



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

g1169d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
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April 18, 2001

WARNING LETTER

NWE-19-01W

VIA FEDEX

Wally Stevens, President
Slade Gorton & Co., Inc.
Rocky Bay Fishing Co.
225 Southampton Street
Boston, MA 02118-2724

Dear Mr. Stevens:

We inspected your firm, located at Southampton Street, Boston, MA, on February 8, 2001. The inspection was conducted to determine compliance with the "Special Requirements for Imported Products" section of FDA's Seafood HACCP Regulations (21 CFR 123.12). During our inspection, we reviewed the verification documents required of U. S. seafood importers under the seafood HACCP regulation.

The seafood processing regulations, which became effective on December 18, 1997, require that seafood processors, both domestic and foreign, processing seafood products destined for U. S. consumers, implement a preventative system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having control at "critical control points" in processing operations to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of demonstrating that processors are routinely practicing food safety by design.

U. S. importers have certain obligations stipulated in the seafood processing regulation. U. S. importers must have evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with safety

requirements outlined in FDA's Seafood HACCP Regulation (21 CFR 123). To achieve this, importers must have and implement written verification procedures to ensure that the fish and fishery products that they import have been processed in accordance with HACCP requirements, and they must maintain records in English that document the performance and results of the steps they have taken. At a minimum, the verification procedures must list (1) product specifications designed to ensure each product is not adulterated under Section 402 of the Federal Food, Drug, and Cosmetic Act, and (2) the affirmative steps taken by the importer. You can find this Act and the Seafood HACCP Regulation through links in FDA's home page www.fda.gov.

Our inspection found that you have serious deviations from the requirements for importers under the U. S. Seafood HACCP Regulation for imported products (21 CFR 123.12). The deviations determined by our inspection were as follows:

You must implement affirmative steps that ensure that the fish and fishery product(s) you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii).

- However, your firm did not perform an affirmative step for Frozen Vacuum Packed Pasteurized (Precooked) Whole Mussels manufactured by [REDACTED]. You must maintain, in English, a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with HACCP requirements. The Health Certificate issued by [REDACTED] is not an equivalent substitute. It does not address the conditions the product was processed under.
- However, your firm performed an affirmative step of maintaining a copy of the foreign processor's HACCP plan for Frozen Vacuum Packed Pasteurized (Precooked) Whole Mussels manufactured [REDACTED] in Chile that was not adequate. The HACCP plan does not list the hazards of Natural Toxins and Environmental Hazards.

You must have product specifications that cover each of the seafood products you import. If you chose to maintain a copy of your foreign processor's HACCP plan as an affirmative step, you must be able to identify the hazards reasonably likely to occur in the seafood products provided by that processor.

With regard to the product currently detained under entry number 406-0296264-5, we have determined that product is considered adulterated within the meaning of the Food, Drug, and Cosmetic Act, U. S. C. 342(a)(4), in that the product was not processed in accordance with seafood HACCP regulations (21 CFR 123). The product is not eligible for reconditioning under these circumstances.

Given the serious nature of these violations of the Act, all *Frozen Vacuum Packed Pasteurized (Precooked) Whole Mussels* processed by [REDACTED], in Chile will be detained without physical examination (under Import Alert 16-119 – “DETENTION ... OF FISH AND FISHERY PRODUCTS FOR IMPORTER AND FOREIGN PROCESSOR (MANUFACTURER) COMBINATIONS WHERE THE IMPORTER HAS FAILED TO PROVIDE VERIFICATION OF COMPLIANCE WITH SEAFOOD HACCP, 21 CFR 123.12(d)”) when offered for entry into the United States until these violations are corrected.

In order to remove this product from detention, it will be necessary to provide for our review a written response with documentation that these violations have been corrected.

We encourage you to make the necessary improvements to your importer verification procedures and records as soon as possible. However, if you disagree with FDA’s assessment of deviations determined from our inspection of your firm, your response should explain how your system identifies hazards and critical control points in a manner that the agency should regard as complying with the requirements of the seafood HACCP regulation.

In either case, it is essential that you respond to FDA on this matter within fifteen (15) days from your receipt of this letter. Your response should outline specifically what you are doing to correct these deviations. You may wish to include in your response documentation such as your written verification procedures, a corrected HACCP plan, a copy of the foreign processor’s guarantee, and 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 your delay and state when you will correct any remaining deviations. Failure to provide us evidence of corrections to the deviations may result in your products being placed on “Detention Without Physical Examination.”

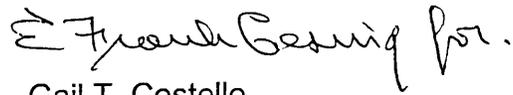
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the attention of Bruce Ota, Compliance Officer, Food and Drug Administration, One Montvale Ave., Stoneham, MA 02180.

Slade Gorton & Co.
Boston, MA
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If you have questions regarding any issue in this letter, please contact Mr. Ota at (781)279-1719.

Sincerely,

A handwritten signature in black ink that reads "Gail T. Costello for." The signature is written in a cursive, flowing style.

Gail T. Costello
District Director
New England District Office

cc: Michael LeVasseur
HACCP Coordinator
Slade Gorton & Co., Inc.
Rocky Bay Fishing Co.
225 Southampton Street
Boston, MA 02118-2724