



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-35 6/20/99 NAG

Public Health Service  
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Food and Drug Administration  
Florida District  
555 Winderley Place  
Suite 200  
Maitland, Florida 32751  
Telephone: 407-475-4700  
FAX: 407-475-4769

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

FLA-99-61

June 8, 1999

Gilbert R. Migliano, President  
Save On Seafood, Inc.  
4520 Eighth Ave South  
St. Petersburg, Florida 33711

Dear Mr. Migliano:

On August 27-28, 1998, the Food and Drug Administration (FDA) conducted an inspection of your seafood processing plant, located at 4520 Eighth Ave. South, St. Petersburg, Florida. The investigator documented serious deviations from the seafood processing regulations in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123) causing the histamine forming fish species, e.g., fresh tuna and mahi mahi, being received, processed, stored, and distributed by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), as follows:

Failure to identify, in your HACCP plan, Cold Storage as a critical control point for the chemical hazard of scombrototoxin (histamine) formation in fresh tuna and mahi mahi [21 CFR 123.6(c)(2)]

Failure to list appropriate critical limits that must be met at the Receiving critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the food safety hazard of scombrototoxin (histamine) formation in fresh tuna [21 CFR 123.6(c)(3)]. By itself, the frequency of histamine testing in your HACCP plan is not an adequate indicator of process safety. Although 50 ppm is appropriate as a critical limit for the chemical testing for histamine in fresh tuna, chemical testing alone will not normally provide adequate assurance that the hazard has been controlled.

Failure to take any of the affirmative steps listed in 21 CFR 123.12(a)(2)(ii) A-F to ensure that the seafood products you import were processed in compliance with the HACCP regulation.

Other deficiencies noted during the inspection include: failure to sign and date your HACCP plan to signify that the plan has been accepted for implementation by your firm, failure to follow your HACCP plan procedures to document record reviews, and failure to have and implement written verification procedures.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your seafood processing plant. It is your responsibility as president to ensure that all fish and fishery products received, stored, processed, and distributed by all of your seafood processing plants are in compliance with the Act and the requirements of the regulations.

You should take prompt action to correct these and all violations at your firm. Failure to promptly correct these violations may result in regulatory action without further notice. These actions may include seizure or injunction under the Federal Food, Drug, and Cosmetic Act. In addition, failure to correct the above deficiencies may affect your firm's ability to obtain European Union (EU) certificates. As you know, FDA, as a service to the U.S. seafood industry to facilitate the free flow of trade, has voluntarily undertaken to certify that seafood exports meet the EU's food safety requirements. Unless the above deficiencies are corrected, FDA may remove your firm from the EU list. In addition, until these deficiencies are corrected, the agency may not issue EU certificates for shipments.

We request that you notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent their reoccurrence. Your response should include copies of any documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

An administrative review indicates a shortcoming in your HACCP program that appears to be a deviation from the principles of HACCP and from a significant requirement of the seafood HACCP regulation. The observation of concern to us is as follows:

Failure to control the biological hazard of *Clostridium botulinum* toxin formation that is reasonably likely to occur in your modified atmosphere packaged products [21 CFR 123.6(b)].

Your reply should be directed to Ken Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4730.

Sincerely,



Douglas D. Tolen  
Director, Florida District