



DEPARTMENT OF HEALTH & HUMAN SERVICES  
Food and Drug Administration  
New England District

93519d

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**WARNING LETTER**

**NWE-36-02W**

VIA FEDERAL EXPRESS

**September 30, 2002**

Thomas Carroll  
Owner  
Bass Harbor Seafood  
Route 102A  
Bass Harbor, ME 04653

Dear Mr. Carroll:

On August 20, 2002, we inspected your firm located at Route 102A, in Bass Harbor, Maine. During the inspection, Inspectors identified serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your ready-to-eat crabmeat to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The serious seafood HACCP deviations were as follows:

1. You must implement a record keeping system, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at a cooking critical control point (CCP) to control a pathogen hazard for your cooked, ready-to-eat crabmeat. Specifically, there were no cooking records for the processing of crabmeat for at least 41 days from April 2002 through July 2002. Moreover, during the August 20th inspection, there were no cooking records for the processing of crabmeat that had occurred that day. Additionally, your firm also lacked temperature storage records for at least 8 dates in April and June.
2. You must have a HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm could not provide a HACCP plan for ready-to-eat crabmeat to demonstrate that you control the food safety hazard of pathogens. During the inspection, cooked crabmeat was processed.

3. You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor two of the eight areas of sanitation with sufficient frequency to ensure control. In particular, your firm did not have a current well water test.

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

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 may also wish to include documentation such as your current monitoring records 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 processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110).

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,



Gail T. Costello  
District Director  
New England District Office