

15A NCAC 18A .0434 HACCP PLAN

(a) Each shellfish dealer shall have and implement a written HACCP plan specific to each kind of shellfish product processed. The owner or authorized individual shall sign the plan when implemented, which shall signify that the plan has been accepted for implementation by the dealer. The HACCP plan shall also be signed by the owner or authorized individual after any modification or verification of the plan as required by this Rule. 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.

For the purpose of this Rule, "reasonably likely to occur" shall mean a food safety hazard for which a processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the absence of those controls, as defined in 21 CFR 123.6, 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-123>, at no cost.

(b) With the exception of a shellfish dealer that has not been permitted for interstate commerce, the following functions shall be performed by an individual who has successfully completed Segment one and Segment two of a seafood HACCP training course approved by the Seafood HACCP Alliance or an equivalent training course where the curriculum covers the principles of HACCP, conducting a hazard analysis, and developing a HACCP plan for a seafood business:

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

(c) If a deviation from a critical limit occurs, the shellfish dealer shall take corrective action in accordance with 21 CFR 123.7, 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-123/subpart-A/section-123.7#p-123.7\(b\)](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-123/subpart-A/section-123.7#p-123.7(b)), at no cost.

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

- (1) a reassessment of the plan when a change occurs that could affect the hazard analysis, and a review of any consumer complaints that have been received; and
- (2) a review, including signing and dating by the trained individual or responsible individual, of the records that document the monitoring of critical control points, the taking of corrective actions, and the calibrating of any process-monitoring instruments. This review shall occur within one week of the day that the records are made.

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

- (1) the name and location of the dealer;
- (2) the date and time of the activity that the record reflects;
- (3) the signature or initials of the individual performing the operation; and
- (4) the identity of the product and the production code, if any.

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