



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

g3547d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

September 27, 2002

WARNING LETTER

NWE-35-02W

FEDERAL EXPRESS

Carl Hampe III, President
New Hampshire Fisheries, Inc.
239 Western Avenue
Route 22
Essex, Massachusetts 01929

Dear Mr. Hampe:

We inspected your firm, located at 239 Western Avenue in Essex, Massachusetts, on August 21 - 23, 2002, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR 123). These deviations cause the tuna, mackerel, mahi mahi and marlin processed by your firm 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 are as follows:

As a Domestic Processor

1. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for scombrototoxin species does not list the critical control point of Cooler Storage for controlling the food safety hazard of histamines. Further the FDA investigator reported that you sometimes store these fish in your cooler over the weekends. You must assure the critical temperature limit is met at the Cooler Storage critical control point throughout the weekends, when these fish are held over the weekend.

2. 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 scombrototoxin species at the Receiving, Packing and Transportation critical control points to control histamines is not appropriate. For example, under what conditions are the fish rejected?
3. 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 firm's HACCP plan for scombrototoxin species lists as a critical limit: "Repacking should be done quickly so the internal temperature does not rise." This is not adequate to control histamines because it does not specify what is meant by "quickly", nor does it specify the highest allowable temperature that will control histamines.

As an Importer

1. The HACCP regulations require, but your firm does not maintain, written product specifications for the scallops that you import from Canada (21 CFR 123(a)(2)(i)).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your violative 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 documentation in your response, such as a completed HACCP plan, or other useful information that would assist 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 §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.

We note that your HACCP plan for Scombrototoxin species is difficult to follow. This is not a violation, but you may want to refer to the Fish and Fisheries Products Hazards & Controls Guidances: *Third Edition* for an easier reading format.

- New Hampshire Fisheries, Inc.
Essex, Massachusetts 01929
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Please send your reply to the deviations listed above to the Food and Drug Administration, Attention: Bruce R. Ota, Compliance Officer, One Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issues in this letter, please contact Mr. Ota at (781) 596-7762.

Sincerely,



Gail T. Costello
District Director
New England District