



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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VIA FEDERAL EXPRESS

Our Reference: 3002331255

August 22, 2003

Andrew Tardio, President  
Tardio Enterprises, Inc. dba Newport Fish Co.  
457 South Canal Street  
South San Francisco, California 94080

**WARNING LETTER**

Dear Mr. Tardio:

On May 20, 21, 28, and 29, 2003, we inspected your seafood processing facility, located at 457 South Canal Street, South San Francisco, CA. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, 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 the following products are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health:

- Fresh tuna, Albacore, Escolar, Mahi-Mahi, Spear fish, and Yellowtail
- Refrigerated, vacuum packed Yellowtail and smoked Atlantic salmon
- Imported aqua-cultured King salmon

You may 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 acknowledge receiving the letter of June 19, 2003 from [REDACTED] presenting your firm's hazard analyses and HACCP plans for aqua-cultured salmon and vacuum packed Yellowtail (Hamachi).

The deviations, based on the inspection and taking into account your letter of June 19, 2003, 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 you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for refrigerated vacuum packed Atlantic smoked salmon to control the food safety hazards of pathogen growth and toxin formation including *Clostridium botulinum*.
2. 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 refrigerated vacuum packed fresh Yellowtail (Hamachi) does not list the food safety hazards of pathogen growth and toxin formation including *Clostridium botulinum*. FDA considers *Clostridium botulinum* toxin formation to be a hazard that is reasonably likely to occur in your fresh vacuum packaged fishery product. You may refer to Chapter 13 of the Fish and Fisheries Products and Hazards Guidance: Third Edition, Chapter 13, for information regarding the control of *Clostridium botulinum* in vacuum-packaged seafood products.

Moreover, once you have identified the hazards of pathogen growth and toxin formation including *Clostridium botulinum*, you must take steps to control these food safety hazards. FDA recommends that the temperatures of vacuum packaged raw fish be maintained strictly at or below 38°F from packing to consumption. Specifically, as a secondary processor, you should take steps to ensure that that vacuum packaged product was not temperature abused during transit prior to your receipt of product (FDA recommends the use of time temperature indicators on all packages of incoming product that you receive), or during further processing and storage at your firm.

3. 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 critical control points, to comply with 21 CFR 123.6 (a) and (c)(2). A critical control point is defined in 21 CFR Part 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for refrigerated vacuum packed fresh Yellowtail (Hamachi) does not list the critical control point (CCP) of Cooler Storage for controlling the food safety hazard of histamine formation.

The monitoring procedure and frequency listed at the Receiving CCP in your firm's HACCP plan attempts to combine receiving and storage steps into one CCP. Once you have identified a separate Cooler Storage CCP, you should take

steps to control temperatures for mechanically refrigerated product. FDA recommends continuous temperature monitoring of refrigerated storage by means of recorder thermometers, time/temperature integrators, high temperature alarms, maximum indicating thermometers, or digital data loggers, with a visual check at least once per day. If you are using ice or cooling media to completely surround product, this is considered a continuous application of cooling, and you should check the adequacy of ice or cooling media at least twice per day.

4. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6 (c)(4). However, your firm's HACCP plan for refrigerated vacuum packed fresh Yellowtail (Hamachi) lists a monitoring procedure "Observe thermometer" at the Receiving critical control point that is not adequate to control histamine formation as a result of time/temperature abuse during transit.

As a secondary processor, you should ensure that fresh histamine forming fish are delivered under ice or cooling media, with an adequate quantity of ice or cooling media at the time of delivery to completely surround the product, or that they are received with records documenting the fish were held at or below 40°F throughout transit. However since this product is received as vacuum packaged, if you control the food safety hazards associated with reduced oxygen packaging (i.e. pathogen growth and *Clostridium botulinum* toxin formation), you will adequately address the hazard of histamine formation.

5. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plans for the Tuna, Fresh, Small Loins, Albacore, Fresh Escolar, Mahi-Mahi, Spear fish, and Yellowtail are not appropriate because they do not address the cause of the deviation from the critical limits. FDA recommends that the use of the supplier be discontinued until evidence is obtained that transportation practices have changed.
6. You must have product specifications that are designed to ensure that the fishery products you import are not adulterated, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for the imported fresh King salmon obtained from [REDACTED] in [REDACTED].
7. You must implement an affirmative step which ensures that the fishery products you import are processed in accordance with the seafood HACCP regulations, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for fresh King salmon obtained from [REDACTED]. We have enclosed a copy of 21 CFR 123 that describes the different affirmative steps that you may take.

8. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor key sanitation areas on May 20, 2003, with sufficient frequency to ensure control of:
- a. Prevention of cross contamination from insanitary objects to food, food packaging materials, and other food contact surfaces (21 CFR 123.11(b)(3)), as evidenced by our observation of several employees not wearing appropriate outer garments during manufacturing operations; an employee observed to not wash his hands prior to repacking scallops and packaging fish; several employees wearing unsecured jewelry; and several employees observed as not wearing appropriate hair restraints during processing.
  - b. Maintenance of hand washing, hand sanitizing, and toilet facilities (21 CFR 123.11(b)(4)), as evidenced by our observation of an empty soap dispenser located at the hand-washing sink in the filleting room, and an empty paper towel dispenser located in the lunch room.
  - c. Protection of food, food packaging material, and food contact surfaces from adulteration (21 CFR 123.11(b)(5)), as evidenced by our observation of three bottles of cleaning products located near the live lobster and crab water tanks; and two drinking containers observed on a shelf near filleting tables.

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 Current Good Manufacturing Practice Regulations (21 CFR 110).

We may take further action if you do not promptly correct these violations. 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 should include in your response documentation 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.