



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

Telephone: 407-475-4700
FAX: 407-475-4769

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-03-44

September 9, 2003

Beryl N. Stokes, Jr., President
Stokes Fish Company Inc.
P.O. Box 490298
Leesburg, Florida 34749

Dear Mr. Stokes:

We inspected your firm, at the above address, on June 16 and 20, 2003 and found that you have serious deviations from the seafood Hazard Analysis Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) – Fish and Fishery Products. 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 fishery products are adulterated, in that the ready-to-eat fishery products, such as cooked stone crab claws and canned pasteurized crabmeat products, as well as histamine forming fish 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 can find the Act and the seafood HACCP regulation through links in FDA's home page at www.fda.gov.

The deviations are as follows:

1. You must, at a minimum, conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that 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 prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for fishery products does not list the critical control point of Receiving for controlling the food safety hazards of pathogen growth and toxin formation in the refrigerated cooked stone crab claws you receive and of *Clostridium botulinum* in the refrigerated canned pasteurized crabmeat that you receive.

2. You must implement the record keeping system that you 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 listed in your HACCP plan. Our investigator reported that although your firm monitors the adequacy of the ice at receiving, you do not keep a record of that observation. Your histamine forming fish are transported for more than 4 hours. Under these conditions, FDA recommends that you monitor the adequacy of the ice as listed in your plan. Internal temperatures are not considered an adequate method of assuring consistent safe transport temperatures when transport times exceed 4 hours.
- Your firm did not record monitoring observations at the Storage critical control point to control histamine in histamine forming fish and microbial growth in your ready to eat product, cooked stone crab claws, listed in your HACCP plan.

Our investigator observed that your fresh fish and stone crab claws are stored in ice in your cooler. Your plan lists that you will monitor this ice. Your firm appears to have chosen to monitor your cooler temperatures three times a day instead. FDA does not consider intermittent temperature checks during storage periods to be an adequate method of assuring that histamine forming fish are held at safe temperatures throughout storage. Monitoring the adequacy of the ice twice a day is considered the preferable method given your storage conditions.

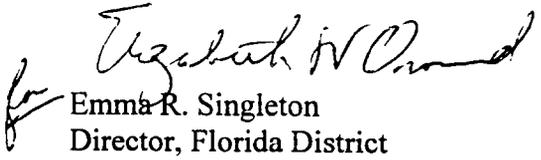
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries 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 such as revised HACCP plans and completed 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 regulation and the Current Good Manufacturing Practice regulation (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: Shari H. Shambaugh, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mrs. Shambaugh at (407) 475-4730.

Sincerely,


for Emma R. Singleton
Director, Florida District