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Food and Drug Administration  
Washington DC 20204

NOV 8 2001

Mr. Henry Quek  
Far Ocean Sea Products Pte., Ltd.  
25 Fishery Port Road  
Singapore 619739

### WARNING LETTER

Dear Mr. Quek:

FDA inspected your firm located at 25 Fishery Port Road Singapore 619739, on April 25, 2001 and found that your firm has serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention at the conclusion of the inspection, cause your Frozen Raw Tuna (Loins and Steaks) to be in violation of section 402(a)(4) of the Federal Food, Drug and Cosmetic Act. You can find this Act and the Seafood HACCP Regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

1. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). Your firm's HACCP plan for Yellowfin Tuna Gilled and Gutted does not list a critical limit for sensory evaluations. If you receive your fish directly from the harvest vessels, you are a "*primary processor*." You must have adequate procedures in place to assure that your fish have been handled in a safe manner prior to your receiving them. Chapter 7 of the Fish and Fishery Products Hazards and Controls Guide: Third Edition can help you determine an appropriate critical limit and monitoring procedures.
2. You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). Your firm did not follow the monitoring procedure of checking the Letter of Guarantee at your "Receiving critical control point" listed in your HACCP plan for Yellowfin Tuna Gilled and Gutted.

**Note:** *Letters of Guarantee are not usually considered an appropriate monitoring procedure for histamine testing unless that letter includes the test results with an adequate number of samples.*

3. Your representative told our investigator that your firm tests one tuna from each lot as a monitoring procedure for your histamine critical limit. You must list the procedures your firm is using to monitor critical limits in your HACCP plan. In addition, the FDA recommends testing a minimum sample size of 18 fish per lot. If the lot is 18 fish or less, the entire lot must be sampled. Again, Chapter 7 of the Fish and Fishery Products Hazards and Controls Guide: *Third Edition* can help you determine appropriate monitoring procedures and corrective actions.

Please respond in writing within six weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. Please include in your response documentation such as a corrected HACCP plan, monitoring records for your "Receiving critical control point" for five days, and any other useful information (including photographs). 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 deviations. Failure to provide us evidence of corrections to the deviations may result in your products being placed on "Detention Without Physical Examination."

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.

Please send your reply to the:

Food and Drug Administration  
Attention: Frank Sikorsky, Consumer Safety Officer  
Office of Field Programs, HFS-606  
200 C Street S.W.  
Washington, DC 20204

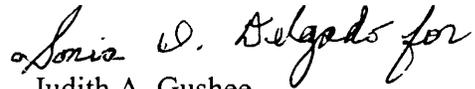
If you have questions regarding any issue in this letter, please contact Mr. Sikorsky at:

Phone: 202 205-5247/4606

FAX: (202) 260-0208, or

E-mail: Frank.Sikorsky@CFSAN.FDA.GOV.

Sincerely,



Judith A. Gushee

Director

Division of Enforcement and Programs

Office of Field Programs

Center for Food Safety

and Applied Nutrition