DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
College Park, MD 20740

June 24, 2016

VIA EXPRESS MAIL

Ansley Wu
General Manager
A. O. Kingdom International Co., Ltd
No. 101, Shennong Rd.
Changzhi Township
Pingtung, Taiwan

Reference #489774

Dear Mr. Wu:

This letter follows a review by the U.S. Food and Drug Administration of documentation provided by Alpha Broker's Corp., on behalf of your firm A.O. Kingdom International Co., Ltd. This documentation included your firm's HACCP plan for Mahi-Mahi, a process flow diagram, a Hazard Analysis, and raw material control sheets. We received these documents on November 13, 2015. Our review of that HACCP plan (copy attached) and associated documentation revealed deviations from the requirements of the seafood HACCP regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123).

In accordance with 21 CFR l 23.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 123, renders the fish or 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 Mahi-Mahi products are adulterated, in that they have been prepared, packed or held under conditions whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation and the 4th Edition of the Fish and Fisheries Products Hazards & Controls Guidance (the Hazards Guide) through links in FDA's home page at www.fda.gov. The Guide can be found on our web site at:
http://www.fda.gov/Food/GuidanceComplianceRegulatorylnformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/default.htm

Your significant deviations are as follows:

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 21CFR 123.3
Your significant deviations are as follows:

(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 Mahi-Mahi lists critical limits at "(b)(4) " and "(b)(4) " critical control points that are not adequate to control scombrotoxin (histamine) formation. Specifically,

a. The critical limits at the "(b)(4) " critical control point do not include internal temperature monitoring of the fish at the time they are off-loaded from the harvest vessel to control scombrotoxin (histamine) formation. FDA recommends setting a maximum temperature, and monitoring a representative number of the largest fish in the lot to ensure that appropriate harvesting and onboard practices were used while the fish were onboard the harvest vessel. FDA recommends that:
   - For fish held iced or refrigerated (not frozen) onboard the vessel 24 or more hours after death:
     - The internal temperature should be 40°F (4.4°C) or below;

     OR
   - For fish held iced or refrigerated (not frozen) onboard the vessel from 15 to less than 24 hours after death:
     - The internal temperature should be 50°F (10°C) or below;

     OR
   - For fish held iced or refrigerated (not frozen) onboard the vessel from 12 to less than 15 hours after death:
     - The internal temperature should be 60°F (15.6°C) or below;

     OR
   - For fish held iced or refrigerated (not frozen) onboard the vessel less than 12 hours after death:
     - The internal temperature should be sufficiently below water and air temperatures to indicate that appropriate chilling methods were implemented onboard the harvest vessel. Chilling of the fish should begin on the harvest vessel regardless of the time from death until off-loading from the vessel by the processor, unless the environmental conditions (e.g. air and water temperatures) are below 40°F (4.4°C) from the time of death until off-loading from the vessel by the processor;

     OR
   - For fish held iced or refrigerated (not frozen) onboard the vessel:
     - Elapsed time from death and internal temperatures at the time of off-loading from the vessel by the processor should be consistent with cooling curves that will prevent development of an unsafe level of histamine in the specific species, as established through a scientific study.

b. The critical limit at the "(b)(4) " critical control point for temperature at the time of receipt listed as "Keep product temperature at <5°C

(except live fish)" does not ensure that appropriate transportation and handling practices were maintained during transit from the harvest vessel and/or previous processor to your processing plant to control scombrotoxin (histamine) formation. Monitoring product temperature at the time of delivery, by itself, is not adequate to ensure that the fish were held at appropriate temperatures during the entire transit time. FDA recommends that:

- For fish delivered refrigerated (not frozen):
  - All lots received are accompanied by transportation records that show that the fish were held at or below an ambient or internal temperature of 40°F (4.4°C) throughout transit. Note that allowance for routine refrigeration defrost cycles may be necessary;

  OR
- For fish delivered under ice:
  - Fish are completely surrounded by ice at the time of delivery;

  OR
- For fish delivered under ice on an open-bed truck:
  - Fish are stored completely surrounded by ice;
    AND
  - The internal temperature of the fish at the time of delivery is 40°F (4.4°C) or below;

  OR
- For fish delivered under chemical cooling media such as gel packs:
  - There is an adequate quantity of cooling media that remain frozen to have maintained product at an internal temperature of 40°F (4.4°C) or below throughout transit;
    AND
  - The internal temperature of the fish at the time of delivery is 40°F (4.4°C) or below;

  OR
- For fish delivered refrigerated (not frozen) with a transit time (including all time outside a controlled temperature environment) of 4 hours or less (optional control strategy):
  - Time of transit does not exceed 4 hours;

  AND
  - Internal temperature of the fish at the time of delivery does not exceed 40°F (4.4°C).

c. The critical limit at the "(b)(4) " critical control point for sensory examination of "(b)(4) " listed in table 6.8.2 in the Material Control Sheet (Document #MQ-01 - incorporated by reference) does not ensure that appropriate harvesting and onboard practices were used onboard the harvest vessel to control decomposition. FDA recommends that sensory examination of a representative sample of scombrotoxin-forming fish shows decomposition (persistent and readily perceptible) in less than 2.5% of the fish in the sample.

d. The critical limits of "(b)(4) " and "(b)(4) (b)(4) ", at the "(b)(4) (b)(4) " critical control point is not adequate to control scombrotoxin (histamine) formation. Specifically, the critical limits do not address extended time period of exposure at ambient temperatures during processing. FDA recommends that:

- During processing (e.g., butchering, cleaning, packing, labeling, and staging) of scombrotoxin-forming fish that have not been previously frozen or heat processed sufficiently to destroy scombrotoxin-forming bacteria:
  - The fish are not exposed to ambient temperatures above 40°F (4.4°C) for more than 4 hours, cumulatively, if any portion of that time is at temperatures above 70°F (21.1°C);

  OR

  - The fish are not exposed to ambient temperatures above 40°F (4.4°C) for more than 8 hours, cumulatively, as long as no portion of that time is at temperatures above 70°F (21.1°C).

Please note: If the product is thawed in water or in a slurry of ice and water, the ambient temperature during thawing is the temperature of the water at the warmest location in the thawing vessel. In addition, your firm's HACCP plan should list procedures and frequencies at this critical control point that will ensure compliance with these critical limits.

2. You must have a HACCP plan that, at a minimum, lists monitoring procedures and their frequency for each critical control point, to comply with 21 CFR 123.6 (c) (4). However, your firm's HACCP plan for Mahi-Mahi lists a monitoring procedure at the "(b)(4) " critical control point that is not adequate to control scombrotoxin (histamine) formation. Specifically, your firm's monitoring procedure indicates that you are implementing a (b)(4) however, your monitoring procedures do not include the number of fish that will be tested at receipt. FDA recommends that you monitor the histamine content in the scombrotoxin-forming fish flesh in every lot of scombrotoxin-forming fish received by testing a minimum of 18 fish, collected representatively throughout each lot (or the entire lot when there are fewer than 18 fish in the lot). Additional fish should be examined if variability in fish-to-fish histamine content is expected to be high. Moreover, FDA recommends that firms reject the entire lot of fish if any fish are found with histamine greater than or equal to 50 ppm. As a side note, the fish collected for analysis may be composited if the critical limit is reduced accordingly. For example, a sample of (b)(4) fish may be composited into (b)(4) units of (b)(4) fish each, provided the critical limit is reduced from (b)(4) ppm to (b)(4) ppm for each unit.

3. Because you chose to include a corrective action plan in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for Mahi-Mahi at the "(b)(4 " and "(b)(4) " critical control points to control scombrotoxin (histamine) formation are not appropriate. Specifically,

a. At the "(b)(4)" critical control point, your firm's corrective action plan does not ensure that the cause of the deviation is corrected. FDA recommends that firms discontinue use of the supplier, or carrier, until evidence is obtained that the identified harvesting and onboard practices, or transportation-handling practices when applicable, have been improved.

b. At the "(b)(4)" critical control point, your corrective action plan does note ensure that adulterated product does not enter commerce and does not correct the cause of the deviation. FDA recommends you:
   - Chill and hold the affected product until histamine analysis is performed on a minimum of 60 fish representatively collected from throughout the affected lot. Destroy the lot or divert it to a non-food use if any fish is found with histamine greater than or equal to 50 ppm. The fish collected for analysis may be composited if the action plan is reduced accordingly. For example, a sample of (b)(4) fish may be composited into (b)(4) units of (b)(4) fish each, provided the action point is reduced from (b)(4) ppm to (b)(4) ppm for each unit;
     OR
   - Destroy the product;
     OR
   - Divert the product to a non-food use.
     AND
   - Add ice to the product;
     OR
   - Return the affected product to the cooler;
     AND
   - Modify the process as needed to reduce the time and temperature exposure.

You should respond in writing within thirty (30) working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct these deviations. More specifically, your response should include documentation reflecting the changes you made, such as a copy of your revised HACCP plan or plans, five (5) consecutive product days of completed monitoring records (i.e., records for the production of five production date codes of the products) to demonstrate implementation of the plan or plans, any verification records and any additional information that you wish to supply that provides assurance of your intent to fully comply now and in the future with the applicable laws and regulations. Submission of the information in English will assist in our review. If you cannot complete all corrections within 30 days, you should explain the reason for your delay and state when you will correct any remaining violations.

Additional comments concerning your firm's HACCP plan for Mahi-Mahi:

Your firm's HACCP plan lists a monitoring procedure for sensory examination at the "(b)(4)" critical control point that indicates that you will only monitor the eyes

and smell of the fish for every batch. However, your firm's Material Control Sheet (Document #MQ-01 - incorporated by reference) indicates that you have (b)(4) for additional attributes for sensory examination. Sensory examination should include all of the attributes listed in material control sheet. In addition, although the Material Control Sheet indicates that you will perform sensory examination on (b)(4) pieces from each batch, this is not consistent with the sampling protocols listed for "(b)(4)" for products received in bulk and product received in containers (carton/bag/block) AND does not address samples of less than (b)(4) pieces. FDA recommends that firm's monitor the amount of decomposition in the lot by examine at least 118 fish, collected representatively throughout each lot (or the entire lot, for lots smaller than 118 fish) for every lot of scombrotoxin-forming fish received. All fish within a lot should have a similar history of harvest. If the fish are received frozen, this monitoring procedure may be performed by a sensory examination on the warmed flesh produced by drilling the frozen fish (drill method). It may also be performed after thawing, rather than at receipt.

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 and all applicable regulations, including the Seafood HACCP regulation 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 Food and Drug Administration, Attention: Kerry Kurdilla, Consumer Safety Officer, Office of Compliance, Division of Enforcement, Food Adulteration and Assessment Branch (HFS-607), 5100 Paint Branch Parkway, College Park, MD 20740 U.S.A. Please reference #489774 on any submissions and within the subject line of any emails to us. You may also send any information related to this case and/or any questions you may have regarding this letter to Kerry Kurdilla at kerry.kurdilla@fda.hhs.gov.

Sincerely,

/s/

Sabina Reilly
Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition

Enclosure