



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

24542d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
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WARNING LETTER

NWE-20-04W

February 4, 2004

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Vincent Mortillaro, Co-owner
Mortillaro Lobster Company, LLC
60 Commercial Street
Gloucester, Massachusetts 01930

Dear Mr. Mortillaro:

On September 22-30, 2003, we inspected your seafood processing facility located in Gloucester, Massachusetts. We 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). 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 cooked lobster has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find this Act and the seafood HACCP regulation though links in FDA's home page at: www.fda.gov.

The deviations were as follows:

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). However, your firm's HACCP plan for cooked lobster lists a critical limit at the "cooking" critical

control point that is not adequate to control pathogen growth/survival. Specifically, you list that the cooked lobster must reach an internal temperature of not less than [REDACTED]. FDA does not recommend monitoring product internal temperature at the end of the cooking cycle because of the variability in heating rates among individual units or pieces of product due to differences in size and location within the cooking unit. The piece being monitored may not represent the cook cycle of the entire batch. Instead, processors should monitor the cooking temperature and time, which have been established by a study. You provided a document to our investigator entitled "HACCP Cook Plan" that provides heat penetration studies listing scheduled process parameters for various cook times, cook temperatures, and batch sizes to achieve various internal product temperatures. If you have ascertained that these processing parameters will result in a safe product, the cook time, cook temperature and batch size listed in this document will be critical to achieving an adequate cook to control pathogen survival and should be included as critical limits in your HACCP plan.

2. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for cooked lobster lists the monitoring frequency as "Daily" at the "Pack & Store" critical control point that is not adequate to control pathogens. Because you chose to monitor the ambient temperature of your cooler, FDA recommends that the refrigerated storage cooler temperature be monitored continuously with the use of a digital time/temperature data logger, or by an equivalent continuous method, with a visual check once per day. Daily temperature checks are not frequent enough to ensure safety.
3. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b) & 123.6(c)(7). However, your firm did not accurately record the monitoring observations at the cooking and "Shuck & Pick" critical control points to control pathogens as listed in your HACCP plan for cooked lobster. On 9/22/03, our investigator observed your production employee pre-recording values for the cooking and "Shuck & Pick" critical control points.
4. You must record the actual values and observations obtained during monitoring to comply with 21 CFR 123.6(c)(7). However, you failed to record the actual value for the temperature of your cooler at your "Pack & Store" critical control point observed during HACCP monitoring activities.

On 9/24/03, our investigator accompanied a representative of your company during monitoring of your cooler. Your cooler thermometer registered [REDACTED]. The investigator's calibrated thermometer read [REDACTED]. The observation recorded on your monitoring record was [REDACTED].

5. You must take corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). Sections 123.7(b) and (c) require that a corrective action ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation and that the cause of the deviation is corrected. However, your firm did not take a corrective action to control pathogens when your process for cooked lobster deviated from your critical limit at the "Pack & Store" critical control point. On 9/24/2003, and 9/30/03, our investigator, along with your representative, observed temperatures in your cooler exceeding your listed critical limit of [REDACTED]. No corrective action was observed being taken on 9/24/03. On 9/30/03, under similar conditions, your firm failed to implement a corrective action until after our investigator questioned whether or not one would be taken.
6. You must fully document, in records, all corrective actions taken, to comply with 21 CFR 123.7(d). However, you did not document that a corrective action was taken when you deviated from your critical limit of [REDACTED] for your cooked lobster meat at the "Pack & Store" critical control point to control pathogen growth. On 9/13/03, 9/16/03, 9/17/03, 9/19/03, and 9/21/03, your monitoring records listed observations that exceeded your listed critical limit. Your firm did not have records showing the corrective actions taken. In addition, a representative of your firm stated that you did not maintain records of corrective actions.
7. Because you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for cooked lobster at the "Pack & Store" critical control point does not ensure that unsafe product does not reach consumers and does not address correcting the cause of the deviation. It merely provides: "If cooler temperature goes [REDACTED] cooling unit is restarted and/or repaired. Uncleaned containers are cleaned before use. Labels are checked for proper labeling at inventory and shipping."
8. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the following areas of sanitation with adequate frequency:
 - a. Safety of water that comes into contact with food or food contact surfaces – as evidenced by missing anti-siphonage devices in the grading room.

- b. Condition and cleanliness of food contact surfaces – as evidenced by the lack of cleaning and sanitizing solutions for the cleaning of equipment.
- c. Maintenance of hand washing, hand sanitizing and toilet facilities – as evidenced by the lack of paper towels and hand washing solution at the hand wash sink adjacent to the lobster cooking area.
- d. Exclusion of pests – as evidenced by the openings around your loading dock door.

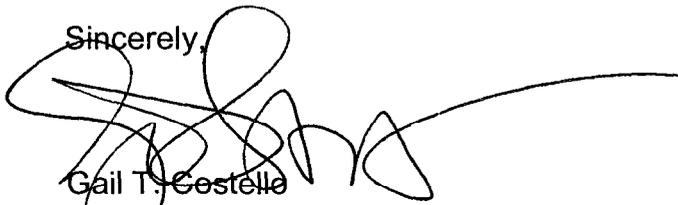
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operation.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation, such as a completed HACCP plan, or other useful information that would assist 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.

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: Bruce R. Ota, Compliance Officer, One Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issues in this letter, please contact Mr. Ota at (781) 596-7762.

Sincerely,



Gail T. Costello
District Director
New England District