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Public Health Service

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Food and Drug Administration  
Washington DC 20204

NOV 9 2001

Mr. Andrew Kaye  
Managing Director  
Kaytrad Commodities, Ltd.  
Yorke Point Road, Hout Bay  
Capetown 8012  
Republic of South Africa

**Warning Letter**

Dear Mr. Kaye:

This is to acknowledge receipt of your facsimile dated July 9, 2001, responding to our letter dated May 19, 2001, concerning the serious deviations from the U.S. Seafood HACCP Regulations (21 CFR Part 123) that we found during our inspection of your firm on September 21-22, 2000.

We have reviewed your letter and need further information to determine if modifications to your HACCP plan and procedures are adequate. We have made the following determinations:

1. You have changed your HACCP plan critical limit at your receiving critical control point to 50 ppm and isolate fish with histamine content that exceeds 50 ppm.

The corrective action stated in your letter is still inadequate. Sampling is used to indicate the overall condition of the lot. Isolating poor samples, without rejecting or accepting the lot based on your sample results, is inappropriate. USFDA requires a minimum sample size of 18 fish with the acceptance/rejection criteria of 0 accept/1 reject. In addition to rejecting a lot is to subdivide the lot and retest it according to USFDA guidelines listed in the Fish and Fishery Products Hazards and Controls Guide: Third Edition, Chapter 7.

2. You require all harvest vessels to supply you with harvest vessel records upon receipt. If the records are not available or inadequate, the lot is isolated and tested for histamine content.
3. You have elaborated on your sampling procedure for organoleptic evaluation and your handling of fish that are of questionable quality.

The sampling plan (Form XI B) supplied to our investigator lists inappropriate acceptance and rejection values for decomposition. Your letter states that for lots of 118 fish or less you inspect the entire lot, and that you inspect 80% of the fish in lots of more than 118 fish. You have not stated your acceptance/rejection values. USFDA has determined that lots that contain more than 2.5% fish exhibiting decomposition have been subjected to time/temperature abuse and have a significant likelihood of elevated histamine levels within the lot.

Your letter states that you will isolate all suspect fish as a corrective action for decomposition. Again, isolating suspect fish is not considered an appropriate corrective action by itself. Lots where over 2.5% of the sample exhibits decomposition must be rejected or you have the option of performing histamine analysis on the suspect fish or the entire lot according USFDA guidelines. In addition, you must perform a sensory examination of all the fish in the lot and divert decomposed fish to non-food use. You must also discontinue use of the supplier until evidence of improved harvesting practices is received.

4. You have stated that your Analysis records are not kept at your processing facility.

The USFDA Seafood HACCP Regulation 21 CFR 123.9(b)(1) requires that all records be retained at the processing facility for at least 1 year for fresh products and 2 years for frozen product. These records can include your plan, monitoring records, test results, sanitation monitoring records, corrective actions, calibration results, and validation records. You may keep these records in a secure area, but they must be at your processing facility and available to USFDA investigators during your hours of operation.

We thank you for your prompt response to our letter. In addition to a letter stating you have made corrections, we must also have a copy of your corrected HACCP plan and five days of completed receiving monitoring records to help us better evaluate your implementation of your revised HACCP plan. Please include relevant histamine test results with your monitoring records.

We encourage you to make the necessary improvements as soon as possible. It is essential that you respond to this office on this matter within six weeks of receipt of this letter. Failure to adequately respond to our requests may result in your product being placed on "Detention without Physical Examination."

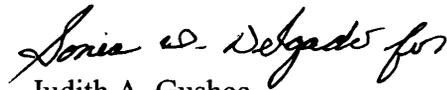
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Please send your reply to:

Food and Drug Administration  
Attention: Brian Landesberg, Consumer Safety Officer  
Office of Field Programs, Division of Enforcement and Programs  
Import Branch, HFS-606  
200 C Street S.W.  
Washington, DC 20204

If you have questions regarding any issue in this letter, please contact Mr. Landesberg at (202) 205-5247.

Sincerely,



Judith A. Gushee  
Director  
Division of Enforcement and Programs  
Office of Field Programs  
Center for Food Safety  
and Applied Nutrition