DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

March 23, 2016

VIA EXPRESS DELIVERY

Mr. Kampol Chantachote, Senior Plant Manager
Unicord Public Company Ltd.
39/3 Moo 8, Setthakij 1 Road, Thasai
Muang 74000
Thailand

Reference # 490222

Dear Mr. Kampol Chantachote:

We inspected your seafood processing facility Unicord Public Company Ltd located at 39/3 Moo 8, Setthakij 1 Road, Thasai, Muang, Thailand on September 14-15, 2015. During that inspection we found that you had serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (2l CFR 123). That inspection resulted in FDA's issuance of an FDA-483, Inspectional Observations, listing the deviations found at your firm at the conclusion of the inspection. We acknowledge receipt of your responses sent via email on October 1st, 2nd, and 4th, 2015. Your responses included various documents, including a revised HACCP plan for "Canned Tuna," monitoring records, packing records, sanitation records, and training records in response to the observations of concern noted on the FDA-483. However, our evaluation of the documentation revealed that the response was not adequate, as further described in this letter.

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 canned 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 the 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 seafood HACCP regulation requires that you implement a preventative system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP involves:

- Identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and
- Having controls at each "critical control point" in the processing operation to eliminate or minimize the likelihood that the identified hazard will occur.

HACCP provides a systematic way to identify, implement, and document those measures that demonstrate to FDA, to your customers, and to consumers that you are routinely practicing food safety by design. During our review of your plan, we found shortcomings that are violations of the seafood HACCP regulation.

We note the following violations in your seafood HACCP plan:

1. 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 revised HACCP plan for "Canned Tuna' provided with your October 4th response lists monitoring procedures at the following critical control points that are not adequate to control their respective food safety hazards:

    a. Frozen Tuna Receiving ("CCP 1")
        - At the Receiving critical control point your plan lists that you will collect a minimum of (b)(4) samples for (b)(4) testing from (b)(4) of fish to control scombrotoxin formation. FDA has not objected to applying a minimum sample size of (b)(4) samples for lots of (b)(4) MT or less, but considers that amount insufficient to provide the necessary safety assurances for larger lots. The investigator observed and your plan defines that a (b)(4) Your sample size should be increased accordingly to provide an adequate assurance of safety.

        - At the Receiving critical control point, the sample size used to monitor the decomposition critical limit is inadequate to control scombrotoxin formation. Your plan indicates that (b)(4) . The minimum sample size recommended in the Hazards Guide does not provide the necessary safety assurances for very large lots, such as (b)(4) MT. Your sample size should be increased to provide a safety assurance comparable to (b)(4) fish representing a smaller lot, such as (b)(4) MT.

    b. Pre-cooking ("CCP 3")

        - At the Pre-cooking critical control point, the monitoring frequency of "(b)(4) fish per pre-cooker" is not adequate to control scrombrotoxin formation. Your heat distribution study does not support the reduced number of samples (b)(4) for end-point internal product temperature (EPIPT). FDA recommends a minimum of 34 samples be obtained from each precooker load to compensate for the fluctuation in heat distribution within the load.

2. 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 plans listed in your revised HACCP plan for "Canned Tuna" at the following critical control points are not appropriate:

    a. Frozen Tuna Receiving ("CCP 1")
        - Your corrective action indicates you will (b)(4) [redacted]. The (b)(4) tuna should include the fish found to be decomposed, with the remaining fish collected from throughout the lot.

    b. Pre-cooking ("CCP 3")
        - Your corrective action indicates you will immediately (b)(4) [redacted].
          However, you should include the previous cook time as part of the cumulative exposure times prior to the pre-cooking process. It is reasonably likely that scombrotoxin could continue to form during the precooking process where safe temperatures were not achieved.

    c. Processing Pre-cooked Fish (CCP 5")
        - Your corrective action indicates you will (b)(4) [redacted] FDA recommends that product that has been exposed to unsafe conditions that could result in the formation of *Staphylococcus aureus* toxin should be either destroyed or diverted to a non-food use.

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. Your response should include documentation reflecting the changes you made, such as a copy of your revised HACCP plan, 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, 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.

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

Sincerely,

/s/

Latasha A. Robinson
Acting Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition