



DEPARTMENT OF HEALTH AND HUMAN SERVICE

24117d

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

Telephone: 504-253-4519
FAX: 504-253-4520

June 27, 2003

WARNING LETTER NO. 2003-NOL-18

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. Taravuth A. Suon, Owner
Interland Seafood, Inc.
13871 Shell Belt Road
Bayou La Batre, Alabama 36509

Dear Mr. Suon:

On May 12 – 14, 2003, we inspected your seafood processing facility, located at 13871 Shell Belt Road, Bayou La Batre, Alabama. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) regulations, Title 21, *Code of Federal Regulations* (C.F.R.), Part 123 (21 C.F.R. 123). In accordance with 21 C.F.R. 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), 21 U.S.C § 342(a)(4). Accordingly, your crab meat is adulterated, in that the crab meat 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 regulations through links in FDA's Internet home page at <http://www.fda.gov>.

The deviations were as follows:

1. You must implement the record keeping system that you listed in your HACCP plan to comply with 21 C.F.R. 123.6(b). However, your firm did not record monitoring observations at the following critical control points to control pathogen growth and toxin formation as listed in your HACCP plan for cooked, ready-to-eat crab meat:
 - a. You did not monitor the cooking operations during the period September 18, 2002 through May 12, 2003;
 - b. You did not monitor the picking and packing operations on January 29, 2003, and during the month of June 2002; and,
 - c. You did not monitor the temperature/level of the ice on the product in the finished product cooler.

2. You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 C.F.R. 123.11(c). However, your firm did not maintain sanitation monitoring records as required for the processing of crab meat from April 4, 2002 through May 13, 2003.
3. You must implement the monitoring procedures that you have listed in your HACCP plan to comply with 21 C.F.R. 123.6(b). However, your firm did not follow the monitoring procedure of boiling the crabs for [REDACTED] at the cooking critical control point to control pathogen survival as listed in your HACCP plan for crab meat. During the cooking operations on May 12, 2003, crab parts were not submerged fully under the boiling water for the first 10 minutes of the cook.

Moreover, our inspection revealed numerous deviations from the Current Good Manufacturing Practice (CGMP) regulations that apply to all foods. These regulations are codified at 21 C.F.R. 110. At the conclusion of the inspection, you were issued a Form FDA 483, Inspectional Observations, which describes the insanitary conditions observed in your firm during the inspection. These conditions also cause the products you process to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act .

The observations of concern to us include:

1. You use [REDACTED] a cleaning compound that is not safe and adequate under conditions of use, to clean cooking equipment and tables [21 C.F.R. 110.35(b)].
2. Employees working in direct contact with food and food contact surfaces did not take necessary precautions to protect against contamination of the food with microorganisms or foreign substances [21 C.F.R. 110.10(b)]. For example:
 - a. Employees working in the backing operation routinely handled unsanitized equipment and then cooked crabs without washing or sanitizing their hands;
 - b. An employee was observed to handle an unsanitized waste basket and then handle cooked crabs without washing or sanitizing his hands; and,
 - c. Employees failed to remove or cover hand jewelry and remove earrings during picking operations.
3. You have not taken effective measures to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests [21 C.F.R. 110.35(c)]. Failure to exclude fly pests is a potential contributing factor to microbiological contamination in that:
 - a. Flies were observed landing on cooked, backed crabs;
 - b. Flies were observed landing on raw crabs temporarily stored in the cooking/backing room; and,

- c. Flies were observed landing on the ceilings, walls, and plastic curtain strips located in the cooking/backing room.
4. You have not provided adequate hand washing facilities [21 C.F.R. 110.37(e)]:
 - a. You do not have hand cleaning solutions or hand drying supplies available at stations in the rooms and directly outside of the restrooms;
 - b. Employees were observed dipping their hands in water containing crab meat residues;
 - c. Employees did not wash their gloved hands prior to dipping them into the sanitizer; and,
 - d. You failed to provide lighting in the restrooms.
5. The plumbing within your facility was observed to constitute a source of contamination to the food [21 C.F.R. 110.37(b)]. For example:
 - a. A brown residue was observed inside the plumbing line used to rinse the backed crabs;
 - b. The plumbing of the hand wash station located in the cooking/backing room drains directly onto the floor; and,
 - c. Standing water from a clogged drain was observed in the cooking/backing room.
6. You have not taken reasonable measures and precautions to ensure that persons working in direct contact with food wore the appropriate hair nets, headbands, caps, beard covers or other effective hair restraints [21 C.F.R. 110.10(b)]. For example, on May 13, 2003, three employees did not wear adequate hair restraints while handling food products.
7. The grounds about your food plant are not kept in a condition that will protect against the contamination of your product. Oyster shells and crab shell residues, observed in the front of your facility, have not been removed and are an attractant, breeding place, or harborage for pests [21 C.F.R. 110.20(a)].

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

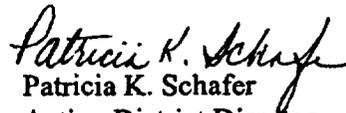
We are aware that you made a verbal commitment to correct the deviations during the inspection. Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation, such as copies of your monitoring records documenting the cooking and picking operations or other useful information that would 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.

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 C.F.R. 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 U.S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4514.

Sincerely,


Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483