



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
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New Orleans, LA 70127

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December 29, 2003

WARNING LETTER NO. 2004-NOL-09

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mrs. Patricia A. Zirlott, Owner
Zirlott's Gulf Products
14735 Commodore Avenue
Codens, Alabama 36523

Dear Mrs. Zirlott:

On September 8 – 9, 12 and 16, 2003, we inspected your seafood processing facility, located at 14735 Commodore Avenue, Codens, Alabama. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Point (HACCP) regulation, 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 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 Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly, your cooked, ready-to-eat crabmeat, raw shrimp, and specialty seafood items are adulterated, in that they 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, the seafood HACCP regulations, and FDA's Fish and Fisheries Products Hazards and Controls Guidance (Hazards Guide) through links in FDA's Internet home page at <http://www.fda.gov>.

The deviations were as follows:

1. You must conduct 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, your firm does not have HACCP plans for the following seafood products:
 - Raw shrimp to control the food safety hazard of sulfites; and,
 - Breaded, stuffed fishery products (e.g. mushrooms with crabmeat and crab claws) to control the food safety hazard of pathogen growth and toxin formation.

2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). 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." However, your HACCP plan lists a critical limit at the Cooked Crab Cooler Storage critical control point, "[REDACTED]" that is not adequate. The Hazards Guide recommends a maximum storage temperature of 40°F, which is commonly recognized as the safe temperature for most refrigerated, microbiologically sensitive products.
3. You must take corrective action when a deviation from a critical limit occurs to comply with 21 CFR 123.7(a). Sections 123.7(b) and (c) require that a corrective action ensures that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation and that the cause of the deviation is corrected. However, your firm did not take a corrective action to control pathogen growth and toxin formation when your process for cooked crabs deviated from your critical limit at the cooking critical control point. Specifically, your firm's critical limit for cooked crabs is "[REDACTED]". A review of production records revealed that on August 8, 2003 and on August 12 or 13, 2003 (the date is illegible because of a write-over), the actual cook times were 5 minutes and 9 minutes, respectively, but your firm did not take corrective action to limit the hazards of pathogen growth and toxin formation or to correct the cause of the deviation.
4. Because 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, none of your HACCP plan's corrective actions for cooked crab and stuffed seafood products to control pathogen growth and toxin formation are adequate because they do not address the cause of the deviation.
5. You must implement the record keeping system that you listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the following critical control points that are listed in your HACCP plan for Cooked Crab Product to control pathogen growth and toxin formation:
 - You failed to record the monitoring observations at the Cooking Crabs CCP and at the Backing Hot Crabs CCP between August 22 and September 8, 2003; and,
 - You failed to record the monitoring observations at the Picking and Packing CCP on June 12, 13, 23, and July 11, and September 2, 3, and 5, 2003.
6. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for stuffed shrimp, crab cakes, stuffed crabs, stuffing mix, quiches, coconut shrimp, shrimp patties, stuffed mushrooms, and quesadillas lists a monitoring procedure/frequency at the preparation critical control point that is not adequate to control pathogen growth and toxin formation. Specifically, your HACCP plan for these products and the design of the monitoring record you utilized from April 14, 2003 to May 30, 2003, does not contain enough detail to determine whether your critical limit of the "[REDACTED]"

[REDACTED] was exceeded. For example, the monitoring frequency is listed as [REDACTED], but this is not sufficiently specific to assure compliance with the critical limit. To better achieve temperature control, FDA recommends that you change the monitoring frequency to "record temperature every one hour during batch processing," which is consistent with your critical limit of [REDACTED]. In addition, you did not record the actual temperature during batch processing in your monitoring records. Instead, you only recorded whether the temperature was less than [REDACTED]. To comply with 21 CFR 123.6(c)(7), you must record the actual values obtained during monitoring.

There is a disparity noted between the HACCP plan and the monitoring record. The HACCP plan states that the critical limit time frame is [REDACTED] but the bottom of the monitoring record contains the statements "[REDACTED]" and "[REDACTED]"

7. You must monitor sanitation conditions and practices adequately during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the safety of water, the condition and cleanliness of food contact surfaces, prevention of cross-contamination and exclusion of pests with sufficient frequency as evidenced by the following observations:
 - On September 8, 2003, cooked crabs repeatedly contacted yellowish-brown residues on an unsanitized wall adjacent to a rusted table used during backing operations. This insanitary condition was listed in FDA's letter to you dated October 29, 2001;
 - Employees picking crabs used knives with etched handles that contained a black residue from previous operations;
 - Cooked crabs and cooked crab parts were stored in plastic baskets, the rims of which were scratched and/or gouged, that contained a yellowish-brown residue from previous manufacturing operations;
 - The scratched and gouged handle of the shovel used to transfer ice onto cooked crabs contained yellowish-brown residues;
 - The metal, meshed net used to stir cooked crabs and transfer them from the boiling pot to the backing table was observed to be rusted and constructed of plastic lock ties that contained a brown residue;
 - The rim of a plastic pipe used to convey ice from the ice machine to the ice bin was encrusted with a brown, slimy substance;
 - There are gaps in the metal fan guard leading directly from the exterior of the facility into the cooking/backing room;
 - A gray and black slimy film coated the floor surrounding a drainage pipe in the cooler used to store raw ingredients and finished cooked crabmeat products;

- At least five employees were observed picking crabmeat without adequate hair restraints;
 - During backing operations on September 9, 2003, a large, black, and wasp-like insect was observed flying around the cooking/backing room;
 - During picking/packing operations on September 9, 2003, at least two flies were observed flying around the room;
 - On September 8, 9, and 12, 2003, at least seven live spiders were observed in the building within approximately 5-20 feet of the firm's manufacturing areas;
 - There were gaps approximately ¼ inch wide between the metal rings of the cooking/backing room exhaust fan's blade guard and between the exterior cooking/backing room wall and the fan;
 - The screens in the screen doors at the front and rear of the building had been ripped from portions of the door frames and were not installed and/or maintained to eliminate gaps between the edges of the doors and the door frames, which allowed pests unrestricted access to the production facility; and,
 - There was a crescent-shaped gap approximately ¼ inch x ¼ inch on the exterior wall of Cooler A.
8. You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records required for the processing of cooked crabmeat on June 12, 13, 23, July 11, and August 12, and September 2, 3, and 5, 2003, and for the processing of your specialty seafood products on July 21, 2003.
9. 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 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR 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 crabs does not list the critical control point of finished product refrigerated storage for controlling the food safety hazards of pathogens and toxin formation.

In addition, we note that during the inspection you stated you were no longer processing frozen shrimp egg rolls and vacuum-packed seafood products (e.g., raw soft shell crabs, frozen cooked shrimp). If you choose to continue manufacturing these products, you also must conduct 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). Packaging conditions, such as vacuum-packaging that reduce the amount of oxygen present in the package, increase the potential for formation of *Clostridium botulinum* toxin.

Finally, we have observed that at the Backing Hot Crabs critical control point, your HACCP plan appears to list a total exposure time of [REDACTED] hours that is not adequate. If there is significant handling taking place before the product is fully cooled, FDA's Hazard Guide recommends that cumulative time/temperature exposure be limited to 4 hours. If the product is held at internal temperatures both above and below 70°F, FDA recommends that exposure times above 50°F be limited to 4 hours, as long as no more than 2 of those hours are above 70°F.

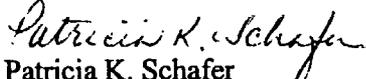
We may take further action if you do not correct these violations promptly. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

We are aware that you made a verbal commitment to correct the deviations during the inspection. Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation, such as copies of your revised HACCP plans, temperature 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 Current Good Manufacturing Practice regulations, 21 CFR 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 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) 253-4519.

Sincerely,


Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483