



OCT 13 2000

Johan Suryadarma  
Marketing Director  
P.T. Sekar Bumi  
Jl. Jenggolo II/17  
Sigoarjo 61219, Indonesia

WARNING LETTER

Dear Mr. Suryadarma:

We inspected your firm, located at Jl. Jenggolo II/17, Sigoarjo 61219, Indonesia, on 4/10 & 11/00 and found that you have serious deviations from the U.S. Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your **frozen shrimp and frozen froglegs** to be in violation of section 402(a)(4) of the U.S. 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:

You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP Plan for frozen froglegs does not list the food safety hazards of metal inclusion.

You must fully document, in records, all corrective actions taken, to comply with 21 CFR 123.7 (d). However, you did not document the disposition of affected product when taking corrective action when metal was found in head-on semi IQF shrimp during the processing operations.

We have reviewed your response to the FDA 483, list of Inspectional Observations, issued during the 4/10 & 11/00 inspection of your firm and have determined that the information you have provided for correction of the deviations listed above is not adequate. A copy of the revised HACCP plan and/or supporting documentation is needed to determine the adequacy of the changes you have made to include the critical limit of metal inclusion and the full documentation of corrective actions.

Please respond in writing within six (6) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response, documentation such as your revised HACCP plan or other useful information that would assist us in evaluating your corrections. If you believe the hazards listed above are not reasonably likely to occur in your products, you must provide U.S. FDA

with adequate, written documentation that clearly supports your reasoning. 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 U.S. Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the following address:

Mr. Frank Sikorsky  
Import Branch, HFS-606  
Division of Enforcement and Programs  
U.S. Food and Drug Administration  
200 C. Street, S.W.  
Washington, DC 20204

If you have any question regarding any issues in the letter, please contact Mr. Sikorsky at (202) 205-1922

Sincerely,



Dennis M. Dignan, Ph.D.  
Acting Director  
Division of Enforcement and Programs  
Office of Field Programs  
Center for Food Safety  
and applied Nutrients