



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region g1491d

Telephone (973) 526-6010

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

July 11, 2001

**WARNING LETTER**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Mr. John Cole  
President  
Fisherman's Cooperative, Inc.  
57 Channel Drive  
Point Pleasant, New Jersey 08742

**01-NWJ-30**

Dear Mr. Cole:

We inspected your firm, located at 57 Channel Drive, Point Pleasant, NJ, on April 30 and May 2, 2001, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh Shad, fresh Bluefish, fresh Mackerel, et al. to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

1. You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3), however, your HACCP plan for fresh fish does not list adequate critical limits at the following control points:
  - a. Your HACCP plan lists critical limits of **1.0ppm** or less for histamine producing fish and "follow government guidelines 1.0ppm." (We note with respect to the latter critical limit, the identity of what is being controlled at 1.0ppm is not apparent, and whether 1.0ppm is an upper or lower limit is not clear. We also note that there is no monitoring procedure for this critical limit.). As the primary processor, your receiving critical control point must list one of the following combinations of critical limits to control the hazard of histamine formation:
    1. Harvest vessel records and sensory evaluation – Your firm may list vessel records to insure that the histamine producing species have been handled safely during the harvest and storage aboard the harvest vessel. In this combination, the vessel records would be augmented by sensory evaluation to insure that the histamine producing fish were handled properly while in transit. In addition, the internal temperatures must be taken at receiving to insure that the fish has been cooled properly and that no temperature abuse has taken place during transit.

Fisherman's Dock Cooperative, Inc.  
Point Pleasant, New Jersey  
Warning Letter

-- Page Two --

2. Histamine testing and sensory evaluation – Your firm may choose to list the results of histamine testing against a fixed maximum allowable histamine level coupled with sensory evaluation to establish the level of decomposition in the fish. In addition, the internal temperature must be taken at receiving to insure that the fish has been cooled properly and no temperature abuse has taken place during transit.

**Note:** *Please refer to the FDA Fish and Fishery Products Hazards & Controls Guide, Third Edition, for recommended maximum critical limits that could vary depending on harvest conditions.*

- b. The critical control point for processing (weigh, pack and label) does not list a critical limit for temperature control of histamine producing fish during processing.
2. You must implement the record keeping system listed in your HACCP plan to comply with 21 CFR 123.6(b). You did not record monitoring observations at the storage critical control point to control the hazard of histamine formation listed in your HACCP plan for fresh fish.

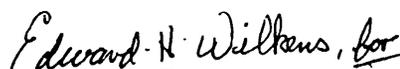
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within three weeks 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 a revised HACCP plan, revised monitoring procedures, 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 regulations and the Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

You may send your response to: U.S. Food & Drug Administration, 10 Waterview Boulevard, 3<sup>rd</sup> Floor, Parsippany, New Jersey 07054, Attn: Sarah A. Della Fave, Compliance Officer.

Sincerely,

  
Douglas I. Ellsworth  
District Director