



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

g1361d  
San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

**VIA INT'L FEDERAL EXPRESS**

June 1, 2001

Our Reference: 2954558

Maria M. F. Cheung, President  
Ocean Fishery Trading  
Lot 1116-B-1 Part  
Mongmong, Guam 96921

**WARNING LETTER**

Dear Ms. Cheung:

On April 12 and 16, 2001, we inspected your seafood firm to determine your compliance with FDA's Seafood HACCP regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deviations. These deviations cause your refrigerated scombroid fish, specifically tuna and marlin, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, or held under insanitary conditions, whereby they may be rendered injurious to health. We listed the deficiencies on a Form FDA 483 (Inspectional Observations) and discussed them with Mr. Raymond C. H. Ko, Manager, at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your reference. The deviations are as follows:

1. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for refrigerated scombroid fish, including tuna and marlin, does not list the critical control point (CCP) of Cooler Storage, for controlling the food safety hazard of histamine formation.
2. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for refrigerated scombroid fish lists a critical limit at the Receiving CCP that is not

adequate to control histamine formation (listed as toxin development in your plan) in tuna, marlin, and other scombroid fish received directly from the harvest vessel.

3. 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 refrigerated scombroid fish at the Receiving CCP to control histamine formation (toxin development) is not appropriate. Specifically, for fish that exceeded the temperature critical limit, re-icing the lot and taking the temperature after three hours are not adequate. These steps do not prevent the introduction into commerce of adulterated product.

4. You must adequately monitor and document sanitation conditions and practices, to comply with 21 CFR 123.11(b) and (c). However, your firm did not monitor and maintain records related to the following areas of sanitation to ensure control:

- a) Safety of water;
- b) Condition and cleanliness of food contact surfaces;
- c) Prevention of cross-contamination;
- d) Maintenance of hand washing, hand sanitizing, and toilet facilities;
- e) Protection of food and food contact surfaces from adulterants;
- f) Proper labeling and storage of toxic compounds;
- g) Control of employee health conditions; and
- h) Exclusion of pests from the processing area.

During our current inspection, we performed organoleptic examinations on twenty (20) whole tuna fish held in your fish storage boxes. We found three tuna fish to be decomposed. 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.

We may take further regulatory action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

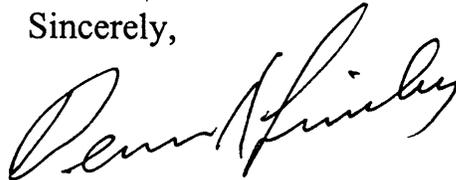
Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You may wish to include in your response documentation such as time/temperature monitoring records, sanitation records, revised HACCP plans, etc. If you cannot complete all the 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 seafood firm operates in compliance with the Act, the Seafood HACCP regulations, and the 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 Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,



Dennis K. Linsley  
Director  
San Francisco District

Enclosure

cc: Raymond C. H. Ko, Manager  
Ocean Fishery Trading  
P. O. Box 23727  
Barrigada, Guam 96921