



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

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WARNING LETTER
NWE-05-04W

VIA FEDERAL EXPRESS

November 3, 2003

Lewis P. Barbera
President
South Pier Fish Company
20 Walts Way
Narragansett, RI 02882

Dear Mr. Barbera:

We inspected your seafood processing facility, located at 20 Walts Way, Narragansett, RI, on August 26 through 28, 2003. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly, your seafood products (scromboid species, ready-to-eat smoked seafood, and ready-to-eat snail salad) are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The serious deviations observed were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur, and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (a) and (b). However, your firm does not have a written HACCP plan for refrigerated ready-to-eat smoked seafood and ready-to-eat snail salad to control the food safety hazard of pathogens.

2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR Part 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter that must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified safety hazard." However, your firm's HACCP plan for scombroid species lists a critical limit at the receiving (vessel) critical control point that is not adequate to control the histamine hazard. Your plan fails to list critical limits for sensory evaluation and adequate internal temperature of a representative sample of the fish you receive directly from the vessels. FDA recommends that you monitor internal temperatures at the vessel if the fish are held or transported for a significant period of time prior to receipt at your plant.
3. You must implement the monitoring procedures that you listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of ensuring that each lot has a harvest vessel record at the receiving critical control point to control the histamine hazard listed in your HACCP plan for scombroid species. Your firm received Bluefish from harvesting vessels on [REDACTED] occasions from May 25, 2003 through August 26, 2003. There were no harvest vessel records at your firm for the receipt of these products as required by your HACCP plan.
4. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the Storage critical control point to control the histamine hazard listed in your HACCP plan for scombroid species. Specifically, on June 30, 2003 and July 3, 2003, you failed to record the adequacy of ice in the outside cooler.
5. 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 scombroid species at the receiving and storage critical control points to control histamine is not appropriate. In addition to checking the internal temperatures of the fish, you should list what will be done to correct the cause of the deviation. You should also include what you will do to ensure that unsafe fish are prevented from entering commerce, such as, evaluating time/temperature exposures and/or histamine testing.

We may take further action if you do not promptly correct these above violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within fifteen (15) working days 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 any documentation, such as your HACCP plan, 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 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 regulation and the Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,



Gail I. Costello
District Director
New England District Office