



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

September 18, 2003

94872d
Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

Ref: 03-DAL-WL-20

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Kazuya Kurokawa, President
K & T Oriental Imports
9256 Markville Drive
Dallas, Texas 75243

Dear Mr. Kurokawa:

We inspected your firm, K & T Oriental Imports, located at 9256 Markville Drive, Dallas, Texas, on July 9-14, 2003. We have found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulations Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 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 fresh, vacuum packed Yellowtail, fresh Flounder, and fresh Tuna are adulterated, in that the fresh, vacuum packed Yellowtail, fresh Flounder, and fresh Tuna 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 home page at 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 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 fresh, vacuum packed Yellowtail does not list the critical control point of 38° Fahrenheit temperature for controlling the food safety hazard of potential growth and toxin formation of *Clostridium botulinum* and your firm's HACCP plan for fresh Flounder does not list the critical control point of freezing for controlling the food safety hazard of potential parasites.

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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 firm’s HACCP plan for fresh, vacuum packed Yellowtail does not list the critical limit at 38° Fahrenheit, a critical control point to control potential growth and toxin formation of *Clostridium botulinum*. Your firm’s HACCP plan for Tuna lists a critical limit of 40° Fahrenheit, but your firm accepts Tuna at 48° Fahrenheit, a critical control point that is not adequate to control histamine forming bacteria.
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 the utilized 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 the receiving temperatures at the critical limit of 38° Fahrenheit for fresh, vacuum packed Yellowtail when the actual receiving temperature was 42° Fahrenheit for fresh, vacuum packed Yellowtail. In addition, the temperature exposure indicator tags in use could only detect temperature abuse beginning at 41° Fahrenheit and the tags displayed moderate to prolonged temperature abuse.
4. Since you chose to include corrective actions in the HACCP plan, your described corrective actions must be appropriate for the particular deviation, to comply with 21 CFR § 123.7(b). However, your corrective action plan for fresh Tuna received up to the temperature of 48° Fahrenheit at the receiving temperature critical control point to control the formation of histamine is not appropriate. The critical control point of 40° Fahrenheit and below is required to control the growth of histamine forming bacteria in scombroid fish.
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 storage temperature critical control point to control *Clostridium botulinum* for fresh, vacuum packed Yellowtail and histamine forming bacteria for Tuna.

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6. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR § 123.6(c)(7). Section 123.6(c)(7) requires that actual values and observations observed during monitoring be included in these records. However, your firm did not record the actual values of the receiving temperatures for the months of May and June 2003 but instead, recorded 35° Fahrenheit on all these records.

We may take further action if you do not promptly correct these violations. For instance, we may initiate regulatory action without further informal notice. Such actions may include the initiation of a seizure action against your products and/or an action to enjoin your firm from operating.

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 your HACCP plan, copies of all related temperature monitoring records and corrective actions, 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 Part 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 Food and Drug Administration, Attention: Carolyn A. Pinney, Compliance Officer, at the above letterhead address. If you have any questions regarding any issue in the letter, please contact Carolyn A. Pinney at (214) 253-5312.

Sincerely,


Michael A. Chappell
Dallas District Director

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