



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
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WARNING LETTER
NWE-08-04W

VIA FEDERAL EXPRESS

December 2, 2003

William Silkes, President and Owner
American Mussel Harvesters, Inc.
165 Tidal Drive
North Kingstown, RI 02852

Dear Mr. Silkes:

We inspected your seafood processing facility, American Mussel Harvesters, Inc., located at 165 Tidal Drive, North Kingstown, RI on September 5, 8-10, 2003. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). 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 processed there 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 ready-to-eat (RTE) refrigerated seafood salad products are adulterated in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find this Act and the seafood HACCP regulation through links in FDA's home page at www.fda.gov.

We observed the following serious deviations:

1. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR Part 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard."

- However, your firm's HACCP plan covering RTE refrigerated prepared seafood salads fails to list a critical limit at the Receiving critical control point to control the hazard of "Pathogen Growth & Toxin Formation" to ensure that your product is maintained at safe temperatures throughout transport.
 - Since your product is transported by refrigerated truck in less than four hours, FDA recommends that you monitor either the internal temperature of a representative number of samples or require your transporter to provide continuous temperature monitoring records.
 - Your firm's HACCP plan covering RTE refrigerated prepared seafood salads lists a critical limit, "Storage temperatures do not exceed 45 degrees F," at the Refrigerated Storage critical control point that is not adequate to control the hazard, "Pathogen Growth & Toxin Formation as a Result of Time/Temperature Abuse." FDA recommends 40 degrees F as an appropriate critical limit to control pathogen growth in ready to eat seafood.
2. You must have a HACCP plan that, at a minimum, lists monitoring procedures, together with their frequency, for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan covering RTE refrigerated prepared seafood salads lists a monitoring procedure and frequency, "refrigerator temperatures are recorded twice each day," at the Refrigerated Storage critical control point that is not adequate to control the hazard, "Pathogen Growth & Toxin Formation as a Result of Time/Temperature Abuse." FDA currently recommends a method of continuous temperature monitoring to ensure that safe temperatures are maintained throughout the storage of RTE seafood products. Intermittent temperature checks do not provide a sufficient assurance of safety. In addition, your listed monitoring frequency cannot assure that your [REDACTED] critical limit is not exceeded.

We may take further action if you do not promptly correct the above violations. For instance, we may 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.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct this deviation. You should include in your response any documentation, such as your HACCP plan, 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 your delay and state when you will correct any remaining deficiencies.

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

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North Kingstown, RI 02852
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You may direct your reply to Ann Simoneau, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Simoneau at (781) 596-7732.

Sincerely,

A handwritten signature in black ink, appearing to read "Gail E. Costello". The signature is stylized with large loops and a long horizontal stroke at the end.

Gail E. Costello
District Director
New England District Office