



Food and Drug Administration  
New Orleans District  
Southeast Region  
6600 Plaza Drive, Suite 400  
New Orleans, Louisiana 70127

Telephone: 504-253-4519  
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July 10, 2001

**WARNING LETTER NO. 2001-NOL-34**

**FEDERAL EXPRESS  
OVERNIGHT DELIVERY**

Mr. Kham Silavong, Owner  
Kham Silavong d.b.a. Heron Bay Seafood  
8850 Satsuma Street  
Codon, Alabama 36523

Dear Mr. Silavong:

The U.S. Food and Drug Administration inspected your crab processing facility, located at 4310 Heron Bay Loop Road, Codon, Alabama, June 5 - 7, 2001. During the inspection, our investigator collected six 16-ounce containers of cooked, lump crabmeat, labeled as Heron Bay Seafood Lump Crab Meat. Laboratory analysis revealed that three of the containers contained adult flies and adult fly fragments. The cooked, lump crabmeat is in violation of Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (the Act), in that it consists in whole or in part of a filthy substance. 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).

Our investigator documented numerous insanitary conditions, which cause the food products manufactured at your facility to become adulterated. The products are in violation of Section 402(a)(4) of the Act, in that they had been processed under insanitary conditions whereby they may have become contaminated with filth. The following deficiencies were documented during the inspection:

- You have not taken effective measures to exclude pests from the processing areas and to prevent contamination of filth in your crabmeat. For example, numerous flying insects were observed on cooked crabmeat, on processing equipment throughout the facility, and in finished crabmeat products.
- Employees working in direct contact with food and food-contact surfaces did not take necessary precautions to protect against cross-contamination. For example, employees handled unclean objects and then handled cooked products without washing and sanitizing their hands, employees did not wear adequate hair restraints, and they coughed over uncovered containers of cooked crabmeat.

- The inspection found that equipment is cleaned in an unsafe manner. For example, our investigator documented an excessive concentration of chlorine (greater than 200 PPM) in the sanitizing solution used on food-processing equipment and utensils, and the sanitizers are not allowed to dry before contact with cooked crabmeat products.
- Food processing equipment is not maintained in a sanitary condition to prevent food from becoming adulterated. For example, our investigator observed employees killing flies on food contact surfaces and they did not wash and sanitize the surfaces before contacting cooked crabs, and knife handles were encrusted with a black material in the etchings.
- Your plant building and structures are not constructed in such a manner that prevents cross contamination. For example, condensation was observed dripping from the ceiling onto cooked crabs.

In addition, our investigator found that you have serious deviations from the Seafood HACCP regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations also cause your crabmeat to be in violation of Section 402(a)(4) of the Act. The deviations were as follows:

- Your firm has not conducted a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur in your crabmeat product to comply with 21 CFR 123.6(a).
- You must implement the record keeping system listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the backing, picking, packing, and cooler storage critical control points to control pathogen growth and toxin formation as listed in your HACCP plan for cooked crabmeat.
- You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the exclusion of pests from the food plant as evidenced by numerous flying insects within the facility during processing.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within three (3) 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 copies of temperature monitoring records or other useful information that would assist us in evaluating the corrections. If all the corrections cannot be completed before you respond, please explain the reason for the delay and state when you will correct any remaining deviations.

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 Current

Good Manufacturing Practice regulations (21 CFR 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.

Your response should be directed to Mark W. Rivero, Compliance Officer, at the above address.

Sincerely,



Patricia K. Schafer  
Acting District Director  
New Orleans District

Enclosure: Form FDA 483