



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
San Francisco District

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1431 Harbor Bay Parkway  
Alameda, California 94502-7070  
Telephone: (510) 337-6700

VIA FEDERAL EXPRESS

April 29, 1999

Our Reference: 2953303

Robert Costarella, Owner  
Costarella Seafoods, Inc.  
Pier 45, Shed B, #8  
San Francisco, California 94119

**WARNING LETTER**

Dear Mr. Costarella:

On February 18 and 22, 1999, Investigators Darla Bracy and Bruce Broidy of the U.S. Food and Drug Administration (FDA) conducted an inspection of your seafood processing facility. The inspection was conducted to determine compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110). The inspection documented deviations which constitute violations of the Federal Food, Drug, and Cosmetic Act, and related regulations for seafood processing and good manufacturing practices.

At the conclusion of the inspection, the FDA investigators provided you with a copy of the Domestic Seafood HACCP Report (form FDA 3501), and the FDA 483 (Inspectional Observations) and discussed the findings with you. Briefly, these deviations are as follows:

1. Failure to implement the monitoring procedures specified in your HACCP plan for the cooler storage of histamine forming species, including tuna, as required by 21 CFR 123.6(b). Temperature measurements of fish and cooler equipment are not always performed and monitoring records are not always maintained. For example, on February 12, the receiving temperature of tuna was not recorded.

2. The critical limits and monitoring procedures listed in your HACCP plan for histamine forming species are inadequate to address the histamine hazard at the critical control point of receiving [21 CFR 123.6(c)(3) & (4)]. The corrective action listed in your HACCP plan for histamine species is not appropriate [21 CFR 123.7(a)(1)]. Examples of adequate critical limits for your firm might include either: a) adequate ice or coolant is present at the time of delivery; or b) the shipment is accompanied by transportation records showing that the fish were held at or below 40 degrees F throughout transit. Examples of adequate monitoring procedures for the above critical limits might include either: a) visually check the adequacy of ice or chemical coolant at receipt, for every shipment; or b) continuous temperature monitoring throughout transit, for every shipment. Appropriate corrective actions for either of the above critical limits might include either: a) reject the lot, or b) hold the lot until the total time/temperature exposure can be determined and evaluated; or c) test the lot for histamine.

3. Failure to maintain sanitation control records, as required by 21 CFR 123.11(c), that document the monitoring and corrections of sanitary conditions specified in 21 CFR 123.11(b) during processing. For example, no documentation is available to show monitoring of plant water safety for ice production and processing; condition and cleanliness of food contact surfaces; prevention of cross contamination; maintenance of hand washing, hand sanitizing, and toilet facilities; protection from adulterants; proper labeling, storage, and use of toxic compounds; control of employee health conditions; and exclusion of pests.

The USFDA investigators also reported a deficiency related to the handling and processing of raw molluscan shellfish at your firm and requires your immediate attention and follow-up action. Regulatory follow-up on the deficiency will be conducted by the State Shellfish Control Authority, who is responsible for molluscan shellfish sanitation in California. Your firm has failed to maintain monitoring records documenting the presence of certified shellfish tags during the receipt of molluscan shellfish by your firm [21 CFR 123.28(c)].

Foods processed in your facility under these conditions are adulterated within the meaning of Section 402(a)(4) of the Act in that they were prepared, packed, or held under insanitary conditions whereby they may become contaminated with filth, or whereby they may be rendered injurious to health. Adulterated foods are subject to seizure as authorized by Section 304 of the Act. Adulteration of food while held for sale after receipt in interstate commerce, is prohibited by Section 301(k).

Similar HACCP deviations were observed during the previous inspection on January 8 and 9, 1998. Following the January 1998 inspection, the FDA investigators presented a written list of inspectional observations and discussed the findings with you. These

HACCP deviations were also reported to you by correspondence from this office on April 15, 1998. We are concerned that you have not corrected all of the HACCP deviations cited in our previous letter although you told the investigator that you would correct them. We acknowledge, however, your efforts in preparing HACCPs plans for cooked crab and scombroid fish, and that you have corrected the insanitary conditions found previously.

You must immediately take appropriate steps to correct the violations at your facility. Failure to correct the violations may result in legal sanctions such as seizure and/or injunction without further notice.

Please advise us in writing, within fifteen working days of receipt of this letter, the measures you have implemented to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. Please direct your response to Ms. Erlinda N. Figueroa, Compliance Officer (Telephone: 510-337-6795; FAX: 510-337-6707).

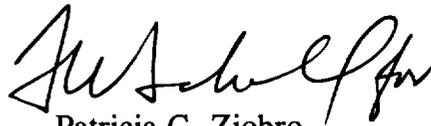
In addition to the violations mentioned above, there are other HACCP deviations which should be brought to your attention. These deviations are as follows:

1. Failure to develop and implement a written HACCP plan to address potential hazards associated with smoked fish and fishery products, including salmon, trout, mackerel, shrimp, tuna, and trout/salmon pate received and stored by your firm [21 CFR 123.6(b)].
2. Failure to implement the monitoring procedures specified in your HACCP plan for the receipt and cooler storage of cooked crab, as required by 21 CFR 123.6(b).
3. Failure to calibrate thermometers used to monitor critical control points [21 CFR 123.8(a)(2)(ii)].
4. Records do not include mandatory descriptive information such as the name and location of the processor on each record and the time of the activity that the record reflects [21 CFR 123.9(a)].
5. Monitoring records are not being reviewed weekly [21 CFR 123.8(a)(3)]. For example, the Fresh Fish Checklist and Seafood Checklist HACCP monitoring records do not have weekly verification signatures and dates for the months of February and May 1998.
6. Monitoring records for tuna received from [REDACTED] on February 11 were not signed by the person performing the monitoring activity [21 CFR 123.9(a)(3)].

7. Neither of your HACCP plans for cooked crab and scombroid fish are signed and dated [21 CFR 123.6(d)].

We encourage you to make the necessary improvements to your HACCP system as soon as possible. If you have questions regarding the implementation of the HACCP regulation, you may contact Ms. Darla Bracy, Investigator, at (510) 337-6773 for answers and/or direction towards guidance and sources of training in achieving compliance.

Sincerely,

A handwritten signature in black ink, appearing to read 'Patricia C. Ziobro', written in a cursive style.

Patricia C. Ziobro  
District Director  
San Francisco District