

WARNING LETTER

NOV 14 2000

Mr. Guillermo Ley Ibarra  
General Manager  
Figorifico Coppel  
Puerto Mazatlan Avenue  
Parque Industrial Alfredo V. Bonfil  
Mazatlan, Sinaloa, Mexico 82050

Dear Mr. Ley Ibarra:

We inspected your firm, located at Puerto Mazatlan Avenue, Parque Industrial Alfredo V. Bonfil Mazatlan, Sinaloa, Mexico on September 5, 2000 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 wild caught and farm-raised shrimp to be in violation of section 402(a)(4) of the U.S. Federal Food, Drug, and Cosmetic Act when the shrimp is imported into the U.S. 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 critical limits that must be met, to comply with 21 CFR 123.6(c)(3).

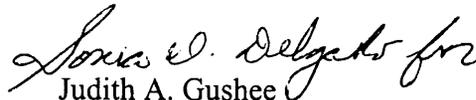
- Your firm's HACCP plan for **Frozen Head-on Shrimp (Camaron Congelado Con Cabeza)** lists a critical limit of 100 ppm to 150 ppm for sulfites at the Receiving (*Recepcion*) critical control point. This is not an appropriate critical limit because it does not relate to the hazard that must be covered which is undeclared sulfites. The *Fish & Fisheries Products Hazards & Controls Guidance*: Third Edition, Chapter 19, provides guidance on how to address this hazard of undeclared sulfites.
- Your firm's HACCP plan for **Frozen Head-on Shrimp (Camaron Congelado Con Cabeza)** covers the hazard of aquaculture drugs. However, the plan does not provide an adequate critical limit for this hazard. The *Fish & Fisheries Products Hazards & Controls Guidance*: Third Edition, Chapter 11, provides examples of critical limits for aquaculture drugs. Drugs used in shrimp production must be approved by FDA.

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. 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. You may wish to include in your response documentation such as corrected HACCP plans, completed monitoring records and other useful information that will 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: Brian Landesberg, Consumer Safety Officer, Office of Field Programs, Division of Enforcement, 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 & Programs

Office of Field Programs

Center for Food Safety

and Applied Nutrition