



July 30, 2002

WARNING LETTER No. 2002-NOL-39

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Vinh Q. Tran, Owner
St. Vincent Seafood Co., Inc.
105 East 18th Street
Cut Off, Louisiana 70345

Dear Mr. Tran:

We inspected your firm, located at 24189 Highway 1, Leesville, Louisiana, on May 10 & 14, 2002, and found that you have serious deviations from seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations cause your fish products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the seafood HACCP regulations through links in FDA's home page at <http://www.fda.gov>.

The deviations were as follows:

- You must have a HACCP plan that lists the critical limits that must be met at each critical control point to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for fresh fish lists critical limits at the receiving critical control point that are not adequate to control histamine formation in scombrototoxin species.

As a primary (first) processor, the critical limits for your receipt of fish from harvest vessels must ensure that the fish have been handled in a safe manner prior to their receipt by your firm. FDA suggests that either histamine testing or requiring harvest vessel records from your suppliers be monitored in addition to internal temperatures and sensory examinations. Chapter 7 of the "Fish and Fisheries Products Hazards and Controls Guidance" can provide guidance in determining which method is best suited to your process and the critical limits and monitoring procedures FDA considers adequate to control the hazard of histamine. This guidance can be accessed on-line at <http://www.fda.gov>.

- 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 the receiving critical control point to control scombrototoxin formation as listed in your HACCP plan for fresh fish. In addition, your firm did not record monitoring observations for your internal temperature and decomposition critical limits.

- You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for tuna (and other scombroid species) lists a monitoring frequency at the receiving critical control point that is not adequate. FDA currently suggests that a minimum of twelve fish, or a frequency that provides an equivalent assurance of safety, be checked.

We may take action without further notice if you do not promptly correct these violations. For instance, we may seize your product(s) and/or enjoin your firm from operating. We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. However, you must respond in writing, within three (3) weeks from your receipt of this letter, outlining specific actions you have taken to correct the deficiencies and to assure that such violations will not recur. You may wish to include in your response documentation such as your HACCP plan and 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 you will explain the reason for the delay and a deadline by which you will correct any remaining deficiencies.

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 Current Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Nicole F. Hardin, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Hardin at (504) 253-4519.

Sincerely,


Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483