



DEPARTMENT OF HEALTH & HUMAN SERVICES

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San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

October 19, 1999  
Our Reference: 2950460

Robert S. Fram, President  
Garden & Valley Isle Seafood, Inc.  
225 Nimitz Highway, #3Pier 28  
Honolulu, Hawaii 96817

**WARNING LETTER**

Dear Mr. Fram:

On August 30 and 31, 1999, a team consisting of U.S. Food and Drug Administration (FDA) investigators and a biologist conducted an inspection of your seafood processing facility. The inspection was conducted to determine compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110).

During our current inspection, we performed organoleptic examinations on several lots of swordfish, held for sale by your firm. We found odors indicative of decomposition on the lot of swordfish received from the [REDACTED] on August 11, 1999. We collected and tested a sample of this fish. Our laboratory analysis confirmed the presence of decomposition in the swordfish. You voluntarily destroyed the decomposed fish during the inspection. Fish is adulterated within the meaning of Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act, if it is entirely or partially decomposed. Your products must not be adulterated and they must be manufactured under Current Good Manufacturing Practices.

Our previous inspection of your firm in May 1998 also found decomposed swordfish being held for sale. These repeated violations greatly concern us that you have not taken adequate measures to prevent decomposition of fish at your facility.

You must immediately take appropriate steps to permanently correct this violation at your facility. Failure to correct the violation may result in legal sanctions such as seizure and/or injunction without further notice.

Please advise this office in writing, within fifteen (15) working days of receipt of this letter, the measures you have taken to prevent recurrence of the noted violation and preclude distribution of adulterated seafood. Please direct your response to Ms. Erlinda N. Figueroa, Compliance Officer, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070 (Telephone: 510-337-6795; FAX: 510-337-6707).

In addition to the violation mentioned above, we bring the following Hazard Analysis Critical Control Point (HACCP) deviations to your attention. The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as HACCP. During the inspection, the investigators observed shortcomings in your system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. At the conclusion of the inspection, the investigators provided Mr. Jeff A. Gehlke, Operations Manager, with a copy of the Domestic Seafood HACCP Report (form FDA 3501), the Importer Seafood HACCP Report (form FDA 3502), and the FDA 483 (Inspectional Observations), which present their evaluation of your firm's performance regarding various aspects of the HACCP. A copy of the FDA 483 is enclosed for your reference. The observations of concern to us are as follows:

1. Failure to have and implement a written HACCP plan for vacuum packed raw fish, to control the food safety hazard of *Clostridium botulinum* toxin formation, as required by 21 CFR 123.6(b). While you are already controlling the hazard by freezing, this level of control is inadequate because the product is not appropriately labeled and there is no assurance that it will be held frozen throughout distribution. An example of appropriate labeling for a vacuum packed raw fish product is to have a statement on the label to keep the product frozen until use and to thaw under refrigeration immediately before use.
2. Failure to have a HACCP plan to control histamine formation in scombroid fish in which adequate critical limits at the receiving critical control point (CCP) are listed, as required by 21 CFR 123.6(b). Specifically, your HACCP plan does not include critical limits for harvest vessel records for scombroid fish received directly from the harvester, and critical limits for controlling temperatures during transportation of fish from other processors. In addition, the critical limit of "No evidence of decomposition" is inappropriate because it does not include a specific measurable value to which the hazard of histamine is controlled at the receiving CCP.
3. Failure to maintain HACCP records that document the monitoring of extensive decomposition at the receiving CCP, as required by 21 CFR 123.6(c)(7).

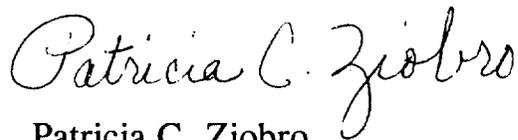
4. Failure to fully document the corrective action taken when a deviation from a critical limit occurs, as required by 21 CFR 123.7(d).
5. Failure to have written product specifications that are designed to ensure that the dried tuna offered for import into the United States is not adulterated, as required by 21 CFR 123.12(a)(2)(i).
6. Failure to have written verification procedures, as required by 21 CFR 123.12(a)(2), to ensure that the imported dried tuna was processed in accordance with the requirements of the seafood HACCP regulations.

We acknowledge Mr. Gehlke's response of September 8, 1999 to the inspectional observations presented to him at the end of the inspection. His response has been appended to a file maintained for your company. We will verify the changes and adequacy of your HACCP plan and system during the next inspection of your facility.

In the meantime, if you have questions regarding implementation of the seafood HACCP regulation, you may contact Erlinda Figueroa, Compliance Officer (Telephone: 510-337-6795; Fax: 510-337-6707) or Ms. Darla Bracy, Investigator, at (510) 337-6773 for answers and/or direction towards guidance and for sources of training in achieving compliance.

We look forward to working with you to achieve a successful HACCP program.

Sincerely,



Patricia C. Ziobro  
Director  
San Francisco District

Enclosure

cc: Jeff A. Gehlke, Operations Manager