



June 16, 2004

**WARNING LETTER NO. 2004-NOL-28**

**FEDERAL EXPRESS  
OVERNIGHT DELIVERY**

Mr. Nolton A. Bailey, Jr., President  
Bailey's Basin Seafood, Inc.  
1683 Front Street  
Morgan City, Louisiana 70381

Dear Mr. Bailey:

We inspected your firm, Bailey's Basin Seafood, Inc., located at 1683 Front Street, Morgan City, Louisiana, on April 26 and 28, 2004, and found serious deviations from Seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). Pursuant to 21 CFR 123.6(g), the 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 that part renders the fish or fishery products of that processor adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Accordingly, your vacuum-packaged crawfish tail meat 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 and the seafood HACCP regulations through links on FDA's home page at [www.fda.gov](http://www.fda.gov).

The following deviations were found during the inspection:

1. Pursuant to 21 CFR 123.6(a), your firm is required to conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and to identify the preventive measures that your firm will apply to control those hazards. Your firm also, pursuant to 21 CFR 123.6(b) and (c), must have and implement a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur and thus must be controlled for each fishery product. A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." Your firm's HACCP plan for vacuum-packaged, refrigerated crawfish tail meat does not list *Clostridium botulinum* (*C. botulinum*) toxin formation as a food safety hazard that is reasonably likely to occur. *C. botulinum* is a food hazard that is reasonably likely to occur during the expected shelf-life of your product under your present practices and, therefore, should be listed in your firm's HACCP plan.

*C. botulinum* toxin formation, however, would not be reasonably likely to occur and thus would not need to be included in your firm’s HACCP plan, if actions such as one of the following are taken:

- a) The product is sealed in packaging material with a final thickness that, at 24°C and one atmosphere of pressure, has an oxygen transmission rate of more than 10,000 cubic centimeters per square meter per 24 hour period of time (10,000 cc/m<sup>2</sup>/24hr at 24°C and 1 atm);
- b) The product is frozen immediately after processing, maintained frozen throughout distribution, and labeled prominently with instructions to hold frozen and to thaw under refrigeration immediately before use (e.g., “Important, Keep Frozen, Thaw Under Refrigeration Immediately Before Use”); or,
- c) Alternatively, FDA recognizes the following control as an adequate method of controlling *C. botulinum* in frozen, vacuum-packaged crawfish tail meat, and one that you may wish to consider including in your HACCP plan: the product bears a validated time temperature integrator (TTI), including instructions as to its interpretation, as a monitoring device that is appropriate for control of *C. botulinum* toxin formation on each retail or consumer package. A TTI is a device that provides a clear indication to the retailer/consumer, by color change or other means, that the product may have been exposed to a time and temperature combination that could result in an unsafe product.

2. Pursuant to 21 CFR 123.6(c)(3), your firm’s HACCP plan must, at a minimum, list the critical limits that must be met at each of the critical control points. A critical limit is defined in 21 CFR 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.” Your firm’s HACCP plan for vacuum-packaged crawfish tail meat fails to list a critical limit that is adequate to control *C. botulinum*. Specifically, your firm’s HACCP plan for vacuum-packaged crawfish tail meat lists a critical limit at the finished product step as, [redacted] [redacted]’ This critical limit, however, is not adequate to control *C. botulinum* and, therefore, fails to comply with the requirements of 21 CFR 123.6(c)(3). The appropriate temperature is [redacted]
3. Pursuant to 21 CFR 123.6(b)(7), your firm’s HACCP plan must provide for a record keeping system that documents the monitoring of the critical control points. Moreover, the records from such monitoring must contain the actual values and observations obtained during monitoring. Your firm, however, did not record monitoring observations at the peeling and packaging critical control points to control pathogen growth and toxin formation as listed in your HACCP plan for vacuum-packaged crawfish tail meat. In order to comply with this provision, your firm must implement the record keeping system that you listed to control pathogen growth and toxin formation in your HACCP plan.
4. Pursuant to 21 CFR 123.11(b)(4), your firm is required to monitor the maintenance of hand washing, hand sanitizing and toilet facilities during processing. Your firm, however, failed to adequately maintain hand sanitizing solutions. Specifically, the quantity of free quaternary

ammonia was observed to be 50 ppm, rather than 200 ppm as stated on the label of the sanitizer.

Please respond in writing within fifteen (15) working days of your receipt of this letter, outlining the 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 documentation such as your revised crawfish tail meat labeling HACCP plan, peeling and packaging 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 the delay and a deadline by which you will correct any remaining deficiencies.

During our inspection you made a verbal commitment to correct violations observed at your firm. Please be advised that 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.

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 Current Good Manufacturing Practice regulation, 21 CFR 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 the U.S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4514.

Sincerely,



H. Tyler Thornburg  
District Director  
New Orleans District

Enclosure: Form FDA 483