



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

g2017d

60 8th Street, N.E.
Atlanta, Georgia 30309

November 20,2001

VIA FEDERAL EXPRESS

Alicia R. Lyons, Owner
Red Barn Fish Company
107 Red Barn Road
Hubert, NC 23539

Warning Letter
02-ATL-10

Dear Ms. Lyons:

On August 8, 2001, Investigators Robert P. Neligan and James P. Lewis of the Food and Drug Administration (FDA) conducted an inspection of your plant located at Sneads Ferry, North Carolina. During that inspection, our investigators documented serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your histamine-producing fish 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.

The deviations were as follows:

1. You must have a HACCP plan that lists the critical limits and monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(3) and (4). However, the critical limit and monitoring procedure listed for the "Receiving" critical control point are not adequate to control the food safety hazard of histamine formation.
 - a. Your HACCP plan does not list the critical limit and monitoring procedure to address how the scombrototoxic fish was handled at the harvest vessel. Specifically, you must monitor harvest vessel records for method of capture, date and time of landing, air and water temperatures at time of landing, time of death for fish landed, method of cooling, time cooling began, storage temperature or adequacy of ice and the date and time of off-loading.
 - b. Your HACCP plan does not clarify what "acceptable" means in the critical limit for sensory examination at receiving and establish monitoring procedures for this sensory determination.

- c. Your HACCP plan does not list a critical limit for the adequacy of ice at the "Receiving" critical control point even though it lists a monitoring procedure for the visual check of the adequacy of ice on incoming fish.
2. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the receiving critical control point to control histamine formation as listed in your HACCP plan for histamine-producing fish. Specifically, there was no monitoring of incoming internal temperatures for histamine fish from 5/22/01 until the date of inspection.

We suggest that you refer to Chapter 7 of the *Fish and Fisheries Products Hazards & Controls Guidance: Third Edition, June 2001* (copy enclosed) for guidance in establishing critical limits and monitoring procedures for controlling the hazard of histamine formation in the fish that you process.

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

Please respond in writing within three (3) 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 copies of HACCP plans, and HACCP 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.

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 (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Karen Y. Dodson, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mrs. Dodson at (404) 253-1299.

Sincerely,



Ballard H. Graham, Director
Atlanta District

Enclosure