



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

92079d

60 8th Street, N.E.
Atlanta, Georgia 30309

December 20, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

William G. Garner, Co-owner
Kenneth R. Bryant, Jr., Co-owner
Clarence N. Talbot, Jr., Co-owner
Carolina Seafood Ventures, LLC
d/b/a Engelhard Mattamuskeet Seafood
P.O. Box 3435
Greenville, NC 27836

Warning Letter
02-ATL-17

Dear Messrs. Garner, Bryant, and Talbot:

On August 15 - 16, 2001, an investigator from the Food and Drug Administration (FDA), Billy M. Battles, conducted an inspection of your plant located at 239 Goshen Back Road, Engelhard, North Carolina. During that inspection, our investigator documented deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your fresh histamine-producing fish, and fresh shrimp to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The HACCP deviations of concern are as follows:

1. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plan for fresh shrimp does not list the food safety hazard of undeclared sulfiting agents.
2. Our review of your firm's HACCP plan for histamine-producing fish reveals that it is deficient and fails to meet requirements under 21 CFR 123.6(c), and 123.7(b) as follows:
 - a. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your HACCP plan does not list a critical limit for the adequacy of ice at the "Receiving" critical control point (CCP) even though it lists a monitoring procedure for the visual check of the adequacy of ice on incoming fish.

In addition, your plan's "Receiving" CCP fails to list a critical limit to address how the fishermen handled the fish at the time of catch. Moreover, your critical limit at "Receiving", i.e. "Histamine producing species will not exceed 50 degrees" is not adequate to control the food safety hazard of histamine formation. Specifically, the maximum temperature (critical limit) that would be acceptable for the incoming fish must be directly related to the time that has transpired since the fish's death. For example, an internal temperature of 40°F or below would be acceptable in the case of fish that are delivered 24 or more hours after death.

Finally, you need to clarify what are the limits for decomposition that when exceeded will result in rejection of the incoming fish or other suitable corrective action. An example of an acceptable limit is: "No more than 2.5% decomposition (persistent and readily perceptible) in the incoming lot."

We suggest that you refer to Chapter 7 of the *Fish & Fisheries Products Hazards & Controls Guidance, third edition* (copy enclosed), for guidance in establishing critical limits and monitoring procedures for controlling the histamine hazard in the fish you process.

- b. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan at the "cooler" critical control point is not adequate to control the hazard of histamine formation. Specifically, re-icing the product when the ice has melted or is not sufficient to cover the fish may not be sufficient to prevent histamine formation. The affected product must be evaluated by a trained individual to determine its acceptability for distribution. Note: you also need to clarify the critical limit at this CCP. In other words, you need to describe what is a "proper amount of ice."
3. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at any of the critical control points in your HACCP plan for histamine-producing fish to control the histamine formation hazard.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

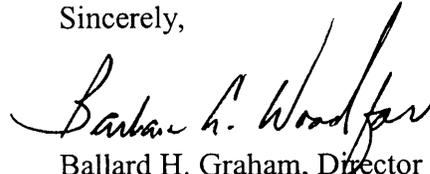
Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and

the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is fluid and cursive, with a large initial "B".

Ballard H. Graham, Director
Atlanta District

Enclosure

cc: Bryan W. Cuthrell, Plant Manager
Engelhard Mattamuskeet Seafood
239 Goshen Back Road
Engelhard, NC 27824