



g35408

VIA FEDERAL EXPRESSFood and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751**WARNING LETTER**

FLA-03-01

October 2, 2002

Norman Barwick, Owner
Barwicks Ocean Fresh Crab Company
34 Joe Mack Smith Road
Post Office Box 641
Panacea, FL 32346

Dear Mr. Barwick:

We inspected your firm, at the above address on December 10 through 13, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your cooked ready-to-eat crabmeat to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). In accordance with 21 CFR 123.6(g), your failure to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part renders your seafood product adulterated within the meaning of Section 402(a)(4) of the Act. Accordingly, your ready-to-eat crabmeat 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 can find the Act, the seafood HACCP regulations, and the Fish and Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001 through links in FDA's home page at <http://www.fda.gov>.

The deviations were as follows:

1. You must have a HACCP plan that lists the critical limits at each critical control point that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plans for ready-to-eat crabmeat list critical limits at the Picking critical control point that are not adequate to control the hazard of pathogen growth because your plans do not contain limits for internal temperature and times and/or ambient temperatures and cumulative times of exposure. 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."

Refer to Chapter 12 of the FDA Fish & Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001 (pages 152-155) for information on critical limit recommendations at the Picking critical control point.

2. You must have a HACCP plan that lists monitoring procedures, including frequency, for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for ready-to-eat crabmeat lists a monitoring procedure and frequency at the Retort critical control point that is not adequate to control the hazard of pathogen survival, because it fails to list monitoring procedures that include cooking time, and because the monitoring frequency is not adequate throughout the cooking process. You may find information on monitoring procedures at the Cooking critical control point in Chapter 16 of the FDA Fish & Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001 (pages 213-214).

In addition, your HACCP plan for ready-to-eat crabmeat lists a monitoring procedure at the Cooler critical control point that is not adequate to control pathogen growth because it fails to describe how the cooler temperature will be monitored. The monitoring procedure is also deficient in that it lists a monitoring frequency of once daily that is not adequate to control pathogen growth and toxin formation during cooler storage.

3. You must have monitoring records that document the actual values and observations during monitoring, to comply with 21 CFR 123.6(c)(7). However, our investigators noted that none of the monitoring records at the Retort/Cooking, Picking or Cooler critical control points listed in your HACCP plan for cooked, ready-to-eat crabmeat, were being completed during their observation of production. Specifically, you retrospectively completed monitoring records related to picking and packing operations on 12/10/01. In addition, monitoring observations must be recorded by an individual actually observing the operations. You completed monitoring records related to picking and packing operations on 12/10/01 even though you were not present to make the observations recorded in the records.
4. Since 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 plans for cooked, ready-to-eat crabmeat at the Retort, Picking, and Cooler critical control points to control the hazards of pathogen survival and growth are not appropriate, as the corrective actions fail to address the disposition of any product that is exposed to a critical limit deviation.
5. You must take an appropriate corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). However, your firm did not take a corrective action to control the hazard of pathogen survival when your process for cooked, ready-to-eat crabmeat deviated from your critical limit at the retort/cooking critical control point.

Specifically, our investigators observed the cooking operation on 12/10/01 was performed at [REDACTED] °F and [REDACTED] PSI, although your HACCP plan lists the critical limits of [REDACTED] and [REDACTED]. According to your cooking records provided during the inspection, your retort temperature has not met the critical limit of [REDACTED] for all of the batches cooked since September 26, 2001.

6. You must have sanitation control records that document monitoring and corrections of sanitation conditions and practices during processing, to comply with 21 CFR 123.11(c).

However, your sanitation control records are not being completed at the time the operation is being performed. During our inspection and in the presence of our investigators, you completed the sanitation control records for 12/12/01 prior to the required time intervals and without any such observations being made.

7. 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 condition and cleanliness of food contact surfaces, prevention of cross-contamination, maintenance of hand sanitizing facilities, protection of food and food contact surfaces, control of employee health conditions, and exclusion of pests from the food plant with sufficient frequency to ensure control as evidenced by:

Processing tables and utensils were not cleaned and sanitized during the day's production observed on 12/10/01. (21 CFR 123.11(b)(2))

Accumulated residues from previous days' production were observed on unsmooth welded seams of food contact surfaces. (21 CFR 123.11(b)(2))

Several employees were observed on 12/10/01, handling cooked crabs and picked meat in direct contact with wet cloths used to wipe down the picking table surface. (21 CFR 123.11(b)(3))

Three picking room employees were observed wearing hand jewelry without hand coverings while picking crabmeat and handling cooked crabs. (21 CFR 123.11(b)(3))

Three picking room employees were observed drinking beverages from aluminum soda cans and plastic cups at their picking station while picking crabmeat. One employee was observed eating her lunch at her picking station while cooked crabs and picked crabmeat were still on the picking table. (21 CFR 123.11(b)(3))

Production employees were observed routinely handling insanitary objects, (such as trashcans, trash shovel, wooden door latches, pen, paper, and phone), and then cooked crabs or crabmeat without sanitizing their hands. (21 CFR 123.11(b)(3))

Your chlorine-sanitizing solutions were found below effective residue levels on all three tests conducted on 12/10/01. (21 CFR 123.11(b)(4))

One picking employee was observed without a hair net or suitable hair restraint, while picking crabmeat throughout the production day. (21 CFR 123.11(b)(5))

Eight fluorescent tubes in the cook area were observed as not having safety covers to protect food from potential physical contaminants. (21 CFR 123.11(b)(5))

Cook personnel were observed handling raw crabs and processing equipment and utensils, and then handling cooked crabs without washing or sanitizing their hands. (21 CFR 123.11(b)(3))

An approximate 4-inch unrepaired tear was observed on a window screen behind the fan in the cook area. (21 CFR 123.11(b)(8))

8. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not maintain a HACCP Plan Sanitation Sheet for 12/10/01. Our investigator did not observe sanitation records being completed on 12/10/01, and there was no record of it when you completed your HACCP Plan Sanitation Sheet and Daily Sanitation Audit Form on 12/12/01.

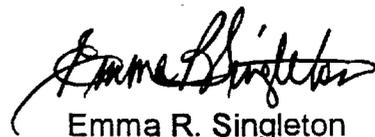
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a revised HACCP plan, revised monitoring or sanitation records 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 the 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 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 Food and Drug Administration, Attention: Shari J. Hromyak, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Ms. Hromyak at (407) 475-4730.

Sincerely,



Emma R. Singleton
Director, Florida District