



DEPARTMENT OF HEALTH AND HUMAN SERVICES

G4311d

Food and Drug Administration  
Los Angeles District  
Pacific Region  
19701 Fairchild  
Irvine, CA 92612-2445

Telephone: 949-798-7600

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

September 18, 2003

Mr. David Tran, General Manager  
South China Seafood Co.  
1225 East 7th Street  
Los Angeles, CA 90021

W/L 51-03

Dear Mr. Tran:

On June 30, 2003 and July 2, 2003 the Food and Drug Administration (FDA) conducted an inspection of your facility located at 1225 East 7<sup>th</sup> Street, Los Angeles, CA 90021. The inspection was conducted to determine your firm's compliance with 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). Accordingly your frozen apple snail meat is adulterated, in that the product has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the seafood HACCP Regulation through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

During our inspection, the FDA investigator observed that your firm did not comply with importer verification requirements. The FDA investigator also provided you with an FDA 483, Inspectional Observations, which presents their evaluation of your firm's performance regarding various aspects of the HACCP requirements. The serious deviations of concern to us are as follows:

- (1) You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health or processed under insanitary conditions, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have a product specification for frozen apple snail meat imported from [REDACTED]. Specifically, your firm did not develop or implement a product safety specifications sheet for the imported frozen apple snail meat. You as an importer, must be aware of the hazards associated with the products you import and assure that those hazards are addressed in the product specification.

- (2) You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for frozen apple snail meat manufactured by [REDACTED] in [REDACTED]. Specifically, your firm chose to maintain a copy of the foreign processor's HACCP plan, but did not maintain a copy of a written guarantee from the foreign processor that the imported frozen apple snail meat is processed in accordance with the requirements of 21 CFR Part 123.

These same deviations with other seafood products were brought to your attention in previous FDA-483's dated 1/13/99, 5/17/00, and 1/21/03 and in a letter to your firm dated 2/11/99.

For additional information regarding hazards associated with particular fish and fishery products, please refer to the Fish and Fishery Products Hazards and Controls Guidance: Third Edition, Chapter 3 (Potential Species-Related & Process-Related Hazards), found at [www.cfsan.fda.gov/~comm/haccp4.html](http://www.cfsan.fda.gov/~comm/haccp4.html).

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility and do not include all items listed on the FDA-483. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all applicable federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action may include seizure and/or injunction. In addition, FDA may detain your seafood products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter of specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their recurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply relating to these concerns should be directed to:

U.S. Food and Drug Administration  
Attn: Director, Import Operations Branch  
Los Angeles District  
222 West 6<sup>th</sup> Street, Suite 700  
San Pedro, CA 90731

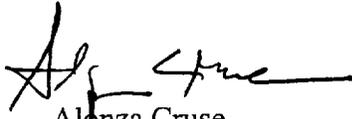
Mr. David Tran – General Manager  
South China Seafood Co. – Los Angeles, CA

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If you have questions regarding the implementation of the seafood HACCP Regulation, you may contact Ruth P. Dixon, Compliance Officer, at (310) 831-6123 extension #155 for answers and/or direction towards guidance and sources of training in achieving compliance.

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Alonza Cruse', written in a cursive style.

Alonza Cruse  
District Director