



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Los Angeles District  
Pacific Region  
19701 Fairchild  
Irvine, CA 92612-2445

Telephone: 949-608-2900  
FAX: 949-608-4415

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

August 19, 2004

Hak Sung Yang, President  
Poseidon Seafood, Inc.  
3690 Noakes Street  
Los Angeles, CA 90023

W/L 43-04

Dear Mr. Yang:

On April 29 and May 3, 2004, this agency inspected your fish processing facility located at the above address and, with regard to the scombrototoxic fish and shrimp you import and process at the facility, found serious deviations from the Seafood HACCP regulation (Title 21, Code of Federal Regulations, Part 123 (21 CFR 123)). These include continuing Importer verification deviations (Section 123.12 (a)(2)) previously brought to your attention during an inspection conducted at your firm on July 10, 2003. 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). Accordingly, products that your firm processes, like shrimp and scombrototoxin (histamine) forming species of fish (e.g. tuna), are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You can find this Act and the Seafood HACCP regulation through the links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations are as follows:

1. You must either obtain your fish and fishery products from a country that has an active memorandum of understanding or similar agreement with FDA that covers the fish or fishery products and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or you must have and implement written verification procedures which ensure that the fish and fishery products you import into the United States were processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a).

2. You must have product specifications that are designed to ensure that the fish and fishery products you import are not adulterated because they may be injurious to health or because they may have been processed under insanitary conditions, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for Big Eye Tuna from Ecuador, frozen tuna from Indonesia, frozen shrimp from Thailand, and frozen cuttlefish from Thailand.
3. You must implement an affirmative step which ensures that the fish and fishery product(s) you import were processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for Big Eye Tuna imported from [REDACTED] in Ecuador, for frozen tuna imported from [REDACTED] in Indonesia, and for frozen shrimp imported from [REDACTED] in Thailand.

On July 10, 2003 during the previous FDA inspection which covered frozen cuttlefish imported from Thailand, the deviations from the seafood HACCP regulation regarding the lack of product specifications and lack of an affirmative step were noted for cuttlefish. At the conclusion of that inspection, you stated that you would correct these deviations for the cuttlefish. The expectation by FDA is that you would also correct these deviations if they exist for any of your other products.

4. You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points for each identified hazard, to comply with 21 CFR 123.6 (a) and (c) (2). A critical control point is defined in 21 CFR Part 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for Tuna (Sashimi Products) does not list the critical control point of receiving to control the food safety hazard(s) of Scombrototoxin formation.
5. Your Sanitation SOP should specify how you will ensure: (1) that the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice, is safe (21 CFR 123.11(b)(1)), and (2) that pests are excluded from the food plant (21 CFR 123.11(b)(8)).

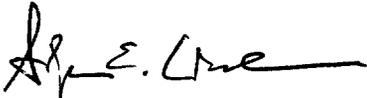
The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your processing plant is operating in compliance with all applicable requirements and regulations. It is also your responsibility to ensure not only that the current objectionable conditions are corrected, but that appropriate policies and procedures are implemented to prevent recurrence of the problems. Failure to make corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Letter to Hak Sung Yank, Poseidon Seafood, Inc.  
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You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective actions cannot be completed within 15 working days, please state the reason for the delay and the time by which the corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Deborah Greco, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Ms. Greco at (949) 608-2959.

Sincerely,



Alonza E. Cruse  
District Director

CC: Hak Sung Yang, President  
Poseidon Seafood, Inc.  
3690 Noakes Street  
Los Angeles, CA 90023