DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

December 22, 2011

Mr. Kenji Tanaka, President Director
P. T. Aneka Tuna Indonesia
Jl. Raya Surabaya-Malang Km. 38
Gempol, Pasuruan 67155
Jawa Timur, Indonesia

Dear Mr. Tanaka:

We inspected your seafood processing facility, located Jl. Raya Surabaya-Malang Km. 38, Jawa Timur, Indonesia on June13, 2011- June 14, 2011. We found that you have serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 Code of Federal Regulations (21 CFR 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 mackerel and herring are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation and the Fish and Fisheries Products Hazards & Controls Guidance 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 inspection, we found shortcomings in your system that are violations of the seafood HACCP regulation. The FDA investigator provided you with the form FDA 483 which presents the investigator's observations.
Please note that FDA recently published a 4th Edition of the Fish and Fisheries Products Hazards and Controls Guidance (the Hazard Guide). This version of the Hazard Guide can be found on our web site at:
http://www.fda.gov/Food/GuidanceComplianceRegulatoryinformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/default.htm

Based on the inspectional findings and the July 1, 2011 response to those findings, we have the following concerns.

1. You must conduct or have conducted for you a hazard analysis for each kind of fish and fishery product that you produce 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 food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (a) and (c) (l). A food safety hazard is defined in 21 CFR 123.3 (f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for "canned tuna" does not list the food safety hazard of *Staphylocccus aureus* growth and potential toxin formation (i.e., following the (b)(4) step).

   FDA recommends that beginning with contact of the precooked fish at the skinning operation, exposures to temperatures in excess of 70 °F (21 °C) should be limited to a maximum of 3 hours by an appropriate critical control point.

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 "canned tuna" lists a critical limit, "cooking at (b)(4) degrees Celsius for (b)(4) minutes or backbone temperature > (b)(4) degrees Celsius" at "pre-cooking" critical control point that is not adequate to control Histamine. Because "or" is utilized with (b)(4) systems the implication is that the cook time and temperature can stand alone without monitoring the backbone temperature. Moreover, there is an exceedingly wide range in critical limits for time and the minimum critical limit of (b)(4) minutes appears inadequate without a scientific study to support that the cook alone is likely to inhibit histamine formation.

3. 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 canned tuna does not list the monitoring for date and time of off-loading at the "(b)(4)" critical control point to control Scombrotoxin (Histamine) Formation.

4. 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 canned tuna at the "(b)(4)" critical control point to control Scombrotoxin (Histamine) Formation is not appropriate. An appropriate corrective action must include steps to ensure that potentially unsafe product does not enter commerce. This would include a step in your process of holding and evaluating finished product to prevent distribution.

Please refer to Chapter 7 of the Fish and Fisheries Products Hazards & Controls Guidance: Fourth Edition for additional information related to the hazard of Scombrotoxin (Histamine) Formation and appropriate control strategies for your products.

This letter may not list all your deviations from the requirements of the Act or applicable regulations. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulation, and the current Good Manufacturing Practice regulations (21 CPR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please respond within thirty (30) working days from your receipt of this letter. You should include in your response documentation such as a copy of your revised HACCP plan, copies of monitoring and verification records, or other useful information that would assist us in evaluating your corrections.

Please send your reply to the Food and Drug Administration, Attention: Reeba Roy, Consumer Safety Officer, Office of Compliance, Division of Enforcement, Manufacturing and Storage Adulteration 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.Roy by phone at (240) 402-1486 or via email at reeba.roy@fda.hhs.gov

Sincerely,

/s/

Kathleen M. Lewis, J.D.
Acting Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition