



January 27, 2003

VIA FEDERAL EXPRESS – NEXT DAY

Mrs. Katherine H. Gregory
A Taste of the Delta, Inc.
1589 Main Street
Tunica, MS 38676

Dear Mrs. Gregory:

Warning Letter 03-NSV-08

An inspection of your smoked catfish processing facility located at 1589 Main Street, Tunica, Mississippi, conducted by investigators of the Food and Drug Administration (FDA) on December 10-12, 2002, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Seafood HACCP (Title 21, Code of Federal Regulations (CFR), Part 123). These deviations, most of which were previously brought to your attention in our letter dated October 4, 1999, cause your seafood products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Seafood HACCP information is available through links in FDA's homepage at <http://www.fda.gov>.

Our investigators found the following violations:

- You must have a written HACCP plan which adequately identifies each food hazard that is reasonably likely to occur, to comply with **21 CFR §123.6(c)(1)**. Your HACCP plan fails to identify *Clostridium botulinum* toxin formation as a hazard which is reasonably likely to occur in your refrigerated, ready-to-eat smoked catfish in modified atmospheric packaging (heat sealed plastic).
- Your HACCP plan does not list satisfactory monitoring procedures for the hot smoking process; your HACCP plan does not list any monitoring procedures to ensure that hot smoked fish is properly cooled to below 40 ° F within a specified timeframe; and your HACCP plan does not list any monitoring procedures to ensure the prevention of the growth of *Clostridium botulinum* and prevention of toxin formation in the heat sealed plastic packages, to conform with **21 CFR §123.6(c)(4)**.
- You must have a written HACCP plan to control each food hazard that is reasonably likely to occur, to comply with **21 CFR §123.6(b)**. However, you continue to lack a HACCP plan to

address the hazard of *Clostridium botulinum* toxin formation and pathogen growth in your smoked catfish product.

- You must take appropriate corrective action when a process deviation from your HACCP plan occurs, to comply with **21 CFR §123.7(c)(3)**. Five instances were identified during the last FDA inspection in which the cooking temperature and/or time did not meet the critical limit parameters for the hot smoking process and no corrective action was implemented.
- You must review or obtain review by a HACCP trained individual to determine the acceptability of the affected product for distribution, when a deviation from a critical limit has occurred in the absence of a predetermined corrective action plan, to comply with **21 CFR §123.7(c)(2)**. As previously noted, five instances were identified during the last inspection in which product was distributed even though the temperature and/or time did not meet the critical limit parameters for the hot smoking process.
- Your HACCP plan identifies a critical control limit that may not be adequate to properly control the hazard, to comply with **21 CFR §123.6(c)(3)**. Your salting method and your cooking method are outside the recommended limits identified in the Seafood Hazards Guide. Although you are salting the catfish up to 10 hours longer than your process authority recommended, you do not have subsequent sample analysis to verify the water phase salt content is satisfactory. Also, the smoking process identified in your HACCP plan does not match the process that you actually complete. Your HACCP plan must identify the minimal temperature and time required (145° F/30 minutes) for this smoking/cooking process.
- You must adequately monitor sanitation conditions and practices during processing, to comply with **21 CFR §123.11(c)**.
- You must include in monitoring records the date and/or time of the activity the record reflects and the initials of the person performing the operation, to comply with **21 CFR §123.9(a)**. You must document the start and end time for the brining process, the start and end time for the smoking/cooking process, and the start and end time for the cooling process for the finished product smoked fish, to verify your critical limits are met.
- A HACCP trained individual must review all records which document monitoring of critical control points, the taking of corrective action in accordance with **21 CFR § 123.7**, and instrument calibration records, to comply with **21 CFR §123.8(a)(3)**.
- You must have a written HACCP plan that lists verification steps that are adequate, to comply with **21 CFR §123.6(c)(6)**. Your firm's HACCP plans do not require a review of monitoring, corrective action and verification records within one week of preparation.
- Your firm has not calibrated your thermometers, to comply with **21 CFR §123.8(a)(2)**.

- You must implement the monitoring procedures listed in your HACCP plan, to comply with **21 CFR §123.6(b)**. However, your firm does not routinely monitor the temperature of the catfish during the smoking operation, the cooling process after smoking, or the refrigerated storage of the finished product.
- Your HACCP plan must be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official in your firm, to signify that the plan has been accepted for implementation by your firm, to comply with **21 CFR§ 123.6(d)**.

The above is not intended as an all-inclusive list of deviations. As a seafood processor, you are responsible for assuring that your 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 Act and all applicable regulations.

You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of the receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made and explain preventative measures to guard against future violations.

Your response should be directed to Kari L. Batey, Compliance Officer, at 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,



Carl E. Draper
Director, New Orleans District

CED: KLB:klb

Enclosures:

21 CFR Part 123
21 CFR Part 110