



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Atlanta District Office

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

August 20, 2001

**VIA FEDERAL EXPRESS**

Jeffrey W. Scott, Owner  
Greenville Loop Seafood  
1700 Trey Court  
Wilmington, NC 28403

**Warning Letter**  
01-ATL-74

Dear Mr. Scott:

On April 17 - 18, 2001, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your plant located at 5826 Greenville Loop Road, Wilmington, North Carolina. During that inspection, our investigator documented deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh histamine-producing fish 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](http://www.fda.gov).

The HACCP deviations of concern are as follows:

1. 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) 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 lists a critical limit, "Check fish for correct temperature," that is inadequate to control the hazard of histamine formation at the "receiving" critical control point (CCP). The critical limit should be specific (e.g. 40°F) so that if exceeded, it will trigger a corrective action. Since you receive histamine-forming fish from both harvesters and other primary processors, your critical limits and monitoring procedures at the receiving CCP must be appropriate for both types of suppliers. It appears that in addition to checking the internal temperature of the incoming fish, your firm also performs a visual observation of the adequacy of ice and a sensory examination for decomposition. However, your HACCP plan fails to list the critical limits and/or complete monitoring procedures for these other controls. 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. You must have a HACCP plan that lists all 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 does not list the food safety hazard of histamine formation at the "Long Term Storage Cooler" CCP.
  - c. Your HACCP plan lists a critical limit, "Not above 45F for more than 4 hours continuous [sic]," that is inadequate to control the hazard of histamine formation at the "Long Term Storage Cooler" CCP. As you may know, the histamine-forming bacteria can grow and produce histamine over a wide temperature range, even at moderate abuse temperatures such as 45°F. Ideally, the closer the product temperature is to the freezing point, the safer the product, and consequently, the longer its shelf life. It is common industry practice to prevent exposure of unfrozen histamine-forming fish to temperatures above 40°F for more than four hours, cumulatively, after chilling on board the harvest vessel. After you establish an adequate critical limit(s), please ensure that the monitoring and record keeping procedures are updated or modified accordingly. Additional guidance on how to control this hazard during storage is available on Chapter 7 of the *Fish & Fisheries Products Hazards & Controls Guidance, third edition*.
2. 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 for histamine-forming fish at the "Long Term Storage Cooler" CCP is not adequate to control the histamine hazard. Your corrective action plan is silent on what your firm will do with product whose safety is questionable after the critical limit has been exceeded or breached.
  3. You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of checking the length of time that histamine-forming fish remains outside the cooler during processing (heading, gutting, filleting/steaking, and portioning) to control the histamine hazard.
  4. You must fully document, in records, all corrective actions taken, to comply with 21 CFR 123.7(d). However, you did not document that a corrective action was taken when you deviated from your critical limit of no more than 4 hours continuous at a temperature above 45°F for histamine-forming fish at the "Long Term Storage Cooler" CCP. Your cooler monitoring records show that on several days during April the temperature reading was over 45°F for more than four hours. However, these records do not show that an appropriate corrective action was taken after each instance where the critical limit was exceeded. In addition, some of these records are incomplete in that the temperatures at the start of operations were not always recorded.

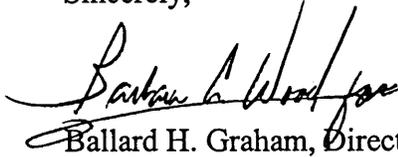
We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

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,

  
Ballard H. Graham, Director  
Atlanta District

Enclosure