



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4519
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July 1, 2004

WARNING LETTER NO. 2004-NOL-29

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Jeffery J. DeRouen, Owner
Prairie Cajun Wholesale Distributors, Inc.
5966 Highway 190
Eunice, Louisiana 70535

Dear Mr. DeRouen:

On May 10 – 12, 2004, a FDA investigator inspected your seafood processing facility, located at 5966 Highway 190, Eunice, Louisiana. We found that you have serious deviations from the Seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement an adequate 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 Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly, your fresh and frozen vacuum-packaged crawfish tail meat and alligator meat are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's Internet home page at <http://www.fda.gov>.

The following deviations were observed during the inspection:

- You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a written HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(a) and (c)(1). 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.” However, your firm’s HACCP plan for crawfish tail meat does not list the food safety hazard of *Clostridium botulinum* (*C. botulinum*) growth and toxin formation. This deviation was brought to your attention in our letter dated June 3, 2003.

We particularly are concerned with your failure to identify and to implement controls for *C. botulinum* toxin formation in your HACCP plan for crawfish. To prevent toxin production

by *C. botulinum*, vacuum-packaged crawfish tail meat must be maintained in a frozen condition until immediately before use by the consumer. Also, it should be labeled with adequate storage instructions such as “Important, keep frozen until used, thaw under refrigeration immediately before use.”

Please note, in place of identifying “Labeling” as a critical control point, you have another option for frozen, vacuum-packaged product under HACCP. The product description on your HACCP plan may identify the product as “vacuum-packed frozen crawfish tail meat, labeled ‘Important, keep frozen until used, thaw under refrigeration immediately before use’.”

- You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(a) and (b). However, the document your firm provided to our investigator as your HACCP plan for vacuum-packaged Alligator Wild is not adequate. It appears to be a Packing Room Monitoring Log and contains none of the elements required in a HACCP plan to control the food safety hazards of *C. botulinum* growth and toxin formation, chemical contaminants, and metal inclusion. Your firm’s lack of a HACCP plan for wild, non-aquacultured alligator meat was brought to your attention in our letter dated June 3, 2003.
- You must implement the monitoring procedures that you have listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of “Clock Continuous” at the “Peeling” and “Packing” critical control points to control the pathogen hazard listed in your HACCP plan for crawfish. This deviation was brought to your attention in our letter dated June 3, 2003.
- 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 from insanitary objects, protection of food from adulteration, and exclusion of pests from the food plant with sufficient frequency to ensure control as evidenced by the following observations:
 - a) Condition and cleanliness of food contact surfaces. For example, on May 12, 2004, cooked crawfish came in contact with black residue in the rough weld seams of the cooker chute and peeling table. Plastic shovels, which contained yellow and black residue stains were used to transport both cooked crawfish and ice on May 10 and 12, 2004. Cooled crawfish were stored in plastic lugs stained with brown residue.
 - b) Prevention of cross-contamination from insanitary objects. For example, during peeling operations on May 12, 2004, an employee contacted his nose/face then peeled, cooked crawfish without first washing and sanitizing his hands; a bearded, peeling employee did not wear a beard cover.
 - c) Protection of food from adulteration. For example, during peeling operations on May 10 and 12, 2004, condensate formed on plastic curtains between the cook and peeling rooms

and then dripped onto cooked crawfish. Also, during peeling operations on May 12, 2004, water from the cooker splashed onto the plastic curtains and then dripped onto cooked crawfish. Condensate formed on the ice maker ceiling and dripped onto ice that later contacted cooked crawfish.

- d) Exclusion of pests from the food plant. On May 10, 2004, live flies were observed in processing areas; three in the cook room and two in the peeling room. On May 12, 2004, one dead fly was observed in a light fixture directly above cooked crawfish on the conveyor belt.

Similar deviations in these four sanitation areas were brought to your attention during our inspection of March 12 – 14, 2003, and in our letter dated June 3, 2003.

- You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, on May 10, 2004, your firm did not maintain sanitation monitoring records that accurately documented the conditions observed at your food plant for the condition and cleanliness of food contact surfaces, prevention of cross-contamination from insanitary objects, protection of food from adulteration, and exclusion of pests from the food plant that are required for the processing of ready-to-eat crawfish.

We may take further action if you do not correct these violations promptly. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

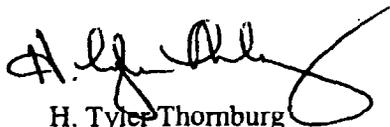
We are aware that Mr. Timothy McGee, Operations Manager, and Mr. Martin Mahon, Plant Manager, made verbal commitments to correct the deviations during the inspection. However, we request that you notify this office in writing, within 15 working days from your receipt of this letter, of the specific steps you have taken to correct these deviations. You should include in your response documentation, such as your HACCP plans and sanitation control 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 110. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

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Please send your reply to the U.S. Food and Drug Administration, Attention: Nicole F. Hardin, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Hardin at (504) 253-4519.

Sincerely,

A handwritten signature in black ink, appearing to read "H. Tyler Thornburg", with a large, sweeping flourish extending to the right.

H. Tyler Thornburg
District Director
New Orleans District

Enclosure: Form FDA 483