

## SECTION .0300 – SANITATION OF SHELLFISH - GENERAL

### 15A NCAC 18A .0301 DEFINITIONS

The following definitions shall apply throughout Sections .0300 through .0800 of this Subchapter:

- (1) "Adulterated" means:
  - (a) any shellfish that have been harvested from polluted areas as defined in 15A NCAC 03I .0101;
  - (b) any shellfish that have been shucked, packed, or otherwise processed in a plant that has not been permitted by the Division of Marine Fisheries in accordance with these Rules or by another state shellfish control "authority" as defined in the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish, Section I: Purposes and Definitions. This definition is incorporated by reference, including subsequent amendments and editions. A copy of the reference material can be found at <https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp>, at no cost;
  - (c) any shellfish that may have been contaminated by flood waters in accordance with Rule .0405 of this Subchapter;
  - (d) any shellfish that exceed the standards in Rule .0430 of this Subchapter; and
  - (e) any shellfish that have been deemed to be an imminent hazard.
- (2) "Certification number" means the unique identification number assigned by the state shellfish control agency to each certified shellfish dealer for each location. It consists of a one-to-five-digit number preceded by the two-letter state abbreviation and followed by the two-letter abbreviation designating the type of operation certified.
- (3) "Clean" means free from dirt, debris, dust, marks, stains, waste materials, litter, or foreign material.
- (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) "Depurate" or "depuration" means the process of reducing the pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as the treatment process.
- (7) "Depuration facility" means any establishment or place where the depuration of shellfish occurs by a shellfish dealer.
- (8) "Division" means the Division of Marine Fisheries.
- (9) "Easily cleanable" has the same meaning as defined in the 2017 U.S. Food Code. This definition is incorporated by reference, not including subsequent amendments and editions. A copy of the reference material can be found at <https://www.fda.gov/food/fda-food-code/food-code-2017>, at no cost.
- (10) "Food contact surface" means the parts of equipment, including auxiliary equipment, that may be in contact with the food being processed, or that may drain into the portion of equipment with which food is in contact.
- (11) "Food safety hazard" means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.
- (12) "Good repair" means maintained to function as designed and without defect.
- (13) "HACCP plan" means a written document that delineates the procedures a shellfish dealer follows to implement food safety controls.
- (14) "Hazard analysis critical control point (HACCP)" means a system of inspection, control, and monitoring measures initiated by a shellfish dealer to identify microbiological, chemical, or physical food safety hazards that are likely to occur in shellfish products produced by the dealer.
- (15) "Heat shock process" means the practice of heating shellstock to facilitate removal of the shellfish meat from the shell.
- (16) "Imminent hazard" has the same meaning as defined in G.S. 130A-2.
- (17) "In-shell product" means non-living, processed shellfish with one or both shells present.

- (18) "Misbranded" as defined in G.S. 106-30 shall include any shellfish that are not labeled in compliance with these Rules.
- (19) "National Shellfish Sanitation Program (NSSP)" means the federal/state cooperative program recognized by the U.S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish produced and sold for human consumption.
- (20) "Pests" means animals or insects, including dogs, cats, birds, rodents, flies, and larvae.
- (21) "Plant" means the establishment or place where shellfish processing occurs by shellfish dealers.
- (22) "Processing" or "processed" means any activity associated with the handling, shucking, freezing, packing, labeling, or storing of shellfish in preparation for distribution. This includes the activities of a shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor.
- (23) "Recall procedure" means the detailed procedure the shellfish dealer will use to retrieve product from the market when it is determined that the product is adulterated or misbranded.
- (24) "Repacking plant" means the establishment or place where a shellfish dealer, other than the original shucker-packer, repacks shucked shellfish into other containers.
- (25) "Reshipper" means a person that purchases shellfish from a shellfish dealer and sells the product without repacking or relabeling to another shellfish dealer, wholesaler, or retailer.
- (26) "Responsible individual" means the individual present at a shellfish dealer that is the supervisor or the supervisor's designee at the time of the inspection.
- (27) "Sanitize" has the same meaning as defined in 21 CFR 110.3, which is incorporated by reference including subsequent amendments and editions. A copy of the reference material can be found at <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-110/subpart-A/section-110.3>, at no cost.
- (28) "SELL BY date" means a date placed on a container or tag by which a consumer is informed of the latest date the product will remain suitable for sale.
- (29) "Shellfish" means oysters, mussels, scallops, and all varieties of clams, whether shucked or in the shell, fresh, frozen, whole, or in part. The requirements of Sections .0300 through .0800 of this Subchapter shall not apply to scallops if the final product is the shucked adductor muscle only.
- (30) "Shellfish dealer" means a plant to which a Shellfish Dealer Permit and Certificate of Compliance is issued by the Division for the activities of shellstock shipping, shucking or packing, repacking, reshipping, or depuration.
- (31) "Shellstock" means any live molluscan shellfish that remain in their shells.
- (32) "Shellstock conveyance" means all trucks, vessels, trailers, or other conveyances used to transport shellstock.
- (33) "Shellstock plant" means any establishment or place where shellstock are washed, packed, or otherwise prepared for sale by a shellfish dealer.
- (34) "Shucking and packing plant" means any establishment or place where shellfish are shucked and packed for sale by a shellfish dealer.
- (35) "Use" means employ, set, operate, or permit to be operated or employed.
- (36) "Wet storage" means the storage by a shellfish dealer of shellstock from a growing area in the open status and classified as "approved" or "conditionally approved" as defined in Rule .0901 of this Subchapter, in containers or floats in natural bodies of water, or in tanks containing natural or synthetic sea water at any permitted land-based activity or facility.

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