



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

19900 MacArthur Blvd., Ste 30  
Irvine, California 92612-2445  
Telephone (949) 798-7600

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

July 25, 2003

W/L 47-03

Mr. Jonathan A. Hahn, Managing Director  
Pacific Export & Import Co. Inc.  
628 South Stanford Avenue  
Los Angeles, CA 90013

Dear Mr. Hahn

On April 29 – May 2, 2003, we inspected your seafood processing facility, located in Los Angeles, California. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, 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 ready-to-eat sashimi grade tuna and other fresh histamine-forming fishes are adulterated, in that the fresh fishes have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP Regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations we found 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 HACCP plan for scrombrotoxin forming species (e.g. fresh tuna, mahi-mahi, wahoo) to control the food safety hazard of histamine formation.
2. You must maintain sanitation control records that, at a minimum, document monitoring and corrections, to comply with 21 CFR 123.11(c). However your firm did not maintain sanitation monitoring records for the prevention of cross-contamination from insanitary

objects to food; the protection of food from adulterants (chemical contaminants); the proper labeling, storage and use of toxic compounds; the control of employee health conditions and exclusion of pests from the food plant required for the processing of your products to be consumed as ready-to-eat sushi.

3. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the condition and cleanliness of food-contact surfaces, the prevention of cross-contamination and the protection of food, food packaging material, and food surfaces from adulteration with sufficient frequency to ensure control as evidenced by:
  - Processed fish fillets were observed coming in direct contact with unsanitary plastic strip curtains during transport between processing and cooler areas.
  - A cutting board used to fillet fish was observed with dark, remnant material embedded in cuts on the board, making it not easily cleanable.
  - The weigh table had a buildup of yellow and brown residue, particles of food, and fish scales.
  - Two light fixtures in the refrigerator, above open boxes and bins of product, lacked safety shields to prevent broken glass from falling into product.
4. You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have a product specification for refrigerated tuna and mahi mahi imported from the [REDACTED] to control the hazard of histamine.

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 fifteen (15) days from your receipt of this letter. Your response should include each step that has been taken to completely correct the current violations and to prevent the recurrence of similar violations, the time within which correction will be completed, and any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please 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 Federal Food, Drug, and Cosmetic Act and all applicable regulations.

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Your written reply should be directed to:

Director, Compliance Branch  
U.S. Food & Drug Administration  
19900 MacArthur Blvd, Suite 300  
Irvine, CA 92612-2445.

If you have questions regarding any issue in this letter, please contact Mr. Robert B. McNab,  
Compliance Officer at (949) 798-7709.

Sincerely,

  
Alonza E. Cruse  
District Director