



DEPARTMENT OF HEALTH & HUMAN SERVICES

94931d

Food and Drug Administration

August 17, 2004

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

Ref: 04-DAL-WL-31

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Hai Huynh, President
Fulton Seafood, Inc.
2818 McKinney Street
Houston, Texas 77003

Dear Mr. Huynh:

The Food and Drug Administration (FDA) inspected your firm, Fulton Seafood, Inc., located at 2818 McKinney Street, Houston, Texas 77003 on June 8-17, 2004. Our inspection found that your firm has serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 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"), 21 U.S.C. §342(a)(4). Accordingly, your fresh refrigerated cooked crabmeat, pasteurized cooked crabmeat, fresh, farm-raised Striped Bass, farm-raised Redfish, farm-raised Catfish, farm-raised Shrimp, and fresh Tuna, are all adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

The deviations that were found during the inspection were as follows:

1. Pursuant to 21 CFR §123.6(a), your firm is required to conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and to identify the preventive measures that your firm will apply to control those hazards. Also, pursuant to 21 CFR §123.6(b), your firm must have and implement a HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur.

Your firm, however, does not have a HACCP plan to control the following food safety hazards that are reasonably likely to occur: pathogen growth in fresh refrigerated cooked crabmeat and pasteurized cooked crabmeat; the use of chemicals and drugs in fresh farm-raised Striped Bass, farm-raised Redfish, farm-raised Catfish, and farm-raised Shrimp, and the use of sulfites in individual quick frozen (IQF) shrimp.

2. Pursuant to 21 CFR §123.6(b), your firm must implement the critical limits listed in your HACCP plan, including the critical limits that must be met at each of the critical control points. "Critical Limit" is defined at 21 CFR §123.3(c) to mean the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Although your firm's HACCP plan lists a critical limit temperature of [redacted] degrees Fahrenheit or less for the Processing critical control point to control histamine forming bacteria, your firm's HACCP plan has not been fully implemented with respect to this critical limit, as evidenced by the fact that one processing area in your firm has temperatures of 79-80 degrees Fahrenheit and the other processing area has temperatures of 52 degrees Fahrenheit or higher.

3. Pursuant to 21 CFR §123.6(c)(4), your firm must have a HACCP plan that, at a minimum, lists the monitoring procedures for each critical control point. However, your firm lists monitoring procedures/frequencies at the Processing and Cold storage critical control points that are not adequate to control histamine forming bacteria or pathogen growth.

One processing area in your firm has temperatures of 79-80 degrees Fahrenheit and the other processing area has temperatures of 52 degrees Fahrenheit or higher but your HACCP plans for histamine forming species and fresh whole fish have the monitoring frequencies listed to visually check the temperatures [redacted] per day for both Processing and Cold storage. Therefore, the monitoring procedures/frequencies do not address the amount of time the histamine producing species are exposed to temperatures above 40 degrees Fahrenheit during processing or the assurance that the cold storage is maintained at 40 degrees Fahrenheit or less to control histamine forming bacteria or pathogen growth if the product is not normally stored in ice.

4. Pursuant to 21 CFR §123.6(c)(7), your firm's HACCP plan must provide for a recordkeeping system that documents the monitoring of the critical control points. Moreover, the records from such monitoring must contain the actual values and observations obtained during monitoring. Your firm, however, did not record monitoring observations at the receiving critical control points listed in your HACCP plan for histamine producing species.

Specifically, the Temperature Receiving Log is not filled out until all processing is completed, which occurs normally in the afternoon. The information is then recorded from memory onto the receiving log; therefore, the temperatures of the fish are neither recorded upon receipt nor by the individual taking the actual temperatures. In addition, upon receipt of product, your firm does not record concurrently the visual check for the adequacy of ice on the product. Finally, the Temperature Receiving Log was not completed by management for June 9, 2004.

5. Pursuant to 21 CFR §123.8(a), your firm must verify that its HACCP plan is adequate to control food safety hazards that are reasonably likely to occur. However, your firm did not verify the adequacy of the monitoring of the critical control points for any of the seafood HACCP records maintained by the firm.

For example, your firm's Temperature Receiving Log that monitors the critical control point of Receiving is not reviewed by the individual at your firm who is trained in seafood HACCP. Therefore, there is no verification that the values are within critical limits and that appropriate corrective actions are being taken. In addition, there are no calibration logs for the thermometers used at the critical control points to verify that the process control temperatures meet the critical limits.

6. Pursuant to 21 CFR §123.9(a)(2)-(4), your firm's records must include: the date and time of the activity; the signature or initials of the individual performing the operation; and processing/receiving information recorded at the time it is observed.

However, your firm's "Daily Temp Inspection of Refrigeration Log" does not identify the actual time that the temperature is recorded. Additionally, the employee who initials the log is not the employee who measures the temperature, and the information on the record is not recorded at the time that it is observed.

We may take further action if you do not promptly correct these violations. For instance, we may initiate regulatory action without further informal notice. Such actions may include the initiation of a seizure action against your products and/or an action to enjoin your firm from operating.

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 your HACCP plans, copies of all related temperature monitoring records and corrective actions, 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.

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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: Carolyn A. Pinney, Compliance Officer, at the above letterhead address. If you have any questions regarding any issue in the letter, please contact Carolyn A. Pinney at (214) 253-5312.

Sincerely,



Michael A. Chappell
Dallas District Director

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