



DEPARTMENT OF HEALTH AND HUMAN SERVICES

g 4070 of

Food and Drug Administration  
Minneapolis District Office  
Central Region  
212 Third Avenue South  
Minneapolis, MN 55401  
Telephone: (612) 334-4100  
FAX: (612) 334-4134

May 30, 2003

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**Refer to MIN 03 - 23**

David B. Mernin  
Chief Financial Officer  
The Fish Guys, Inc.  
301 Royalston Avenue  
Minneapolis, Minnesota 55405

Dear Mr. Mernin:

On February 26-27 and March 4, 6, and 13, 2003, we inspected your seafood processing facility located at 301 Royalston Avenue, Minneapolis, Minnesota. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) Regulation, 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 vacuum packed smoked fish and histamine-producing fish are adulterated in that these products 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 regulation through links on FDA's home page at [www.fda.gov](http://www.fda.gov).

The 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 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

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prevented, eliminated, or reduced to acceptable levels.” However, your firm’s HACCP plan for Smoked Fish does not list the critical control point of Receiving for controlling the food safety hazard of *Clostridium botulinum* growth and toxin formation.

2. You must have a HACCP plan that, at a minimum, lists monitoring procedures, and frequency thereof, for each critical control point, to comply with 21 CFR 123.6(c)(4).
  - Your firm’s HACCP plan for Smoked Fish lists a monitoring frequency at the Storage critical control point that is not adequate to control the hazard of *Clostridium botulinum* growth and toxin formation associated with vacuum-packed smoked fish products. Your plan states that you will monitor your cooler temperature with visual checks once per day. FDA recommends maintenance of refrigerated storage coolers at 38°F or below, with continuous monitoring of the temperature. Continuous monitoring can be achieved by using a temperature data logger or other recording thermometer, with visual checks at least twice a day.
  - Your firm’s HACCP plan for Fresh Fish lists a monitoring frequency that is not adequate to control the hazard of histamine formation. Your plan lists that you will monitor your cooler temperature with visual checks once per day. FDA does not consider periodic checks of cooler temperatures an adequate safety control for the storage of histamine forming species. FDA recommends that firms who choose to monitor cooler storage temperatures for histamine producing species provide some method of continuous temperature monitoring, such as a temperature data logger. Alternatively, if stored fish and fishery products are maintained on ice or chemical cooling media, FDA recommends that the adequacy of ice or chemical media be controlled with visual checks at least twice a day.
3. You must fully document, in records, all corrective actions taken, to comply with 21 CFR 123.7(d). However, you did not document that a corrective action was taken when you deviated from your critical limit of 38°F for smoked fish at the storage critical control point to control pathogens on February 26, 2003.
4. 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 Part 123.3(c) as “the maximum or minimum value to

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which a physical, biological, or chemical parameter must be controlled at a 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 Fresh Fish lists a critical limit at the receiving critical control point that is not adequate to control histamine formation during transportation.

FDA recommends that for fish delivered refrigerated, either all lots be received with transportation records that show the fish were held at or below 40°F throughout transit, or, for fish held under ice or chemical cooling media, all of the product is completely surrounded by an adequate quantity of ice or other cooling media at the time of delivery.

5. You must take corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). Sections 123.7(b) and (c) require that a corrective action ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation and that the cause of the deviation is corrected. Your firm took a corrective action when your process for smoked fish deviated from your critical limit at the storage temperature critical control point that was not adequate to control pathogens. On September 2, 5, 8, 10 and 16, and on March 1, 2003, your storage temperature was recorded above the critical control point of 38°F. However, the corrective action taken did not include review and evaluation of the product stored in the cooler at that time to ensure that no product entered commerce that was injurious to health or otherwise adulterated as a result of the deviation.

We may take further action if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within 15 working 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 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 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

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prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please forward your response to the attention of Compliance Officer Tyra S. Wisecup at the address in the letterhead.

Sincerely,

*for*   
W. Charles Becoat  
Director  
Minneapolis District

TSW/ccl

cc: Brent Casper  
Co-Owner  
The Fish Guys, Inc.  
301 Royalston Avenue  
Minneapolis, MN 55405