TITLE 15A - DEPARTMENT OF ENVIRONMENT, HEALTH, AND NATURAL RESOURCES

CHAPTER 18 - ENVIRONMENTAL HEALTH

SUBCHAPTER 18A - SANITATION

SECTION .0100 - HANDLING: PACKING: AND SHIPPING OF CRUSTACEA MEAT

Rules .0101 - .0133 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18A .0101 - .0133); has been transferred and recodified from Rules .0701 - .0733 Title 10 Subchapter 10B of the North Carolina Administrative Code (T10.10B .0701 - .0733), effective April 4, 1990.

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History Note: Authority G.S. 130A-230;
Eff. February 1, 1976;
Readopted Eff. December 5, 1977;
Amended Eff. September 1, 1991; September 1, 1990; December 1, 1987; July 1, 1985, 1980;

15A NCAC 18A .0133 REFERENCE

History Note: Authority G.S. 130A-230;
Eff. February 1, 1976;
15A NCAC 18A .0134 DEFINITIONS

The following definitions shall apply throughout 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 cooked crustacea or crustacea meat that does not comply with these Rules;
   (b) Any cooked crustacea or crustacea meat which exceeds the bacteriological standards in Rule .0182 of this Section;
   (c) Any cooked crustacea or crustacea meat which has been deemed to be an imminent hazard;

(2) "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, step or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated or reduced to acceptable levels.

(5) "Critical limit" means the maximum or minimum value to which a physical, biological or chemical parameter must be controlled at a critical control point to prevent, 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 or crayfish.

(7) "Division" means the Division of Environmental Health or its authorized agent.

(8) "Food-contact surface" means the parts of equipment, including auxiliary equipment, which may be in contact with the food being processed, or which may drain into the portion of equipment with which food is in contact.

(9) "Food safety hazard" means any biological, chemical or physical property that may cause a food to be unsafe for human consumption.

(10) "Foreign" means any place or location outside the United States.

(11) "Fresh crustacea" means a live, raw or frozen raw crab, lobster, shrimp or crayfish which shows no decomposition.

(12) "HACCP plan" means a written document that delineates the formal procedures a dealer follows to implement food safety controls.

(13) "Hazard analysis critical control point (HACCP)" means a system of inspection, control and monitoring measures initiated by a dealer to identify microbiological, chemical or physical food safety hazards which are likely to occur in shellfish products produced by the dealer.

(14) "Imminent hazard" means a situation which 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) "Internal temperature" means the temperature of the product as opposed to the ambient temperature.

(16) "Misbranded" as used in G.S. 106-130 means any container of cooked crustacea or crustacea meat which is not labeled in compliance with these Rules.

(17) "Operating season" means the season of the year during which a crustacea product is processed.

(18) "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) and holding it continuously at or above this temperature for at least one minute in properly operated equipment. The term includes any other process which has been found equally effective by the Division.

(19) "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.
"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.

"Repacker" means a facility which repacks cooked crustacea meat into other containers.

"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.

"Sanitize" means a bactericidal treatment by a process which meets the temperature and chemical concentration levels in 15A NCAC 18A .2619.

"Standardization report" means a report of tests which show that a piece of equipment can produce time/temperature results as required by these Rules.

"Thermal processing" means the heating of previously cooked crustacea or crustacea meat to a desired temperature for a specified time in properly operated equipment.

History Note: Authority G.S. 106-129; 106-130; 130A-230; Eff. October 1, 1992; Amended Eff. August 1, 2000; August 1, 1998; February 1, 1997.

15A NCAC 18A .0135 PERMITS

(a) No person shall operate a processing facility without a permit issued by the Division.
(b) No person shall operate a repacker facility without a repacker permit issued by the Division.
(c) Application for a permit shall be submitted in writing on an application form available from the Division.
(d) No permit shall be issued by the Division until an inspection shows that the facility and equipment comply with applicable rules of this Section.
(e) A permit issued to one person is not transferrable to another person.
(f) The permit shall be posted in a conspicuous place in the facility. All permits shall expire on March 31 of each year.
(g) Plans and specifications for proposed new construction, expansion of operations or changes in operating processes shall be submitted to the Division for review and approval prior to beginning construction.
(h) A permit may be revoked or suspended pursuant to G.S. 130A-23.
(i) The owner or responsible person shall sign the completed inspection sheet to acknowledge receipt of the inspection sheet.

History Note: Authority G.S. 130A-23; 130A-230; Eff. October 1, 1992.

15A NCAC 18A .0136 APPLICABILITY OF RULES

The Rules in this Section shall apply to the operation of all facilities and persons permitted in Rule .0135 of this Section and all other businesses and persons that buy, sell, transport or ship cooked crustacea or crustacea meat which has not been transformed into another product. Foreign crustacea meat processed in North Carolina shall comply with all applicable Federal requirements.

History Note: Authority G.S. 130A-230; Eff. October 1, 1992; Amended Eff. April 1, 1997.

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 Division.
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.
(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.

15A NCAC 18A .0139 FACILITY FLOODING
If the facility floors are flooded, processing shall be discontinued until flood waters have receded and the facility and equipment are cleaned and sanitized. Any cooked crustacea or crustacea meat which may have been contaminated by flood waters shall be deemed adulterated and disposed of in accordance with G.S. 130A-21(c).

15A NCAC 18A .0140 FLOORS
Floors shall be of concrete or other equally impervious material, constructed so that they may be easily cleaned and shall be sloped so that water drains.

15A NCAC 18A .0141 WALLS AND CEILINGS
(a) Walls and ceilings shall be constructed of smooth, easily cleanable, non-corrosive, impervious material.
(b) Insulation on cooked crustacea cooler walls shall be covered to the ceiling with a smooth, easily cleanable, non-corrosive, impervious material.
(c) Doors and windows shall be properly fitted and maintained in good repair.

15A NCAC 18A .0142 LIGHTING
(a) Natural or artificial lighting shall be provided in all parts of the facility. Minimum lighting intensities shall be as follows:
   (1) 50 foot-candles on working surfaces in the picking and packing rooms and areas.
   (2) 10 foot-candles measured at a height of 30 inches above the floor throughout the rest of the processing portion of the facility.
(b) Light bulbs within the processing portion of the facility shall be shatterproof or shielded to prevent product contamination in case of breakage.
15A NCAC 18A .0143  VENTILATION
All rooms and areas shall be ventilated.

15A NCAC 18A .0144  INSECT CONTROL
All outside openings shall be screened, provided with wind curtains 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.

15A NCAC 18A .0145  RODENT AND ANIMAL CONTROL
Measures shall be taken 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.

15A NCAC 18A .0146  PREMISES
(a) Premises under the control of the owner shall be kept clean at all times. Waste materials, rubbish, other articles or litter shall not be permitted to accumulate on the premises. Other items shall be properly stored.
(b) Measures shall be taken to prevent the harborage and breeding of insects, rodents and other vermin on premises.

15A NCAC 18A .0147  WATER SUPPLY
(a) The water supply used shall be in accordance with 15A NCAC 18A .1700.
(b) A cooked crustacea facility using a non-community water supply shall be listed with the Public Water Supply Section, Division of Environmental Health.
(c) Water samples for bacteriological analysis shall be collected at least annually by the Division and submitted to the Laboratory Division of the Department or another laboratory certified by the Department for analysis.
(d) Cross-connections with unapproved water supplies are prohibited. Hot and cold running water under pressure shall be provided to food preparation, 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, cleaning and other water-using operations.
15A NCAC 18A .0148  ICE
(a) Ice shall be obtained from a water supply approved by the Division pursuant to Rule .0147 of this Section and shall be stored and handled in accordance with these Rules.
(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;

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 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 room or area.
   (2) Toilet or lounge area.
   (3) 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 suitable testing method or equipment shall be available and regularly used to test chemical sanitizers to insure 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 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;

15A NCAC 18A .0150  SEWAGE DISPOSAL
All sewage and other liquid wastes shall be disposed of in a public sewer system or in the absence of a public sewer system, by an on-site method approved by the Division or the Department of Environment, Health, and Natural Resources.

History Note:  Authority G.S. 130A-230;
15A NCAC 18A .0151 TOILETS
(a) Toilets shall be provided in the facility; however, privies may be substituted for toilets when the conditions in Paragraph (d) of this Rule are met.
(b) Toilet tissue shall be provided.
(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;

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.
(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;

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.
(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, picking or packing of cooked crustacea or crustacea meat shall wear clean, washable outer clothing.
(d) Employees shall not eat food, drink nor use tobacco in any form in the areas where cooked crustacea or crustacea meat are stored, processed 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.
(h) Personnel who pick and pack cooked crustacea or crustacea meat shall have clean short 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;

15A NCAC 18A .0154 EMPLOYEES' PERSONAL ARTICLES
Employees' street clothing, aprons, gloves and personal articles shall not be stored in rooms or areas described in Rule .0159(b) of this Section.

History Note: Authority G.S. 130A-230; Eff. October 1, 1992.

15A NCAC 18A .0155 SUPPLY STORAGE
Shipping containers, boxes and other supplies shall be stored in a storage room or area. The storage room or area shall be kept clean.

History Note: Authority G.S. 130A-230; Eff. October 1, 1992.

15A NCAC 18A .0156 EQUIPMENT AND UTENSIL CONSTRUCTION
All processing equipment and utensils shall be smooth, easily cleanable, durable and kept in good repair. The food-contact surfaces of equipment, utensils and processing machinery shall be easily accessible for cleaning, non-toxic, non-corrosive, non-absorbent and free of open seams.

History Note: Authority G.S. 130A-230; 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, rinsed 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 and sanitized each time crustacea meat is delivered to the packing room.

(d) Sanitizing methods are as follows:

(1) By steam in a steam chamber or box equipped with an indicating thermometer located in the coldest zone, by 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 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 (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 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 have to be washed in place will require washing, rinsing and sanitizing.

(4) 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 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 suitable testing method or equipment shall be available and regularly used to test chemical sanitizers to insure minimum prescribed strengths.

History Note: Authority G.S. 130A-230;
15A NCAC 18A .0158  EQUIPMENT STORAGE
Equipment and utensils that have been cleaned and sanitized shall be stored to protect against contamination.

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

15A NCAC 18A .0159  SEPARATION OF OPERATIONS
(a) Facility design shall provide for continuous flow of raw materials and product to prevent contamination by exposure to areas involved in earlier processing steps, refuse or other areas subject to contamination.
(b) The following processes shall be carried out in separate rooms or areas:
   (1) Raw crustacea receiving or refrigeration.
   (2) Crustacea cooking.
   (3) Cooked crustacea air-cool.
   (4) Cooked crustacea refrigeration.
   (5) Picking.
   (6) Packing.
   (7) Picked crustacea meat refrigeration.
   (8) Pasteurizing/thermal processing.
   (9) Machine picking.
   (10) Repacking.
   (11) Other processes when carried out in conjunction with the cooking of crustacea or crustacea meat.

History Note:  Authority G.S. 130A-230;
Eff. October 1, 1992;
Amended Eff. April 1, 1997.

15A NCAC 18A .0160  RAW CRUSTACEA RECEIVING AND REFRIGERATION
(a) Only fresh crustacea shall be accepted for processing.
(b) Within two hours of receipt at the facility, crustacea shall be cooked or placed in a refrigerated area maintaining a temperature of 50° F (10 C) or below.

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

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 has been found equally effective and approved by the Division.
(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 accurate, indicating thermometer with a range that will include 170-270° F (77-132° C) and located with the sensor extending into the heat chamber.
   (2) An operating pressure indicator, at least three inches in diameter, with a 0-30 psig range and located adjacent to the indicating thermometer.
   (3) A safety valve operational at 18-30 psig, located in the upper portion of the retort, protected from 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 and durable material, and shall be designed to allow for equal steam disbursement, ease of handling, dumping and cleaning.

(h) All construction or replacement of retorts after October 1, 1992 shall be "flow-through" type and opening directly into the air-cool room or a protected passageway into the air-cool room.

History Note: Authority G.S. 130A-230; Eff. October 1, 1992.

15A NCAC 18A .0162 COOKED CRUSTACEA AIR-COOL
(a) Cooked crustacea, after removal from the retort, shall be moved immediately to the cooked crustacea air cool area to be air cooled to ambient temperature without being disturbed. Cooked crustacea shall be stored in original cooking basket.

(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; Eff. October 1, 1992.

15A NCAC 18A .0163 COOKED CRUSTACEA REFRIGERATION
(a) The cooked crustacea cooler shall be large enough to store all cooked crustacea and maintain a minimum temperature of 40° F (4.4° C). The cooler shall open directly into the picking room or into a clean, enclosed area leading into the picking room.

(b) Cooked crustacea shall be stored at a temperature between 33° F (0.5° C) and 40° F (4.4° C) ambient air temperature if not immediately processed. The cooler shall be equipped with an accurate, operating thermometer.

History Note: Authority G.S. 130A-230; Eff. October 1, 1992.

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 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 to insure 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 the following:
   (1) time-temperature;
   (2) shipping-destination;
   (3) handling;
(4) labeling;
(5) records;
(6) processing;
(7) sanitation; and
(8) HACCP plan.

History Note:  Authority G.S. 130A-230;
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 PACKING
(a) Crustacea meat shall be packed in a container, 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.
   (2) Frozen crustacea meat.
   (3) Pasteurized crustacea meat.
   (4) Crustacea meat packed in another facility.
(d) Clean shipping containers shall be provided for storing and shipping of packed crustacea meat.
(e) The return of overage 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;

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 and shall be equipped with an accurate, operating thermometer.
(b) Ice boxes shall be easily cleanable, non-corrosive, 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).

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

15A NCAC 18A .0167 DELIVERY WINDOW OR SHELF
A delivery window or a non-corrosive shelf shall be provided between the picking room and packing room or area. The delivery window shall be equipped with a shelf completely covered with smooth, non-corrosive metal or other material approved by the Division and sloped to drain towards the picking room.

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

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 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, embossed or lithographed with the name and address of the original packer, repacker or distributor. The original packer's or repacker's permit number preceded by the state abbreviation shall be legibly impressed, embossed 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, sanitized by a procedure as stated in Rule .0157 of this 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;
Eff. October 1, 1992;
Amended Eff. August 1, 1998; February 1, 1997.

15A NCAC 18A .0169 FREEZING
(a) If crustacea or crustacea meat is to be frozen, the code date shall be followed by the letter "F."
(b) Frozen crustacea or crustacea meat shall be stored at a temperature of 0°F (-18°C) or less.
(c) The frozen storage rooms shall be equipped with an accurate, operating thermometer.

History Note: Authority G.S. 130A-230;
Eff. October 1, 1992;
Amended Eff. August 1, 2002; April 1, 1997.

15A NCAC 18A .0170 SHIPPING
Cooked crustacea and crustacea meat shall be shipped between 33°F (0.5°C) and 40°F (4.4°C). Frozen crustacea products shall be shipped at 0°F (-18°C) or below.

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

15A NCAC 18A .0171 WHOLE CRUSTACEA OR CRUSTACEA PRODUCTS
Whole crustacea, claws or any other crustacea products shall be prepared, packaged and labeled in accordance with the rules of this Section.

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

15A NCAC 18A .0172 COOKED CLAW SHIPPING CONDITIONS
(a) Vehicles used to transport cooked claws shall be mechanically refrigerated, enclosed, tightly constructed, kept clean and equipped with an operating thermometer.
(b) Cooked crab claws shall be stored and transported between 33°F (0.5°C) and 40°F (4.4°C) ambient air temperature.
(c) All vehicles shall be approved by the Division prior to use.
(d) Cooked claw shipping containers shall be marked for intended use, cleaned and sanitized prior to use and approved by the Division.

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

15A NCAC 18A .0173 REPACKING
(a) Crustacea meat for repacking which is processed in North Carolina shall comply with Rules .0134 through .0187 of this Section. Crustacea meat for repacking which is processed outside of North Carolina shall comply with Rule .0182 of this Section. Quarterly bacteriological reports shall be provided to the Division by the repacker of all foreign crustacea meat for repacking.

(b) The repacker shall provide the Division a current written list of all sources of crustacea meat used for repacking.

(c) Repacking of crustacea meat:

(1) Crustacea meat shall not exceed 45° F (7.1° C) during the repacking process.

(2) Repacking shall be conducted separately by time or space from the routine crustacea meat picking and packing process.

(3) The food contact surfaces and utensils utilized in the repacking process shall be cleaned and sanitized prior to repacking and thereafter on 30 minute intervals during repacking.

(4) Repacked crustacea meat shall be maintained at or below 40° F (4.4° C).

(5) Blending or combining of any of the following shall be prohibited:

(A) Fresh crustacea meat.

(B) Frozen crustacea meat.

(C) Pasteurized crustacea meat.

(D) Crustacea meat packed in another facility.

(6) Crustacea meat shall not be repacked more than one time.

(7) All empty containers shall be rendered unusable.

(d) Labeling of repacked crustacea meat:

(1) Each container shall be legibly embossed, impressed or lithographed with the repacker's or the distributor's name and address.

(2) Each container shall be legibly embossed, impressed or lithographed with the repacker's certification number followed by the letters "RP."

(3) Each container shall be permanently and legibly identified with a code indicating the repack date.

(4) Each container shall be sealed so that tampering can be detected.

(5) Each container of foreign crustacea meat which has been repacked shall be labeled in accordance with Federal labeling requirements.

(e) Records shall be kept for all purchases of crustacea meat for repacking and sales of repacked meat for one year. The records shall be available for inspection by the Division.

History Note: Authority G.S. 130A-230; Eff. October 1, 1992; Amended Eff. August 1, 2002; April 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° 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 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. A permanent file of the used thermometer charts shall be maintained by the
pasteurizer and kept available for inspection by the Division 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 of pasteurization.
2. Quantity of each batch pasteurized (pounds of crustacea meat or number and size of containers).
3. Processor's code of each pack.
4. If the pasteurizer processes crustacea meat for someone else, then the packer's name, address and permit number must be recorded. A copy of the recording chart shall be provided to the owner of the crustacea meat.
5. Notation of mechanical or power failure or opening of the recording thermometer case for adjustment or repair during the pasteurizing cycle.
6. 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 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 and records as required in this Rule may be used if approved by the Division.

History Note: Authority G.S. 130A-230; Eff. October 1, 1992; Amended Eff. April 1, 1997.

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

History Note: Authority G.S. 130A-230; Eff. October 1, 1992; Amended Eff. April 1, 1997.

15A NCAC 18A .0176 PASTEURIZATION OF CRUSTACEA MEAT
The pasteurization of crustacea meat shall be in compliance with the following:

1. The minimum pasteurization specifications shall be the raising of the internal temperature of the container of crustacea meat to 185°F (85°C) and holding at that temperature for at least one minute at the geometric center of a container. 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 shall also be posted adjacent to the pasteurization vat. The pasteurizer shall keep on file the standardization report and shall provide the Division a copy of such report.
2. Alteration of the equipment or loading of containers shall require the procedure be restandardized.
3. The containers of crustacea meat shall be cooled to 50°F (10°C) or below within three hours.
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).

History Note: Authority G.S. 130A-230; Eff. October 1, 1992; Amended Eff. August 1, 1998.

15A NCAC 18A .0177 LABELING OF PASTEURIZED CRUSTACEA MEAT
Labeling of pasteurized crustacea meat shall be in compliance with the following:
(1) The label used shall clearly identify the contents of the container as pasteurized crustacea meat.

(2) Each container shall be permanently and legibly identified with a code indicating the batch and day of processing.

(3) The words "Perishable-Keep Under Refrigeration", or equivalent, shall be prominently displayed on the container.

(4) The original packer's or repacker's permit number preceded by the state abbreviation shall be legibly impressed, embossed or lithographed on each container. Each container shall be legibly impressed, embossed or lithographed with the name and address of the original packer, repacker or distributor.

**History Note:** Authority G.S. 130A-230; Eff. October 1, 1992.

### 15A NCAC 18A .0178 INTERFACILITY PASTEURIZATION PROCEDURES

No person shall initiate interfacility pasteurization of crustacea meat without prior written approval by the Division. Interfacility pasteurization of crustacea meat shall be in conjunction with the following:

(1) Crustacea meat shall be packed, labeled 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 meat shall be shipped in an enclosed, easily cleanable vehicle at a temperature between 33° F (0.5° C) and 40° F (4.4° C).

(3) 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; Eff. October 1, 1992.

### 15A NCAC 18A .0179 RECALL PROCEDURE

Each owner of a cooked crustacea or crustacea meat facility or repacker facility shall keep on file a written product recall procedure. A copy of this recall procedure shall be provided to the Division.

**History Note:** Authority G.S. 130A-230; Eff. October 1, 1992.

### 15A NCAC 18A .0180 SAMPLING AND TESTING

Samples of cooked crustacea or crustacea meat may be taken and examined by the Division at any time or place. Samples of cooked crustacea or crustacea meat shall be furnished by the owner or operator of facilities, trucks, carriers, stores, restaurants and other places where cooked crustacea or crustacea meat are sold.

**History Note:** Authority G.S. 130A-230; Eff. October 1, 1992.

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

(a) When it has been determined by the Division that cooked crustacea or crustacea meat have not been stored, transported, handled, cooked, picked, 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, shall be subject to embargo or disposal by the Division in accordance with G.S. 130A-21(c). 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;
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 in Paragraph (a), (b), (c) or (d) of this Rule may be deemed adulterated by the Division.

History Note:  Authority G.S. 130A-230;  
Eff. October 1, 1992;  
Amended Eff. August 1, 1998; February 1, 1997.

15A NCAC 18A .0183  ALTERNATIVE LABELING
A durable label, permanently affixed to the container may be used to meet any labeling requirement in this Section.

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

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° 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 and an inked record being made of the operating time-temperature cycle. Any indication of falsification of a thermometer chart shall constitute a violation. A permanent file of the used thermometer charts shall be maintained by the thermal processor and kept available for inspection by the Division 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 of thermal processing.
(2) 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) If the thermal processor processes crustacea meat for someone else, then the packer's name, address and permit number must be recorded. A copy of the recording chart shall be provided to the owner of the crustacea meat.

(5) Notation of mechanical or power failure or opening of the recording thermometer case for adjustment or repair during the thermal processing cycle.

(6) 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 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 and records as required in this Rule may be used if approved by the Division.

History Note: Authority G.S. 130A-230; Eff. April 1, 1997.

15A NCAC 18A .0185 THERMAL PROCESSING OF CRUSTACEA AND CRUSTACEA MEAT
The thermal processing of crustacea or crustacea meat shall be in compliance with the following:

(1) The minimum thermal processing specifications shall be the raising of the internal temperature of the container of crustacea or crustacea meat to a desired temperature and time at the geometric center of a container. 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 shall also be posted adjacent to the thermal processing unit. The thermal processor shall keep on file the standardization report and shall provide the Division a copy of such report.

(2) Alteration of the equipment or loading of containers shall require the procedure be restandardized.

(3) The containers of crustacea or crustacea meat shall be cooled to 50°F (10°C) or below within three hours.

(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; Eff. August 1, 1998.

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 label used shall clearly identify the contents of the container as thermally processed crustacea or crustacea meat.

(2) Each container shall be permanently and legibly identified with a code indicating the batch and day of processing.

(3) The words "Perishable-Keep Under Refrigeration" or equivalent shall be prominently displayed on the container.

(4) The original packer's or repacker's permit number preceded by the state abbreviation shall be legibly impressed, embossed or lithographed on each container. Each container shall be legibly impressed, embossed or lithographed with the name and address of the original packer, repacker or distributor.

History Note: Authority G.S. 130A-230; Eff. April 1, 1997.

15A NCAC 18A .0187 INTERFACILITY THERMAL PROCESSING PROCEDURES
Interfacility thermal processing of crustacea or crustacea meat shall be in conjunction with the following:

(1) Crustacea or crustacea meat shall be packed, labeled 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.
Crustacea or crustacea meat shall be shipped in an enclosed, easily cleanable vehicle at a temperature between 33°F (0.5°C) and 40°F (4.4°C).

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; Eff. August 1, 1998.

15A NCAC 18A .0188 HAZARD ANALYSIS
Each dealer shall conduct a hazard analysis to determine the food safety hazards that are reasonably likely to occur for each kind of crustacea or crustacea meat product processed by that dealer and to identify the preventative measures that the dealer can apply to control those hazards.

History Note: Authority G.S. 130A-230; Eff. August 1, 2000.

15A NCAC 18A .0189 HACCP PLAN
Each dealer shall have and implement a written HACCP Plan. The owner or authorized designee shall sign the plan when implemented and after any modification. The plan shall be reviewed and updated, if necessary, at least annually. The plan shall, at a minimum:

1. List the food safety hazards that are reasonably likely to occur;
2. List the critical control points for each of the food safety hazards;
3. List the critical limits that must be met for each of the critical control points;
4. List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;
5. List any corrective action plans to be followed in response to deviations from critical limits at critical control points;
6. Provide a record keeping system that documents critical control point monitoring; and
7. List the verification procedures, and frequency thereof, that the dealer will use.

History Note: Authority G.S. 130A-230; Eff. August 1, 2000.

15A NCAC 18A .0190 SANITATION MONITORING REQUIREMENTS
Each dealer shall monitor, at a minimum, the following sanitation items:

1. Safety of water;
2. Condition and cleanliness of food contact surfaces;
3. Prevention of cross contamination;
4. Maintenance of hand washing, hand sanitizing and toilet facilities;
5. Protection of crustacea or crustacea meat, crustacea or crustacea meat packaging materials and food contact surfaces from adulteration;
6. Proper labeling, storage and use of toxic compounds;
7. Control of employees with adverse health conditions; and
8. Exclusion of pests from the facility.

History Note: Authority G.S. 130A-230; Eff. August 1, 2000.

15A NCAC 18A .0191 MONITORING RECORDS
Monitoring records of critical control points and general sanitation requirements shall be recorded, as specified in plan, signed and dated when recorded. The records shall be reviewed by owner or designee within one week of recording.

History Note: Authority G.S. 130A-230; Eff. August 1, 2000.