



July 10, 2003

WARNING LETTER NO. 2003-NOL-19**FEDERAL EXPRESS**
OVERNIGHT DELIVERY

Mr. James Blanchard, Board President
Acadiana Fishermen's Co-Op
1020 Devillier Street
Henderson, Louisiana 70517

Dear Mr. Blanchard:

We inspected your firm, located at 1020 Devillier Street, Henderson, Louisiana, on March 31, April 1, and April 9, 2003. Our observations and test results demonstrate that your firm is in violation of Sections 402(a)(3) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and the implementing regulations of the seafood Hazard Analysis Critical Control Point (HACCP) regulation, Title 21, *Code of Federal Regulations*, Part 123 (21 C.F.R. 123), and the Current Good Manufacturing Practice (CGMP) regulation in manufacturing, packing, or holding food, i.e. cooked crawfish tail meat, for human consumption, Part 110 (21 C.F.R. 110). You can find the Act and the implementing regulations (seafood HACCP and CGMP) regulations through links in FDA's home page at www.fda.gov.

Sample Results

A sample (# 200039) that our investigator collected on April 1, 2003, during the inspection of your cooked and peeled crawfish tail meat, a ready-to-eat product, was found contaminated with *Escherichia coli* (*E. coli*). Your product was packed under the [REDACTED] label. We notified you of this finding in our letter dated April 30, 2003, from FDA's Southeast Regional Laboratory in Atlanta, Georgia. *E. coli* in your ready-to-eat, cooked crawfish causes your crawfish to be in violation of Section 402(a)(3) of the Act in that it contains filth as evidenced by FDA's isolation of *E. coli* in the cooked and peeled crawfish packed by your firm. Further, your product and your firm are in violation of Section 402(a)(4) of the Act in that the cooked, ready-to-eat crawfish have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health.

E. coli is a bacterium commonly associated with fecal contamination of warm blooded animals. In the production of commercially processed crawfish, the cook destroys non-spore forming bacteria, including *E. coli*. Therefore, the presence of *E. coli* in finished product indicates that either the cook was inadequate or the product was re-contaminated after the cook step. Recontamination after the cook step could be a result of insanitary practices by the employees

in the plant. Strict in-plant sanitation measures must be instituted to prevent the presence of the organism in the finished product.

Inspectional Findings

Our inspection revealed serious deviations from the seafood HACCP regulation. In accordance with 21 C.F.R. 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 adulterated within the meaning of Section 402(a)(4) of the Act. Accordingly, your products are adulterated in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. These serious HACCP deviations are as follows:

- A. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point to comply with 21 C.F.R. 123.6(c)(4). However, your firm's HACCP plan for cooked, peeled crawfish tail meat lists a monitoring frequency at the "PEEL/PACK" critical control point that is not adequate to control pathogen survival and toxin formation. Specifically, your HACCP plan does not state that the peeling and packing time should be recorded for each batch of crawfish processed by your facility. Your HACCP plan states that the time will be recorded for only [REDACTED]
- B. You must monitor sanitation conditions and practices adequately during processing, to comply with 21 C.F.R. 123.11(b). However:
 1. Your firm did not monitor adequately the conditions and cleanliness of food contact surfaces, including utensils, gloves, and outer garments as required by 21 C.F.R. 123.11(b)(2). Specifically, your firm's food processing equipment is not maintained in a sanitary condition to prevent food from becoming adulterated. For example:
 - a) The peeling tables and the cooked crawfish catch basin did not drain adequately and allowed for the accumulation of crawfish liquor and crawfish parts in the depressed areas of their food contact surfaces. Cooked crawfish came in direct contact with accumulated liquids on the tables and the cooked crawfish catch basin throughout the inspection;
 - b) The rail of the sliding window through which cooked crawfish tail meat were transported from the peeling room to the packing room was dirty and encrusted with residues. Peeling employees routinely contacted these residues; and,
 - c) The metal receiving bin in the peeling room side of the metal chute between the cook and the peeling room trapped crawfish parts that remained throughout processing on March 31, 2003 and on April 1, 2003. Cooked crawfish parts trapped on the side of the bin averaged 66°F, and were observed to remain exposed to ambient conditions for more than four hours. Cooked crawfish came in direct contact with the crawfish parts as the cooked products were pushed through the chute and collected in the metal bin.

2. Your firm did not monitor adequately the prevention of cross-contamination from insanitary objects to food as required by 21 C.F.R. 123.11(b)(3). Specifically, employees working in direct contact with food and food contact surfaces did not take necessary precautions to protect against contamination of the food with microorganisms or foreign substances. For example:
 - a) Employees splashed water from raw crawfish that had pooled on the cook room floor onto the cooked crawfish basin as they walked through the water;
 - b) Employees handled unsanitized objects and then cooked crawfish without washing or sanitizing their hands. For example:
 - i) the cooking employee allowed the hoist control mechanism to come in direct contact with live, raw crawfish in the cook baskets;
 - ii) the cook employee handled the hoist control mechanism, then handled cooked crawfish in the cook basket, as well as the food contact surface of the cook baskets, with his gloved hands without first washing and sanitizing them;
 - iii) a packing employee routinely used and re-used a single wet, residue-encrusted paper towel, paper, and a pen as she chronicled peeling operations. This employee then handled cooked crawfish and the food contact surfaces of plastic perforated and stainless steel colanders without first washing and sanitizing her hands; and,
 - iv) a peeling employee dropped his perforated plastic colander onto the wet peeling room floor as he returned from the packing room receiving window. This employee touched the floor with his hand when he picked up his colander. He went to a three-compartment sink located in the northeast corner of the picking room and dipped the colander in sanitizer. He did not wash and sanitize the hand that touched the floor. The employee then resumed peeling cooked crawfish.
 - c) Employees used plastic totes previously stored on the floor in dirty water to transport cooked crawfish to their peeling stations without washing or sanitizing the totes.
 3. Your firm did not monitor adequately the protection of food and food contact surfaces from adulteration with condensate, and biological contaminants as required by 21 C.F.R. 123.11(b)(5). Specifically, our investigator observed that the construction and design of your building facilitate insanitary conditions. For example, the investigator observed condensation accumulating on the surface of the cook room ceiling, walls, and equipment. Condensation then dripped directly onto cooked crawfish in the chute between the cook room and the peeling room, and on the food contact surface of the chute.
- C) After completion of the inspection, a further review of your HACCP plan for cooked, peeled crawfish tail meat, noted two additional deviations.

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 to comply with 21 C.F.R. 123.6(a) and (c)(2). A critical control point is defined in 21 C.F.R. 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 firm’s HACCP plan for cooked, peeled crawfish tail meat does not list the critical control point of final product storage for refrigerated, cooked crawfish for controlling the food safety hazard of pathogens.
2. You must take corrective action when a deviation from a critical limit occurs to comply with 21 C.F.R. 123.7(a). Section 123.7(b)(2) requires that the cause of the deviation be corrected. However, your firm’s HACCP plan does not include a requirement to determine how the cause of the deviation will be corrected.

We may take action without further notice if you do not promptly correct these violations. For instance, we may seize your product and/or enjoin your firm from operating. We are aware that during our inspection [REDACTED] Secretary and Plant Manager, made a verbal commitment to correct violations observed at your firm. However, you must respond in writing within 15 working days from your receipt of this letter, outlining specific actions you have taken to correct the deficiencies and to assure that such violations will not recur. You may wish to include in your response your revised HACCP plan, monitoring records, or other useful information that would assist us in evaluating your corrections. In addition, please provide your corrective actions to the product determined to contain *E. coli*. If you cannot complete all corrections before you respond, we expect you will explain the reason for the delay and a deadline by which 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 regulation and the CGMP regulation. 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: U. S. Food and Drug Administration, New Orleans District, Attention: Mr. Mark W. Rivero, Compliance Officer, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127-2601.

If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4519.

Sincerely,



Carl E. Draper
District Director
New Orleans District