



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

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60 8th Street, N.E.
Atlanta, Georgia 30309

November 8, 2001

VIA FEDERAL EXPRESS

William E. Barcliff, President
Quality Crab Company, Inc.
177 Knobbs Creek Drive
Elizabeth City, NC 27909

Warning Letter
02-ATL-07

Dear Mr. Barcliff:

On July 10-12, 2001, investigators Billy M. Battles and Russell R. Zablan of the Food and Drug Administration (FDA) conducted an inspection of your plant located at Elizabeth City, North Carolina. During that inspection, our investigators documented serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh and pasteurized 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.

The deviations were as follows:

1. You must have a HACCP plan that lists the critical control points, in order to comply with 21 CFR 123.6(c) (2). However, your firm's HACCP plan for pasteurized crabmeat does not list the post-pasteurization processing step of Container Cooling as a critical control point (CCP) to address the pathogen recontamination hazard.
2. You must have a HACCP plan that lists the critical limits, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for pasteurized crabmeat does not list a critical limit at the "Pack Out Room" critical control point that is adequate to control pathogen growth and toxin formation. In addition to monitoring the time of exposure, you must also monitor "Pack Out Room" ambient temperature and the internal temperatures of the exposed product. Different exposure temperatures and internal temperatures will affect the time your product can be held safely at room temperature. Chapter 12 of the Fish and Fishery Product Hazards and Controls Guidance: Third Edition can help you determine the most appropriate time and temperature critical limits for your process.

3. You must have a HACCP plan that list the critical limits, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for pasteurized crabmeat does not list a critical limit at the "Pasteurization" critical control point to control pathogen survival through pasteurization. Your firm processes pasteurized crabmeat in 8 oz. Plastic containers with foil lids, but does not list time and temperature critical limits for your process of the this size container.
4. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, in order to comply with 21 CFR 123.7 (b). However, your corrective action plan for pasteurized crabmeat at the Can Seaming CCP to control the re-introduction of pathogenic bacteria does not address what to do with the product that has been packaged prior to a seam check (container tear down) failure.
5. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the "Pack Out Room" critical control point to control pathogen growth and toxin formation listed in your HACCP plan for crabmeat. Our investigator observed your employee's failure to document the time the crabmeat is placed in ice in your Pack Out Room, which is listed as a monitoring procedure at this critical control point.
6. You must adequately monitor sanitation conditions and practices during processing, in order to comply with 21 CFR 123.11(b). However, your firm did not monitor four of the eight areas of sanitation with sufficient frequency to ensure control as evidence by:
 - a. Condition and Cleanliness of Food Contact Surfaces - employees rinsed the picking tables with water that did not have a detectable level of chlorine; firm did not clean and sanitize product contact surfaces, such as picking tables, packing room and counter, and cooked claw buckets, every 4 hours of operation.
 - b. Prevention of Cross-Contamination from Insanitary Objects - employees did not properly wash their knives prior to the start of picking operations; an employee used a picking knife that had a section of a rubber garden hose on the handle; an employee wore a glove that contained holes while picking crabmeat; and employees wearing long loose sleeves of their street clothes in close proximity to cooked crabs, crabmeat and product contact surfaces.
 - c. Protection of Food and Food Contact Surfaces from Adulteration - condensation dripping from the cooling unit on cooked crab cooler; employees responsible for clean-up failed to wash and sanitize their hands after touching unsanitized surfaces prior to replenishing cooked crabs on tables, dumping buckets of cooked claws, etc.; no protective covers on an incandescent light bulbs in the ceiling of the finished product cooler; and cooked crabmeat was packed in metal cans with lids that were not first sanitized.
 - d. Exclusion of Pests - numerous live and dead flies in various areas of the crabmeat picking room and packing room.

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

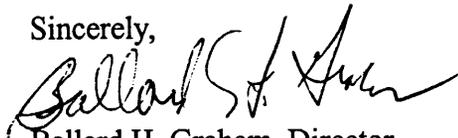
take further action to seize your product(s) and/or enjoin your firm operating.

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 copies of HACCP plans, and HACCP 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 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 Act and all applicable regulations.

Please send your reply to Karen Y. Dodson, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mrs. Dodson at (404) 253-1299.

Sincerely,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is fluid and cursive, with a large initial "B" and "G".

Ballard H. Graham, Director
Atlanta District