DEPARTMENT OF HEALTH AND HUMAN SERVICE Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20742

November 19, 2013

VIA EXPRESS DELIVERY

Matilde Romo
Frigolandia S.A.
Km 9.5 Via A Daule
Guayaquil, Ecuador

Reference No. # 398458

Dear Ms. Romo:

In response to a request by the United States Food and Drug Administration (FDA) for a copy of your firm's HACCP plan for the fish and fishery products, such as mahi mahi and tuna, that your firm imports into the United States, your firm provided HACCP plans for "Fresh Whole, HG, Fillets, Portions, Loins Mahi-Mahi, Tuna BE, Tuna YF" (hereafter referred to as the Fresh Fish plan) and "Frozen, Fillets, Fletshes Portions, Mah-Mahi" (hereafter referred to as the Frozen Mahi plan). Our evaluation of those HACCP plans (copies attached) revealed deviations from the requirements of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123).

In accordance with 21 CFR 123.6(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 and your tuna 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 FDA's 4th Edition of the Fish and Fisheries Products Hazards and Controls Guidance (the Hazards Guide) through links in FDA's home page at www.fda.gov.

The Hazards Guide can be found on our web site at:
http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/default.htm

The following deficiencies and concerns were identified in your firm's Fresh Fish and Frozen Mahi HACCP plans.

1. 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 Fresh Fish plan and Frozen

Mahi plan do not list critical limits at the "(b)(4)" critical control point (CCP) in each plan adequate to control histamine formation.

Your plans list the critical limit of "(b)(4) (b)(4)" as the assurance that the fish are transported from the wharf to the plant in a safe manner to control histamine formation. However, FDA recommends that ice not only cover fish during transport in totes or vats, but that the fish are completely surrounded with ice.

Additionally, your monitoring procedures reference "(b)(4)" in conjunction with monitoring the adequacy of ice; however, there is no corresponding critical limit for internal temperature provided at this critical control point. When fish are transported in totes or vats, FDA recommends measurements of the internal temperatures of the fish at the time of receipt in conjunction with the visual checks for adequacy of ice. When the combination of adequacy of ice and internal temperatures at receipt are used as a control, the HACCP plans should make it clear that both critical limits should be met. Additionally, we recommend 40° F as the internal temperature at receipt.

2. You must have a HACCP plan that, at a minimum, lists monitoring procedures and their frequencies for each critical control point to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plans for Fresh Fish and Frozen Mahi list the following monitoring procedures that are not adequate to control histamine formation:

   a. At the "(b)(4)" CCP, your firm lists a critical limit consisting of variable internal temperatures for fish depending on the time of death of the fish received. However, the monitoring procedures listed in your firm's Fresh Fish and Frozen Mahi HACCP plans do not include an element that ensures reliable documentation of the time of death for fish received. Moreover, your (b)(4) monitoring record form includes a place to record only the estimated ***date*** of death, not the time of death. The date of death is not sufficient to determine the number of hours, which is required to implement the listed critical limit.

      In addition, the monitoring records included in the submission suggest that your firm receives many fish from longliners. Longliners do not typically capture all their fish in one day or with all fish having the same time of death. Meaningful time of death information can typically be documented only by the vessel operators in the case of longliners. Absent reliable information related to time of death, your firm should consider whether a more reliable critical limit would be to ensure all fish off-loaded from the harvest vessels are at 4.4 °C or below.

      Also, the monitoring procedures list a frequency of "(b)(4)" The term "(b)(4)" should be clarified in your plans. The temperature measurements should be specific to each harvest vessel lot and, when applicable, to each scombrotoxin-forming species.

   b. At the "(b)(4)" and the "(b)(4)" CCPs, your firm lists sensory examinations for the assessment of decomposition in the fish. However, in both the monitoring record forms, your firm includes sensory descriptors as the basis of

decomposition scoring decisions that are not appropriate and render the critical limits ineffective as a scombrotoxin prevention control.

The scoring on your firm's two receiving forms are not consistent with each other, i.e., the same descriptive terms listed in both forms result in different classifications and scoring of the fish in the further decomposed two categories. There are also indices listed in each of these lower two categories that are indicative of decomposition and should be registered as rejected fish. Descriptors such as a "(b)(4) (b)(4) " should be counted towards the percent of fish in the sample with decomposition when used as a scombrotoxin hazard control. In addition, the listed descriptors should more clearly delineate which fish are counted as "decomposed" or rejects.

Further, your firm lists conflicting versions of the critical limit to be applied to the decomposition element in various places within the HACCP documents, some of which are inadequate. FDA recommends monitoring procedures that examine at least 118 fish collected representatively throughout each lot (per vessel, per species), examining more fish if the lots are very large or the variability within the decomposition state of the fish in the lot is broad. FDA recommends a critical limit that ensures the sensory examination of a representative sample of fish shows decomposition in less than 2.5% of the fish in the sample, or two or fewer fish in a sample of 118 fish.

In addition to the deviations noted above, we have the following questions and concerns related to your HACCP plans and other documentation you provided:

1. Histamine Sampling and Analysis

   a. The monitoring procedures listed in your firm's HACCP plans in relation to the transport temperature control element do not include how monitoring will be conducted in connection to the checks for the adequacy of ice.

   b. With regard to recordkeeping for the transit temperature control element, FDA recommends that records document the number of containers in the lot received and the number of containers examined for adequacy of ice or fish temperatures taken. This will ensure that monitoring was conducted on a representative number in the lot. However, the records submitted by your firm do not show the number of containers in the lot associated with the 12 temperature measurements. Further, the recording of the adequacy of ice for each delivery as simply "(b)(4) " provides no information on the number of containers actually observed compared to the number of containers in the lot.

   c. Some of your firm's records suggest that your firm is (b)(4) (b)(4) However, your firm's HACCP plans make no mention of compositing and list "less than 50 ppm histamine" as the critical limit. This limit is not applicable to composited samples. If you do composite fish for histamine testing, your plans should be adjusted appropriately. Please clarify whether your firm performs testing on individual fish or composites.

d. In addition, your firm's "(b)(4) " document describes the collection of a (b)(4) (b)(4) steak portion from each fish for histamine analysis. FDA's current recommendations for histamine sampling include collecting a minimum of 250 grams from the lower anterior loin of each of the test fish which should be randomly and representatively collected from the lot. The entire sub-sample from each fish should be individually ground. When compositing, a minimum of 100 grams from each of the individually ground sub-samples should be combined and further homogenized before collecting the test aliquot from the composite sub-sample. It is important that these samples are collected from lots specific to the harvest vessel and species. Please provide a copy of your firm's written protocol, or an explanation of the protocol, for collecting and preparing samples for histamine testing with any future submissions.

2. Cold Storage Controls

Your firm includes (b)(4) critical limits for cold storage, (b)(4) (b)(4)

a. Critical limit: "(b)(4 ":

a. Your firm's "(b)(4) " for "(b)(4) fish shows a number of operations after removing fish from refrigerated raw product storage and then going into "cold storage at – (b)(4)" just prior to shipment. Your firm should ensure that all processing steps are appropriately captured in the hazard analysis and HACCP plan.

b. The HACCP plans list "Continuous" monitoring, which is appropriate for cold storage control, but the monitoring records submitted by your firm show that the data logger for cold storage is set to record the temperature only (b)(4 We recommend logging the temperature every 1 hour or less (more frequently when the cooler is near the critical limit) in order to ensure adequate control.

c. According to your plant receiving/cold storage records, your firm identifies (b)(4) (b)(4) . However, none of the datalogger records submitted is clear as to which of the two chambers the measurements represent. Please confirm that both cold storage chambers are equipped with continuous temperature monitoring devices and provide an explanation of how you distinguish datalogger records from one or the other chambers.

d. Your firm's "(b)(4) " document states that *product* temperatures are measured (b)(4) during cold storage. Please note that internal temperatures, especially in large whole fish like tuna and mahi mahi, can retain cold temperatures for a considerable time longer while edible portions of the fish nearer to the surface of the fish could suffer serious time-temperature abuse. The internal temperatures could deceive a processor into believing the entire fish is unaffected when the icing or cold chamber temperature critical limits are exceeded.

b. Critical limit "(b)(4) "

a. Your firm's HACCP plans list only "(b)(4) " as the corrective action for this critical limit control element. Simply (b)(4) to time-temperature abused fish will not mitigate the hazard of scombrotoxin formation if it was permitted to form.

b. Your firm's HACCP plans suggest a (b)(4) for the raw material cold storage operation, i.e., (b)(4) These controls can be effectively used in tandem; however, your plans do not clearly established how these steps work together. If your firm does not intend to use the (b)(4) control as a true storage control, and prefers to rely on control of the (b)(4) within the cooler, your firm should consider removing the (b)(4) control from the HACCP plans and relegating it to an operating limit outside of the HACCP plan. If your firm intends to retain both elements of control within the plans, the relationship between the two should be clarified in your plans.

c. The Fresh Fish plan includes a corrective action for the cooler temperature control parameter that suggests that product exposed to temperatures in excess of (b)(4) cooler ambient temperature will be monitored "(b)(4) until cooler is functioning reliably." It is not appropriate to monitor the adequacy of ice in a corrective action mode when refrigeration has failed at less frequent increments ((b)(4)) than what your firm has established as appropriate when the refrigeration system is operating properly (three times per day).

3. Your firm's receiving/cold storage records depict monitoring for the adequacy of ice (b)(4) (b)(4) during operations, and, when applicable, (b)(4) (b)(4) overnight.

a. A record for the adequacy of ice depicting a simple "(b)(4) " does not provide adequate documentation of a relationship between the amount of product in the cooler and the amount of product observed for the adequacy of ice. The records should give a more clear understanding of what was actually monitored.

b. Your firm also identifies in the record when the product is (b)(4) . This appears to occur virtually at every interval that the fish are observed for adequacy of ice, i.e., (b)(4) (b)(4) This is a good thing to document. However, the control is effective only if the observations for the adequacy of ice are made prior to the addition of ice and the addition of ice follows only as a precautionary measure. That is not clear in the records since your firm improperly uses pre-established time intervals in its records rather than documenting the actual time of the observations.

4. Prevention of *Clostridium botulinum* Toxin Formation

Your firm's Frozen Mahi plan includes a "(b)(4) " CCP to ensure "All finished product labels must contain a '(b)(4) ' statement." The plan lists monitoring procedures to visually examine a "(b)(4) " Your

firm's process description document confirms that your firm's intention is to conduct a "(b)(4) [redacted]" However:

a. The listed monitoring frequency does not establish how often or how many packages are intended to be examined to be "representative" of any particular "lot."

b. The recordkeeping procedures included in the plan state "(b)(4) [redacted]" which implies that the monitoring of the labels may be occurring at the time the labels are received and not necessarily assurances that the appropriately labeled packages are applied to the appropriate finished products.

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 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 respond in writing within 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 days of completed monitoring records (i.e., records for the production of 5 production date codes of the products) to demonstrate implementation of the plan or plans, 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.

Please send your reply to Food and Drug Administration, Attention: Mildred Benjamin, Consumer Safety Officer, Office of Compliance, Division of Enforcement, Food Adulteration Assessment Branch (HFS-607), 5100 Paint Branch Parkway, College Park, MD 20740 U.S.A. If you have any questions regarding this letter, you may contact Ms. Benjamin via email at: Mildred.Benjamin@fda.hhs.gov.

Sincerely,

/s/

Jennifer A. Thomas
Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition