



March 13, 2013

VIA EXPRESS MAIL

Mr. Fenton Cunningham, President  
Sea Star Seafoods Limited  
69 Courtney Street  
Clarks Harbour, Nova Scotia B0W 1P0,  
Canada

Reference No.: 391505

Dear Mr. Cunningham:

We inspected your seafood processing facility, located at 69 Courtney Street, Clarks Harbour, Nova Scotia B0W 1P0, Canada on July 3-4, 2012. During that inspection, we found that you had serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). That inspection resulted in FDA's issuance of an FDA-483, Inspectional Observations, listing the deviations found at your firm at the conclusion of the inspection. In accordance with 21 CFR 123.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 123, renders the fish or 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 pickled split mackerel product is adulterated in that has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation and the Fish and Fisheries Products Hazards & Controls Guidance through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

We acknowledge receipt of your response to the FDA-483, and supporting documentation that was sent by email on January 18, 2013, outlining the corrective actions you have implemented. We have reviewed the revised HACCP plans and have the following additional concern:

You must conduct or have conducted for you a hazard analysis for each kind of fish and fishery product that you produce to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6 (a) and (c)(1). A food safety hazard is defined in 21 CFR 123.3 (f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption."

- However, your firm's HACCP plan for Pickled Mackerel does not list the food safety hazard of *Clostridium botulinum* germination, growth and toxin formation at the processing step where vacuum packaged product is held under cooler storage. We recommend controlling this hazard at the salting step by setting the critical limits to the maximum and minimum values for the critical factors of salting as

established by a scientific study. These critical factors should ensure for refrigerated products a water phase salt content of at least 5%. We note that if the water phase salt content for this product is 20% or more, refrigeration would not be required to control for *C. botulinum* in the finished product.

- However, your firm's HACCP plans for Pickled Mackerel, Dried Smoked Herring, and Dried Stockfish do not identify the food safety hazard of undeclared allergens. While you have indicated that your only two ingredients in all of your products are salt and fish, FDA recommends your firm include controls in your plan that ensure end product labels accurately declare all food allergens, including the species of finfish.

Please respond in writing within thirty (30) working days from your receipt of this letter. You should include in your response documentation such as HACCP and verification records, or other useful information that would assist us in evaluating your corrections.

Please send your reply to the U.S. Food and Drug Administration, Attention: Priya J. Rathnam, Consumer Safety Officer, Office of Compliance, Division of Enforcement, Food Adulteration Assessment Branch (HFS-607), 5100 Paint Branch Parkway, College Park, MD 20740, USA. If you have any questions regarding this letter, feel free to contact me at (240) 402-2078.

Sincerely,

/s/

Priya J. Rathnam  
Consumer Safety Officer  
Food Adulteration Assessment Branch  
Division of Enforcement  
Office of Compliance  
Center for Food Safety and Applied Nutrition