



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-26

January 23, 2001

Peter M. Bacle, Owner
Stock Island Lobster Co.
6639 Maloney Ave.
Key West, FL 33040

Dear Mr. Bacle:

We inspected your firm at the above address on August 23, 2000 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, most of which were previously brought to your attention, cause your fresh fish and cooked stone crab claws to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic 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 food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plan for Tuna and Dolphin (Mahi Mahi) does not list the food safety hazard of histamine. Your hazard analysis incorrectly associates this hazard with harvest location. The histamine formation is the result of time/temperature abuse after capture and during subsequent handling.

Please note: Your HACCP plan lists only tuna and dolphin (Mahi Mahi) and does not include the other scombroid species you process.

2. 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 Cooked Stone Crab Claws does not list the critical control points of Cooling and Refrigerated Storage for controlling the food safety hazard of Pathogen Growth and Toxin Formation.

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 Cooked Stone Crab Claws does not list a critical limit at the Processing cooking critical control point to control Pathogen Survival through Cooking. In addition to the cooking temperature, you must also list the minimum cook time necessary to control the hazard.

Your plan also lists "Established process schedule" as your critical limit. Your actual critical limits are the temperature of your boiling water or the observation of a rolling boil and your cook time (the time claws are in water that is at a rolling boil). Since your firm uses boiling water to cook the crab claws, listing two different cook temperatures in your HACCP plan is inappropriate. It is only necessary that you list the temperature of the boiling water used to cook the crabs.

NOTE: Seafood HACCP regulations require that you validate your cooking process to assure that your process will consistently attain the critical limits that you have set and adequately control the hazards listed in your plan (Pathogen Survival through Cooking).

4. 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 Cooked Stone Crab Claws does not list the monitoring procedure of visually determining the start and end of your crab claw boiling process at the Processing Cooking critical control point to control the hazard of Pathogen Survival through Cooking.
5. You must provide all mandatory records for official review and copying at reasonable times, to comply with 21 CFR 123.9(c). However, a representative of your firm was unable to provide access to all of your completed HACCP monitoring records and Sanitation monitoring records during your normal working hours.

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 revised HACCP plans and revised 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 the 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 Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Kendall W. Hester, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Hester at (407) 475-4730.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Emma R. Singleton,
Director, Florida District