shall be prohibited from handling cooked crustacea or crustacea meat.
- (f) Hair restraints shall be worn by all employees who handle cooked crustacea or crustacea meat.
- (g) The arms of personnel who pick or pack cooked crustacea or crustacea meat shall be bare to the elbow or covered with an arm guard approved by the Division. Division of Marine Fisheries.
- (h) Personnel who pick and pack cooked crustacea or crustacea meat shall have elean clean, short fingernails, fingernails free from nail polish and shall not wear jewelry other than easily cleanable rings. The use of absorbent wraps or absorbent finger cots shall not be permitted.

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

Eff. October 1, 1992.

15A NCAC 18A .0156 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0156 EQUIPMENT AND UTENSIL CONSTRUCTION

All processing equipment and utensils shall be smooth, easily cleanable, <u>durable durable</u>, and kept in good repair. The food-contact surfaces of equipment, <u>utensils utensils</u>, and processing machinery shall be easily accessible for cleaning, non-toxic, non-corrosive, <u>non-absorbent non-absorbent</u>, and free of open seams.

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

Eff. October 1, 1992.

15A NCAC 18A .0157 FACILITY AND EQUIPMENT SANITATION

- (a) The walls and floors in the picking and packing areas shall be kept clean while operating and shall be sanitized at least daily and whenever there is evidence of contamination.
- (b) All food-contact surfaces shall be washed, <u>rinsed-rinsed</u>, and sanitized prior to starting operation each day and whenever there is evidence of contamination.
- (c) Reusable picking containers and knives shall be washed, rinsed rinsed, and sanitized each time crustacea meat is delivered to the packing room.
- (d) Sanitizing methods are shall be as follows:
 - (1) By by steam in a steam chamber or box equipped with an indicating thermometer located in the coldest zone, by with exposure to a temperature of 170° F (77° C) for at least 15 minutes or to a temperature of 200° F (93° C) for at least five minutes.
 - (2) By by immersion for at least one minute in the third compartment in clean hot water at a temperature of at least 170° F (77° C). A thermometer accurate to 3°F-3° F (1.5° C) shall be available to the compartment. Where hot water is used for bactericidal treatment, a booster heater that maintains a water temperature of at least 170° F (77° C) in the third compartment at all times when utensils are being washed shall be provided. The heating device may be integral with the immersion compartment.
 - (3) By by immersion for at least one minute in, or exposure for at least one minute to a constant flow of, a solution containing not less than 100 ppm chlorine residual. Utensils and equipment which that have to be washed in place will require washing, rinsing rinsing, and sanitizing.
 - (4) By by other equivalent products and procedures approved in 21 CFR 178.1010 "Sanitizing solutions" from the "Food Service Sanitation Manual" published by the U.S. Food and Drug Administration. 21 CFR 178.1010 solutions", which is hereby incorporated by reference including any subsequent amendments and editions. This material is available for inspection, and copies may be obtained at no cost, at the Shellfish Sanitation Branch, 3441 Arendell Street, P.O. Box 769, Morehead City, North Carolina 28557.—A copy of the reference material can be found at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=17d119b223f9451322279713caa2e6ab&ty=HTML&h=L&mc=true&n=pt21.3.178&r=PART#se21.3.178_11010, at no cost. A suitable Division of Marine Fisheries approved testing method or equipment shall be available and regularly used to test chemical sanitizers to insure ensure minimum prescribed strengths.

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

Eff. October 1, 1992;

15A NCAC 18A .0158 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0158 EQUIPMENT STORAGE

Equipment and utensils that have been cleaned and sanitized shall be stored <u>in a manner</u> to protect against contamination.

History Note: Authority G.S. 130A 230; <u>113-134; 113-182; 113-221.2; 143B-289.52;</u>

Eff. October 1, 1992.

15A NCAC 18A .0161 CRUSTACEA COOKING

- (a) The cooking area or room shall be under a roof located between the area for receiving raw crustacea and the air-cool room and shall be vented to assure the removal of steam.
- (b) Crustacea shall be cooked in accordance with the following:
 - (1) Crabs shall be cooked under steam pressure until the internal temperature of the center-most crab reaches 235° F (112.8° C). Temperature shall be measured with an accurate, indicating thermometer having a range of 170-270° F (77-132° C).
 - (2) Other crustacea shall be cooked until the internal temperature of the center-most crustacean reaches 180° F (83° C) and is held at this temperature for one minute. Temperature shall be measured with an accurate, indicating thermometer. Crayfish shall be culled and cleaned prior to cooking.
 - (3) Nothing in this Rule shall prohibit any other cooking process which that has been found equally effective and approved by the Division. Division of Marine Fisheries.
- (c) The retort shall be constructed to permit a working pressure of at least 20 pounds per square inch (psig). Steam inlet and venting shall provide a uniform and complete distribution of steam. Venting shall be sufficient to permit complete elimination of air from the retort. Drains and vents shall be located at least two feet above mean high tide.
- (d) The retorts shall be equipped with:
 - (1) An-an accurate, indicating thermometer with a range that will include 170-270° F (77-132° C) and located with the sensor extending into the heat ehamber: chamber:
 - (2) An-an operating pressure indicator, at least three inches in diameter, with a 0-30 psig range and located adjacent to the indicating thermometer. thermometer; and
 - (3) A a safety valve operational at 18-30 psig, located in the upper portion of the retort, protected from tampering tampering, and designed to prevent injury to the operator.
- (e) The boiler shall be of such capacity as to maintain 45 to 100 psig during cooking. The steam line from the boiler to the retort shall be at least one and one-fourth inch inside diameter.
- (f) Overhead hoists shall be equipped with chain bags or other means of preventing foreign material from falling onto the cooked product.
- (g) Retort cooking baskets shall be of stainless steel or equally impervious, non-corrosive non-corrosive and durable material, and shall be designed to allow for equal steam disbursement, ease of handling, dumping dumping, and cleaning.
- (h) All construction or replacement of retorts after October 1, 1992 shall be "flow-through" type and opening open directly into the air-cool room or a protected passageway into the air-cool room.
- (i) All construction of new or replacement retorts shall require a Process Validation Study Report approved by the Division prior to use.

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

Eff. October 1, 1992.

15A NCAC 18A .0162 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0162 COOKED CRUSTACEA AIR-COOL

- (a) Cooked crustacea, after removal from the retort, shall be moved immediately to the cooked crustacea <u>air cool air cool area</u> area to be air cooled to ambient temperature without being disturbed. Cooked crustacea shall be stored in <u>the original cooking basket</u>.
- (b) The construction and arrangement of the air-cool room shall be designed to provide protection from contamination of the cooked crustacea. The air-cool room shall open directly into the cooked crustacea cooler or other protected area.

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

Eff. October 1, 1992.

15A NCAC 18A .0164 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0164 COOKED CRUSTACEA PICKING

- (a) The picking operation shall be conducted in a manner to prevent contamination.
- (b) All cooked crustacea shall be picked before a new supply is delivered to the picking table.
- (c) Picked crustacea meat shall be delivered to the packing room at least every 90 minutes or upon the accumulation of five pounds per picker-picker, whichever is sooner.
- (d) Paper towels used at the picking table shall be discarded after initial use.
- (e) If provided, bactericidal solutions at picking tables shall be maintained at 100 ppm chlorine solution or an equivalent bactericidal solution. A testing method or equipment approved by the Division of Marine Fisheries to insure ensure minimum prescribed strengths shall be available and used to test chemical sanitizers.
- (f) Handles of picking knives shall not be covered with any material.
- (g) Crustacea shall be cooked and picked in the same permitted facility unless a written plan for interfacility shipment has been filed with the Division. The plan shall address and be approved based upon-on the following:
 - (1) time-temperature; time-temperature requirements;
 - (2) shipping destination; shipping destination;
 - (3) handling;
 - (4) labeling;
 - (5) records;
 - (6) processing;
 - (7) sanitation; and
 - (8) HACCP plan.

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

Eff. October 1, 1992;

Temporary Amendment Eff. July 1, 2000;

Temporary Rule Expired on March 12, 2001;

Amended Eff. August 1, 2002.

15A NCAC 18A .0165 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0165 PACKING

- (a) Crustacea meat shall be packed in a container, container and iced and cooled to an internal temperature of 40° F (4.4° C) or below within two hours of receipt in the packing room.
- (b) The storage of ice in the packing room shall be in an easily cleanable, non-corrosive, non-toxic container.
- (c) Blending or combining of any of the following shall be prohibited:
 - (1) Fresh crustacea meat. meat;
 - (2) Frozen frozen crustacea meat. meat;
 - (3) Pasteurized pasteurized crustacea meat. meat; and
 - (4) Crustacea crustacea meat packed in another facility.
- (d) Clean shipping containers shall be provided by the owner or responsible person for storing and shipping of packed crustacea meat.
- (e) The return of overage of crustacea meat to a picker shall be prohibited.
- (f) Washing of picked crustacea meat shall be under running potable water. The crustacea meat shall be thoroughly drained prior to packing.
- (g) Any substance added to cooked crustacea or crustacea meat shall be approved and labeled according to Federal and State rules and regulations.
- (h) Only those individuals responsible for packing the crustacea or crustacea meat shall be allowed in the packing room or area.

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

Eff. October 1, 1992.

15A NCAC 18A .0166 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0166 PICKED CRUSTACEA MEAT REFRIGERATION

- (a) The refrigeration room or ice box shall be of sufficient size so that a full day's production, with ice, can be properly stored in a sanitary manner and shall be equipped with an accurate, operating thermometer.
- (b) Ice boxes shall be easily cleanable, non-corrosive, and non-toxic with an impervious lining and a drain.
- (c) Picked crustacea meat shall be stored between 33° F (0.5° C) and 40° F (4.4° C). at 40° F (4.4° C) or below.

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

Eff. October 1, 1992.

15A NCAC 18A .0168 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0168 SINGLE-SERVICE CONTAINERS

- (a) Single-service containers used for packing or repacking cooked crustacea and crustacea meat shall be made from food safe food-safe materials approved by the United States Food and Drug Administration.
- (b) Containers shall not be reused for packing or repacking cooked crustacea and crustacea meat.
- (c) No person shall use containers bearing a permit number other than the number assigned to the facility.
- (d) Each container or lid shall be legibly impressed, <u>embossed embossed</u>, or lithographed with the name and address of the original packer, <u>repacker repacker</u>, or distributor. The original packer's or repacker's permit number preceded by the state abbreviation shall be legibly impressed, <u>embossed embossed</u>, or lithographed on each container or lid.
- (e) Each container or lid shall be permanently and legibly identified with a code date.
- (f) All containers and lids shall be stored and handled in accordance with these Rules, in a manner to prevent contamination, sanitized by a procedure as stated in Rule .0157 of this Section Section, and drained prior to filling.
- (g) All containers shall be sealed so that tampering can be detected. The words "Sealed For Your Protection" or equivalent shall be prominently displayed on the container or lid.

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

Eff. October 1, 1992;

Amended Eff. August 1, 1998; February 1, 1997.

15A NCAC 18A .0174 PASTEURIZATION PROCESS CONTROLS - THERMOMETERS

- (a) All pasteurizing equipment shall have a time-temperature recording thermometer with a temperature controller (combined or separately) and an indicating thermometer. The thermometers shall be located to give a true representation of the operating temperature of the water bath. The recording thermometer chart shall be at least a 12-hour chart and at least 10 inches in diameter.
- (b) The recording thermometer shall be installed so that it will be protected from vibration and from striking by loading operations or facility traffic. The thermometer mechanism shall be protected from moisture under prevailing conditions. The thermometer case shall not be opened during the pasteurizing cycle, except for temperature check or for emergency or repair. A record shall be made when the thermometer case has been opened.
- (c) The recording thermometer shall have a range of at least $120-220^{\circ}$ F (48.9-104.4° C). It shall be accurate within plus or minus 1° F between 160° F (71° C) and 200° F (93° C). The chart shall be scaled at a maximum of 2° F intervals in the range of 160° F (71° C) and 200° F (93° C).
- (d) The indicating thermometer shall be a thermometer with an accuracy and readability of plus or minus 1° F between 160° F (71° C) and 200° F (93° C). The thermometer shall be protected against damage.
- (e) The recording thermometer shall be equipped with a spring-operated or electrically operated clock. The recorded elapsed time as indicated by the chart rotation shall not exceed the true elapsed time as shown by an accurate watch. The rotating chart support shall be provided with pins upon which the chart shall be affixed by puncturing the chart.
- (f) The pasteurization unit shall not be operated without a recording thermometer chart in place, the pen in contact with the <u>chart_chart</u>, and an inked record being made of the operating time-temperature cycle. Any indication of <u>falsification of a thermometer chart shall constitute a violation</u>. Falsification of a thermometer chart shall not occur. A permanent file of the used thermometer charts shall be maintained by the pasteurizer and kept available for inspection by the Division of Marine Fisheries for a period of one year. The following information shall be recorded within the confines of the pen markings after the pasteurization cycle has been completed:
 - (1) Date <u>date</u> of pasteurization.
 - (2) Quantity quantity of each batch pasteurized (pounds of crustacea meat or number and size of containers).
 - (3) <u>Processor's processor's code of each pack.</u>
 - (4) <u>If-if</u> the pasteurizer processes crustacea meat for someone else, then the packer's name, <u>address</u> address, and permit number <u>must-shall</u> be recorded. A copy of the recording chart shall be provided to the owner of the crustacea meat.
 - (5) Notation notation of mechanical or power failure or opening of the recording thermometer case for adjustment or repair during the pasteurizing cycle.
 - (6) After after the optimum temperature in the water bath has been reached and during the holding time, the reading of the indicating thermometer and the time of reading shall be recorded on the chart.
 - (7) Signature signature of the pasteurizer operator.
- (g) A constant flow steam control valve is required, if steam is used as a source of heat.
- (h) The water bath shall be provided with effective agitation to maintain a uniform temperature.
- (i) Other technologies that provide the data, information information, and records as required in this Rule may be used if approved by the Division.

History Note: Authority G.S. 130A 230; <u>113-134; 113-182; 113-221.2; 143B-289.52;</u> Eff. October 1, 1992;

Amended Eff. April 1, 1997; Readopted Eff. April 1, 2022. 15A NCAC 18A .0175 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0175 PREPARATION OF CRUSTACEA MEAT FOR PASTEURIZATION

The preparation of crustacea meat for pasteurization shall be in compliance with the following:

- (1) Crustacea crustacea meat shall be prepared in compliance with Rules .0134 through .0183 of this Section.
- (2) The the containers of crustacea meat shall be sealed as quickly as possible after the crustacea meat is picked.
- (3) The the sealed container containers of crustacea meat shall be placed immediately in ice and refrigerated until pasteurized.

History Note: Authority G.S. 130A 230; <u>113-134;</u> 113-182; 113-221.2; 143B-289.52;

Eff. October 1, 1992;

Amended Eff. April 1, 1997;

15A NCAC 18A .0176 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0176 PASTEURIZATION OF CRUSTACEA MEAT

(a) All pasteurization operations shall require a Process Validation Study Report approved by the Division of Marine Fisheries prior to operation.

- (b) The pasteurization of crustacea meat shall be <u>conducted</u> in compliance with the <u>following:following procedures:</u>
 - (1) The the minimum pasteurization specifications shall be the raising of the internal temperature of the container heating every particle of crustacea meat in a hermetically-sealed container to a temperature of at least 185° F (85° C) and holding it continuously at that or above this temperature for at least one minute at the geometric center of a container. container in equipment being operated in compliance with the Process Validation Study Report. Each set of pasteurizing equipment shall be standardized so that the minimum pasteurization procedure in this Subparagraph can be obtained. The pasteurization procedure shall be performed in accordance with the standardization report. This process—A copy of the procedures for operating the pasteurizing equipment shall also—be posted adjacent to the pasteurization vat. The pasteurizer shall keep on file—the standardization—report on file and shall provide the Division a copy of such report.
 - (2) <u>Alteration alteration</u> of the equipment or loading of containers shall require the procedure be restandardized. a new Process Validation Study Report.
 - (3) The the containers of crustacea meat shall be cooled to 50° F (10° C) or below within three hours. hours of the completion of pasteurization.
 - (4) Refrigerated storage shall be provided for the cooled crustacea meat and shall maintain a storage temperature at or below 36° F (2.2° C). 38° F (3.3° C).

History Note: Authority G.S. 130A-230; <u>113-134;</u> <u>113-182;</u> <u>113-221.2;</u> <u>143B-289.52;</u>

Eff. October 1, 1992;

Amended Eff. August 1, 1998;

15A NCAC 18A .0177 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0177 LABELING OF PASTEURIZED CRUSTACEA MEAT

Labeling of pasteurized crustacea meat shall be in compliance with the following:

- (1) The the label used shall clearly identify the contents of the container as pasteurized crustacea meat.
- (2) Each each container shall be permanently and legibly identified with a code indicating the batch and day of processing.
- (3) The the words "Perishable-Keep Under Refrigeration", or equivalent, Refrigeration" or equivalent shall be prominently displayed on the container.
- (4) The the original packer's or repacker's permit number preceded by the state abbreviation shall be legibly impressed, embossed embossed, or lithographed on each container. Each container shall be legibly impressed, embossed embossed, or lithographed with the name and address of the original packer, repacker repacker, or distributor.

History Note: Authority G.S. 130A 230; <u>113-134;</u> <u>113-182;</u> <u>113-221.2;</u> <u>143B-289.52;</u>

Eff. October 1, 1992;

15A NCAC 18A .0178 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0178 INTERFACILITY PASTEURIZATION PROCEDURES

No person shall initiate interfacility pasteurization of crustacea meat without prior written approval by the <u>Division.</u> <u>Division of Marine Fisheries.</u> <u>Interfacility pasteurization of crustacea meat shall be in conjunction compliance with the following:</u>

- (1) <u>Crustacea crustacea meat shall be packed, labeled labeled,</u> and refrigerated in compliance with Rules .0134 through .0182 of this Section. Records shall be maintained to identify each batch of crustacea meat pasteurized.
- (2) Crustacea crustacea meat shall be shipped in an enclosed, easily cleanable vehicle at a temperature between 33° F (0.5° C) and of 40° F (4.4° C). C) or below.
- (3) Crustacea crustacea meat shall be pasteurized in compliance with Rules .0175 through .0177 of this Section. The pasteurizer shall provide a copy of each pasteurization chart to the original packer.

History Note: Authority G.S. 130A-230; <u>113-134;</u> <u>113-182;</u> <u>113-221.2;</u> <u>143B-289.52;</u>

Eff. October 1, 1992;

15A NCAC 18A .0181 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0181 EMBARGO OR DISPOSAL OF COOKED CRUSTACEA OR CRUSTACEA MEAT

- (a) When it has been determined by the Division of Marine Fisheries that cooked crustacea or crustacea meat have not been stored, transported, handled, cooked, picked, packed packed, or offered for sale in compliance with this Section, the cooked crustacea or crustacea meat shall be deemed adulterated.
- (b) Cooked crustacea or crustacea meat prepared for sale to the public-determined to be adulterated or misbranded, misbranded shall be subject to embargo or disposal by the Division in accordance with G.S. 113-221.4. 130A-21(e). The Division may embargo, condemn, destroy or otherwise dispose of all cooked crustacea or crustacea meat found to be adulterated or misbranded.

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

Eff. October 1, 1992;

Amended Eff. April 1, 1997; Readopted Eff. April 1, 2022. 15A NCAC 18A .0182 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0182 BACTERIOLOGICAL AND CONTAMINATION STANDARDS

- (a) Cooked crustacea or crustacea meat shall not exceed Escherichia coli Most Probable Number (MPN) of 36 per 100 grams of sample or exceed a standard plate count of 100,000 per gram.
- (b) Pasteurized crustacea meat shall contain no Escherichia coli or fecal coliform. Samples of pasteurized crustacea meat, taken within 24 hours of pasteurizing, shall not have a standard plate count of more than 3,000 per gram.
- (c) Thermally processed crustacea or crustacea meat shall not exceed Escherichia coli MPN of 36 per 100 grams of sample or exceed a standard plate count of 100,000 per gram.
- (d) Cooked crustacea or crustacea meat shall not be handled in a manner to make it an imminent hazard.
- (e) Cooked crustacea or crustacea meat found not complying with the standards as stated set forth in Paragraph (a),
- (b), (c), (c), or (d) of this Rule may be deemed adulterated by the Division of Marine Fisheries.

History Note: Authority G.S. 130A 230; <u>113-134;</u> <u>113-182;</u> <u>113-221.2;</u> <u>143B-289.52;</u>

Eff. October 1, 1992;

Amended Eff. August 1, 1998; February 1, 1997;

15A NCAC 18A .0183 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0183 ALTERNATIVE LABELING

A durable label, permanently affixed to the <u>container container</u> may be used to meet any labeling requirement in this Section.

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

Eff. October 1, 1992.

15A NCAC 18A .0184 THERMAL PROCESSING CONTROLS - THERMOMETERS

- (a) All thermal processing equipment shall have a time-temperature recording thermometer with a temperature controller (combined or separately) and an indicating thermometer. The thermometers shall be located to give a true representation of the operating temperature of the process. The recording thermometer chart shall be at least a 12-hour chart and at least 10 inches in diameter.
- (b) The recording thermometer shall be installed so that it will be protected from vibration and from striking by loading operations or facility traffic. The thermometer mechanism shall be protected from moisture under prevailing conditions. The thermometer case shall not be opened during the thermal processing cycle, except for temperature check or for emergency or repair. A record shall be made when the thermometer case has been opened.
- (c) The recording thermometer shall have a range of at least $120-220^{\circ}$ F (48.9-104.4° C). It shall be accurate within plus or minus 1° F between 160° F (71° C) and 200° F (93° C). The chart shall be scaled at a maximum of 2° F intervals in the range of 160° F (71° C) and 200° F (93° C).
- (d) The indicating thermometer shall be a thermometer with an accuracy and readability of plus or minus 1° F between 160° F (71° C) and 200° F (93° C). The thermometer shall be protected against damage.
- (e) The recording thermometer shall be equipped with a spring-operated or electrically operated clock. The recorded elapsed time as indicated by the chart rotation shall not exceed the true elapsed time as shown by an accurate watch. The rotating chart support shall be provided with pins upon which the chart shall be affixed by puncturing the chart.
- (f) The thermal processing unit shall not be operated without a recording thermometer chart in place, the pen in contact with the chart-chart, and an inked record being made of the operating time-temperature cycle. Any indication of falsification of a thermometer chart shall constitute a violation. Falsification of a thermometer chart shall not occur. A permanent file of the used thermometer charts shall be maintained by the thermal processor and kept available for inspection by the Division of Marine Fisheries for a period of one year. The following information shall be recorded within the confines of the pen markings after the thermal processing cycle has been completed:
 - (1) Date date of thermal processing.
 - (2) Quantity quantity of each batch thermally processed (pounds of crustacea meat or number and size of containers).
 - (3) Thermal processor's code of each pack.
 - (4) <u>If-if</u> the thermal processor processes crustacea meat for someone else, then the packer's name, <u>address-address,</u> and permit number <u>must-shall</u> be recorded. A copy of the recording chart shall be provided to the owner of the crustacea meat.
 - (5) Notation notation of mechanical or power failure or opening of the recording thermometer case for adjustment or repair during the thermal processing cycle.
 - (6) After after the optimum temperature in the thermal process has been reached and during the holding time, the reading of the indicating thermometer and the time of reading shall be recorded on the chart.
 - (7) Signature signature of the thermal process operator.
- (g) A constant flow steam control valve is required, if steam is used as a source of heat.
- (h) The thermal processing unit shall be provided with effective and uniform temperature.
- (i) Other technologies that provide the data, information information, and records as required in this Rule may be used if approved by the Division.

History Note: Authority G.S. 130A 230; <u>113-134; 113-182; 113-221.2; 143B-289.52;</u>

Eff. April 1, 1997;

15A NCAC 18A .0185 THERMAL PROCESSING OF CRUSTACEA AND CRUSTACEA MEAT

- (a) All thermal processing operations shall require a Process Validation Study Report approved by the Division of Marine Fisheries prior to operation.
- (b) The thermal processing of crustacea or crustacea meat shall be <u>conducted</u> in compliance with the <u>following:following procedures:</u>
 - (1) The the minimum thermal processing specifications shall be the raising of the internal heating of previously cooked temperature of the container of crustacea or crustacea meat to a desired temperature and for a specified time at the geometric center of a container. container in equipment being operated in compliance with the Process Validation Study Report. Each set of thermal processing equipment shall be standardized so that the minimum procedure can be obtained. The thermal process procedure shall be performed in accordance with the standardization report. This process A copy of the procedures for operating the thermal processing equipment shall also be posted adjacent to the thermal processing unit. The thermal processor shall keep on file the standardization report on file and shall provide the Division a copy of such report.
 - (2) <u>Alteration alteration of the equipment or loading of containers shall require the procedure be restandardized.</u> a new Process Validation Study Report.
 - (3) The the containers of crustacea or crustacea meat shall be cooled to 50° F (10° C) or below within three hours, hours of the completion of the thermal process.
 - (4) Refrigerated storage shall be provided for the cooled crustacea or crustacea meat and shall maintain a storage temperature at or below 36° F (2.2° C).

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

Eff. August 1, 1998;

15A NCAC 18A .0186 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0186 LABELING OF THERMALLY PROCESSED CRUSTACEA OR CRUSTACEA MEAT

Labeling of thermally processed crustacea or crustacea meat shall be in compliance with the following:

- (1) The the label used shall clearly identify the contents of the container as thermally processed crustacea or crustacea meat.
- (2) Each each container shall be permanently and legibly identified with a code indicating the batch and day of processing.
- (3) The the words "Perishable-Keep Under Refrigeration" or equivalent shall be prominently displayed on the container.
- (4) The the original packer's or repacker's permit number preceded by the state abbreviation shall be legibly impressed, embossed embossed, or lithographed on each container. Each container shall be legibly impressed, embossed embossed, or lithographed with the name and address of the original packer, repacker repacker, or distributor.

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

Eff. April 1, 1997;

15A NCAC 18A .0187 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0187 INTERFACILITY THERMAL PROCESSING PROCEDURES

Interfacility thermal processing of crustacea or crustacea meat shall be in conjunction compliance with the following:

- (1) <u>Crustacea crustacea</u> or crustacea meat shall be packed, <u>labeled labeled</u>, and refrigerated in compliance with Rules .0134 through .0187 of this Section. Records shall be maintained to identify each batch of crustacea or crustacea meat thermally processed.
- (2) Crustacea crustacea or crustacea meat shall be shipped in an enclosed, easily cleanable vehicle at a temperature between 33° F (0.5° C) and of 40° F (4.4° C). C) or below.
- (3) Crustacea crustacea or crustacea meat shall be thermally processed in compliance with Rules .0184 through .0187 of this Section. The thermal processor shall provide a copy of each thermal processing chart to the original packer.

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

Eff. August 1, 1998;

15A NCAC 18A .0191 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .0191 MONITORING RECORDS

Monitoring records of critical control points and general sanitation requirements shall be recorded, as specified in plan, the HACCP Plan, and signed and dated when recorded. The records shall be reviewed by the owner or designee within one week of recording.

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

Eff. August 1, 2000.