



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

9447.1

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WARNING LETTER
NWE-06-04W

VIA FEDERAL EXPRESS

November 20, 2003

David Thompson
President
Chestnut Directs
P.O. Box 200
Fairfax, Vermont 05454

Dear Mr. Thompson:

We inspected your seafood processing facility, Cuisine Sous-vide, Inc., located at 1126 Main Street, Fairfax, VT, on June 18 and again on August 1, 2003. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Point (HACCP) regulations, 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 crabmeat product is adulterated, in that the product 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 the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The serious deviations observed were as follows:

1. You must conduct a hazard analysis 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 critical control points (CCP), to comply with 21 CFR 123.6 (a) and (c)(2). A CCP is defined in 21 CFR 123.3(b) as a "point, step or procedure in a food process, at which control can be applied and a food safety hazard can, as a result, be prevented, eliminated, or reduced to acceptable levels". However, your firms' HACCP plan # 4 for crab cakes does not list a CCP at Receiving that will assure that refrigerated canned crab meat is maintained at a temperature that will control the food safety hazard of *Clostridium botulinum* during shipping to your firm.

2. You must conduct a hazard analysis 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 critical control points, to comply with 21 CFR 123.6 (a) and (c) (2). Your firm's HACCP Plan #4 for crab cakes does not list a CCP at storage that will assure that refrigerated canned crab meat is maintained at a temperature that will control the food safety hazard of *Clostridium botulinum*.
3. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point (CCP), to comply with 21 CFR 123.6 (c) (4). However, your firm's HACCP Plan #4 for crab cakes lists a monitoring procedure at the "crab cake cook" CCP that is not adequate to control pathogen survival through cooking. Your firm was observed to monitor time at a specific oven temperature. This is an appropriate monitoring method, but monitoring of oven temperature is not listed in the HACCP plan. Critical limits should match what is actually monitored, and they should be verified by a cooking process study.

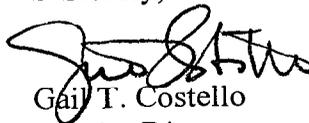
We may take further action if you do not promptly correct this above violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing 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 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.

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