



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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One Montvale Avenue
Stoneham, Massachusetts 02180
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December 23, 2002
WARNING LETTER
NWE-06-03W

VIA FEDERAL EXPRESS

Michael Gambardella, Jr.
President and Owner
Gambardella Wholesale Fish Dealers, Inc.
1 High Street
Stonington, CT 06378

Dear Mr. Gambardella,

The Food and Drug Administration inspected your firm, located at 1 High Street, Stonington, CT on October 3, 9 and 10, 2002 and found that you have serious deviations from Title 21 of the Code of Federal regulations (21 CFR) Part 123 – Fish and Fishery products (Seafood HACCP regulation). 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). Accordingly, your refrigerated Scombroid species (bluefish, tuna, bonito and mackerel) are adulterated, in that the products were 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.

Your serious seafood HACCP deviations are as follows:

1. You must implement the monitoring procedures that you have listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of "Receipt of Harvest Vessel Records" at the Receiving critical control point to control the hazard of histamine listed in your HACCP plan for histamine forming species.

Our investigators observed that your firm obtained Harvest Vessel Records for only three lots of fish between 08/1/02 and 10/01/02. However, your boat landing records indicated that you had received and processed numerous lots of histamine forming fish during that time period in addition to the three lots received with Harvest Vessel Records.

2. You must implement the recordkeeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations (decomposition or sensory evaluation of the fish lot) at the Receiving critical control point as listed in your HACCP plan to control histamine formation in histamine producing species.
3. You must have a HACCP plan that lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for histamine forming species does not list a monitoring procedure at the Storage critical control point that is adequate to control histamine formation. Your HACCP plan lists a critical limit for the presence of ice in the containers, but your monitoring procedures lists that you will monitor the temperature of the cooler.

If you choose to monitor the adequacy of the ice covering the product during storage, FDA recommends that you visually monitor the adequacy of the ice twice a day to ensure that the listed critical limit is not exceeded.

If your firm chooses instead to monitor cooler temperatures, you should use a method that is continuous, such as an alarm system or a temperature data recorder. FDA has determined that intermittent temperature checks do not provide the necessary assurance that fish are held at consistently safe temperatures.

4. 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 plan for histamine forming species at the Receiving and Storage critical control points to control histamine is not adequate.
 - In addition to adding ice to your fish and correcting cooler malfunctions as corrective actions at your Storage critical control point, you should also evaluate the time your fish have been exposed to abusive conditions, determine the internal temperatures of the fish, and, if necessary, analyze the fish for histamine content.
 - Your plan lists that you will reject decomposed fish as a corrective action at the Receiving critical control point. FDA considers rejecting the entire lot of fish an appropriate corrective action when the critical limit of 2.5% decomposition is exceeded.

5. You must have a HACCP plan, that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as the "maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at the critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for histamine forming species does not list a critical limit for temperature at the Receiving critical control point. Please refer to Chapter 7 of the Fish and Fisheries Products Hazards and Controls Guidance for help in determining the most appropriate critical limit for the product you receive.

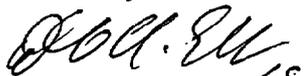
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) days from your 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 your current monitoring records, revised HACCP plan 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.

This letter may not list all of the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulation and the Current Good Manufacturing Practice regulation (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 M. Patricia Murphy, Compliance Officer, at One Montvale Avenue, 4th Floor, Stoneham, MA 02180. If you have any questions concerning this matter, please contact Ms. Murphy at 781-596-7758.

Sincerely,



Gail T. Costello
District Director
New England District Office