



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

93630d

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

VIA CERTIFIED MAIL

Our Reference: 2951114

October 15, 2002

Timothy C. Ports, President
Ports Seafood, Inc.
dba The Fresh Fish Company
P.O. Box 192885
San Francisco, California 94119

WARNING LETTER

Dear Mr. Ports:

On July 10, 11, and 17, 2002, we inspected your seafood processing facility Ports Seafood, Inc. dba The Fresh Fish Company, located at Pier 28, The Embarcadero, San Francisco, 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). 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 scombroid species, vacuum-packed smoked fish, and vacuum-packed crabmeat are 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. See attached handout on how you can obtain a copy of the

Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001. We listed the deviations on a Form FDA 483 and discussed them with you at the conclusion of the inspection. Your serious HACCP deviations are as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR Part 123.3(f) as “any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.” However, your firm’s HACCP plan for “Tuna, Escolar, Mahi, Mackerel, Sardines, Anchovies, Bluefish, Yellowtail, Herring, Jack, Kahawai, Shad Roe, Trevally, Ono” does not list the food safety hazard of *Clostridium botulinum* toxin formation that is likely to occur in the chilled vacuum packaged Yellowtail (Hamachi) that is received and stored at your facility.
2. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3).
 - a) However, your firm’s HACCP plan for “Tuna, Escolar, Mahi, Mackerel, Sardines, Anchovies, Bluefish, Yellowtail, Herring, Jack, Kahawai, Shad Roe, Trevally, Ono” lists a critical limit of 45 degrees maximum temperature at the Receiving critical control point (CCP) that is **not** adequate to control histamine formation. FDA recommends that for fish delivered refrigerated (not frozen) with a transit time of four hours or less, the internal temperature of a representative number of fish in the lot be 40°F or below at the time of delivery. For scombroid species received with a transit time greater than four hours, FDA recommends the firm check the adequacy of ice or cooling media at the time of delivery, or ensure that all lots are accompanied by transportation records that show that the fish have been held below 40°F throughout transit.
 - b) However, your firm’s HACCP plan for Smoked Fish and Vacuum Packed Crabmeat lists a critical limit of maximum temperature of 45°F at the Receiving and Cooler Storage CCPs that is **not** adequate to control pathogen growth and toxin formation, specifically *Clostridium botulinum* toxin formation for products

received and intended to be held under refrigeration. A temperature of 40°F or less is recommended for maintaining the safety of the product (38°F for unpasteurized vacuum packed crabmeat).

- c) However, your firm's HACCP plan for "Tuna, Escolar, Mahi, Mackerel, Sardines, Anchovies, Bluefish, Yellowtail, Herring, Jack, Kahawai, Shad Roe, Trevally, Ono" lists a critical limit of "Standard Operating Procedures for product handling" at the Weigh, Bag, pack, Repack critical control point (CCP) that is not adequate to control histamine formation. Your HACCP plan should list the minimum and maximum values to which a physical, biological, or chemical parameter must be controlled, as defined by 21 CFR 123.3(c). Your firm's HACCP plan should list the cumulative time that the histamine producing species are held at temperatures that exceed 40°F during processing. The FDA *Fish & Fisheries Products Hazards & Controls Guidance, Third Edition, June 2001* recommends one of the following temperature critical limits to control histamine formation during processing of fish received refrigerated:
- The fish are not exposed to ambient temperatures above 40°F for more than 4 hours cumulatively, if any portion of that time is at temperatures above 70°F.
 - The fish are not exposed to ambient temperatures above 40°F for more than 8 hours, cumulatively, as long as no portion of that time is at temperatures above 70°F.
3. You must have a HACCP plan that, at a minimum, lists monitoring procedures and frequencies for each critical control point to ensure compliance with critical limits, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for "Tuna, Escolar, Mahi, Mackerel, Sardines, Anchovies, Bluefish, Yellowtail, Herring, Jack, Kahawai, Shad Roe, Trevally, Ono" list a monitoring frequency at the Cooler Storage CCP that is not adequate to control the hazard of histamine formation. During the refrigerated storage of these products, FDA recommends

maintenance of refrigerated storage coolers at 40°F or below, with continuous monitoring of the temperature.

4. You must fully document, in records, all corrective actions taken, to comply with 21 CFR 123.7(d). However, your incoming logs of 2/06/02, 2/11/02, and 2/13/02 indicated deviations to the critical limit as evidenced by the remarks "See Corrective Action" but your firm did not have additional documentation of any corrective action taken.

You should be aware that since you chose to include corrective actions as a part of your HACCP plan, they must ensure that no product enters commerce that is either injurious to health or is otherwise adulterated and the cause of the deviation is corrected.

You must immediately take appropriate steps to correct the violations at your facility. We may initiate regulatory action without further notice if you do not correct these problems. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

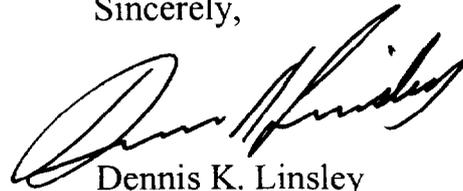
Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of the revised HACCP plans, temperature monitoring records, 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. We acknowledge your response of July 31, 2002 to the inspectional observations presented to you at the close of the inspection. Your corrections however, do not address all the issues raised in this Warning Letter.

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 (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.

Your response should be directed to: Ms. Erlinda N. Figueroa, 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. Figueroa at (510) 337-6795.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis K. Linsley". The signature is fluid and cursive, with a large initial "D" and "L".

Dennis K. Linsley
District Director
San Francisco District

Enclosures

Handout on Fish & Fisheries Products Hazards & Controls Guidance,
3rd edition, June 2001