



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 2954424

August 2, 2002

Dennis J. Barone, General Manager  
Craig & Hamilton Meat Co.  
721 North Union Street  
Stockton, California 95208

**WARNING LETTER**

Dear Mr. Barone:

On December 10-14, and 17, 2001, we inspected your seafood firm located at 721 North Union Street, Stockton, California and found that you have serious deviations from the Seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause your Scombroid species Fin-Fish, refrigerated vacuum-packaged Smoked Salmon, and Roe to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the seafood products had been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You can find the Act and the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov). See attached handout, which gives information on how to obtain the Fish & Fisheries Products Hazards & Controls Guidance, 3<sup>rd</sup> edition, June 2001.

We have chosen to focus on the following products: (1) Scombroid species Fin-Fish (includes Bluefish, Bonito, Escolar, Trevally, Mahi-Mahi, Marlin, Mackerel, Tuna, Wahoo (Ono), Yellowtail (Amberjack), (2) refrigerated vacuum-packaged Smoked Salmon, and (3) Roe (Caviar). However, as a seafood processor, you are responsible for ensuring that all of your products are processed in compliance with the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations.

Your serious HACCP deviations are as follows:

- 1 You must conduct, or have conducted for you, a hazard analysis to determine the food safety hazards that are reasonably likely to occur and to identify the preventive measures necessary to control those hazards, and you must have a HACCP plan that lists the critical control points to comply with 21 CFR 123.6(a) and 123.6(c)(2).  
However,

- a. Your firm's HACCP plan for Scombroid species Fin-Fish did not list the critical control point of storage for controlling the food safety hazard of histamine formation.
- b. Your firm's HACCP plan for hot-smoked and cold-smoked seafood products, vacuum- packaged, did not list the critical control points of receiving and storage for controlling the food safety hazard of *Clostridium botulinum* toxin formation in the refrigerated and iced vacuum-packaged smoked products.
- c. Your firm's HACCP plan for refrigerated Roe did not list the critical control points of receiving and storage for controlling the food safety hazard of *Clostridium botulinum*.
- d. Your firm's HACCP plan for Refrigerated Cooked Ready-to-Eat products did not list the critical control points of receiving and storage to control the food safety hazard of pathogen growth and toxin formation.
- e. Your firm's HACCP plan for Refrigerated Ready-to-Eat Value Added seafood products did not list the critical control points of receiving and storage to control the food safety hazard of pathogen growth and toxin formation.

Since your firm stores refrigerated ready-to-eat seafood, vacuum-packaged seafood, and histamine species, you should have some method in place to assure that stored products are maintained at 40°F or less. FDA suggests either monitoring the adequacy of the ice surrounding your products twice a day or installing some method of continuous temperature monitoring, such as a high-temperature alarm or temperature data recorder.

2. You must have sanitation control records that are adequate to comply with 21 CFR 123.11(c). However, your sanitation control records did not address four of the eight key areas of sanitation: maintenance of toilet facilities; safety of water; exclusion of pests; and prevention of cross-contamination. Your records should include monitoring observations for these key areas.
3. 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 receiving critical control point to control histamine in your HACCP plan for Scombroid species.
4. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor sanitation for the prevention of cross contamination with sufficient frequency to ensure control as evidenced by:
  - improperly positioned ceiling tiles;
  - open containers stationed next to open doorway;

- dirty ceiling and overhead cooling unit in cooler; and
- rusted overhead ceiling supports.

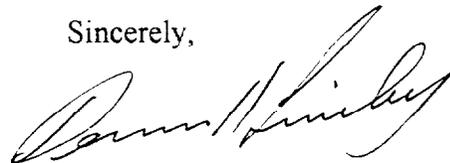
At the conclusion of the inspection, the deviations were listed on Form FDA 483 and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR 110).

Over seven months have elapsed since FDA inspection which should have been sufficient time to correct the violations. We may take further action if you have not corrected these violations. For instance, we may move to seize your products and/or enjoin your firm from operating.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the deviations conveyed to you by FDA at the close of the inspection. Your response should outline the specific things you have done and are doing to correct the above-listed deviations. You may wish to include in your response documentation that would assist us in evaluating your corrections. If you have not completed 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.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,



Dennis K. Linsley  
District Director  
San Francisco District

Enclosures:

Handout on Fish & Fisheries Products Hazards & Controls Guidance, 3<sup>rd</sup> edition  
Form FDA 483

cc Kent L. Smith, Seafood Production Supervisor

