



HFI-35
4/1/00
wig
M3817n

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-55

May 9, 2000

John N. Posey, Jr., president and owner
Posey Crab Company
P.O. Box 554
Panacea, FL 32346

Dear Mr. Posey:

We inspected your firm, located at 1501 Coastal Hwy., Panacea, FL on September 17, 1999 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 fresh crabmeat to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic 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:

You must have a HACCP plan that lists all necessary critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for fresh crabmeat in one-pound plastic cups does not list the critical control point of picking for controlling the food safety hazard of pathogen growth.

You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for fresh crabmeat in one-pound plastic cups lists a monitoring procedure at the cooking critical control point that is not adequate to control the pathogen survival hazard, as it fails to include monitoring of the cooking time and only requires monitoring of the cook temperature once each cook cycle.

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 plan for fresh crabmeat in one-pound plastic cups at the crabmeat cooler critical control point to control the pathogen growth hazard is not appropriate, as it fails to address the disposition of any product that is exposed to a critical limit deviation.

You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm maintained sanitation control records that are not adequate, as they do not include safety of the water or ice that comes in contact with food, prevention of cross-contamination, maintenance of toilet facilities, protection of food from contaminants, proper labeling, storage, and use of toxic compounds, control of employee health conditions, or exclusion of pests.

You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor exclusion of pests, prevention of cross-contamination and protection of food from adulteration with sufficient frequency to ensure control as evidenced by:

Numerous live flies noted in the production area on processing tables, a basket of cooked crabs, and on the walls and ceiling of the processing room.

Employees routinely touched their faces and handled their stools, then handled cooked crabs without washing and sanitizing their hands.

Perforated baskets of cooked crabs were routinely stored against the wall in the processing area and the storage cooler, with cooked crabs protruding from the baskets in direct contact with the walls. This deviation was previously brought to your attention in our letter of January 12, 1999.

Baskets of cooked crabs stored directly underneath the cooling unit in the cooler, with condensate dripping onto the cooked crabs during storage.

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 records, revised sanitation check lists 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 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: Kendall W. Hester, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Hester at (407) 475-4730.

Sincerely,

A handwritten signature in black ink that reads "Edward R. Atkins". The signature is written in a cursive style with a large initial "E".

Edward R. Atkins
Acting Director, Florida District