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VIA FEDERAL EXPRESS

Our Reference: 2915096

June 21, 2002

Donald J. Binotto, Managing Director  
Seafood Business Unit  
Heinz North America Divisional Headquarters  
Heinz 57 Center  
357 - 6<sup>th</sup> Avenue  
Pittsburgh, PA 15222-2530

**WARNING LETTER**

Dear Mr. Binotto:

On December 7, 8, 10-14, 2001, we inspected your seafood processing facility, located in Pago Pago, American Samoa. We found that you have serious deviations from the seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 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). Accordingly, your canned tuna is adulterated, in that the fish have been prepared, packed or held under insanitary conditions 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](http://www.fda.gov). See attached handout on how you can obtain a copy of the Fish & Fisheries Products Hazards & Controls Guidance, 3<sup>rd</sup> edition, June 2001.

The serious deviations were as follows:

- 1 You must have a HACCP plan that is signed and dated, either by the most responsible individual on-site at your processing facility or by a higher level official of your firm. The signature is to signify that the HACCP plan has been accepted for implementation by your firm. However, not all of the components you presented to investigators as your HACCP plan were signed and dated, nor did they represent current implementation of a plan by your firm.

During the December 2001 inspection, components of your HACCP plan presented to the investigators consisted of a "Canned Tuna HACCP Plan" package dated 3/10/01,

including a "HACCP Plan Summary" (which did not reflect major components of the overall plan), with a 6/13/01 updated section for "Incoming Fish/Loin Handling Procedures" (confusingly signed on 5/25/01). You also provided a separate updated "Incoming Fish/Loin Handling Procedures" dated 6/26/01 (without signature) which referred to a separate "██████████ Test Lot Protocol" document dated 1/10/96 with various updated sections within. Prior to the end of the inspection, you also presented an additional, yet to be implemented, unsigned, "Canned Tuna HACCP Manual," dated 5/15/01, which included another "HACCP Plan Summary" (which again does not reflect major components of the overall plan). Inconsistencies in the various components presented caused confusion for the investigators and plant personnel as discussed with your firm during the inspection. This concern was previously discussed with management of your firm following the July 2000 inspection, as well as at a meeting with your Senior Manager of Quality Assurance, Mr. Mario Piccinin, held at the Office of Seafood in September 2000. Your firm needs to establish a HACCP plan that can be clearly understood and properly implemented by all responsible individuals in your facility.

Further, your 5/15/01 proposed HACCP plan includes a draft protocol prepared by the ██████████ for the Receiving critical control point which addresses numerous deficiencies noted in your previous operating plans in effect at the time of our last inspection. Although FDA was assured in May 2001 that your firm would be implementing the ██████████ protocol, the investigators found this was not the case in December 2001.

2. You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for canned tuna lists critical limits that are not adequate to control the food safety hazard of histamine formation when you receive fresh, unfrozen fish.

There were a number of deficiencies identified in various components of the HACCP plan in effect at your facility during the inspection. However, prior to the end of the inspection, you presented the investigator with a significantly modified HACCP plan (30 pages with attachments, dated 5/15/01 but unsigned) that you stated was going to be accepted and implemented by your firm. There are still deficiencies at the Receiving critical control point noted in the proposed plan. Specifically:

- a. You list, "Histamine levels shall not exceed FDA DAL of 5 mg%" on your "Canned Tuna HACCP Plan Summary". There is no mention of sensory examinations or internal temperature monitoring in the summary plan. Page 16 of 5/15/01 proposed plan (Critical Control Point - 1) presents the same critical limit for histamine in addition to a sensory critical limit that states, "Odors associated with decomposition shall not be present in more than 0% of each test lot." Page 19 (Critical Control Point - 2) introduces an internal temperature critical limit for incoming fresh fish lots delivered 12 to 24 hours from death. The inconsistencies between the summary plan and the elaborated plan make it difficult to determine what your operative plan consists of, and this is unacceptable.

Note: The critical limit for histamine content should more accurately state that the histamine content of all fish should be less than 5 mg%, wherein any fish at 5 mg% or greater exceeds the critical limit. And the critical limit for sensory findings should more accurately state that less than 5% of the fish are decomposed wherein any sample at 5% or greater exceeds the critical limit.

- b. Page 19 of your 5/15/01 proposed HACCP plan, Critical Control Point - 2, does not make it clear that the internal temperature critical limit for fresh scombrotoxin-forming fish at the Receiving critical control point is an additional control measure to be monitored in conjunction with histamine testing and organoleptic examinations as prescribed in Critical Control Point - 1. FDA recommends that all three components, i.e., histamine testing, sensory examination, and internal temperature checks, be included as controls at receiving of fresh scombrotoxin-forming fish.
- c. The January 8, 2002 response letter from Mr. Mario Puccinin, QA Senior Manager, states that your new plan provides a critical limit of "evidence of icing for fish that are delivered after [redacted] hours from the time of death of the fish." This is an inadequate measure for histamine control. FDA recommends that the temperature of fresh fish received 24 hours or more after death be 40°F or less. A temperature of 50°F is adequate for fresh fish received between 12 and 24 hours of death. Fresh fish that are received less than 12 hours after death should have internal temperatures that are indicative of the use of appropriate chilling methods onboard the vessel. Documentation of the time of death and the time of receipt of the fish would be needed to ensure that the appropriate internal temperature critical limits is applied.

FDA does not discourage primary processors from examining fish for adequacy of ice or chilling medium upon receipt. However, internal temperatures provide a more reliable indicator of histamine prevention practices onboard the vessel.

- 3 Adjustments to your canned tuna HACCP plan's corrective actions and their implementation are needed.
  - a You must take an appropriate corrective action when a deviation from a critical limit occurs to comply with 21 CFR 123.7(a). However, your firm took a corrective action when your process for canned tuna deviated from your critical limit at the Receiving critical control point that was not adequate to control the hazard of histamine formation. Specifically, you failed to follow the corrective action plan outlined in the attachment to your HACCP plan, [redacted] COMING FISH/LOIN HANDLING PROCEDURES, dated June 26, 2001.

For example, you failed to sample and test [redacted] fish for histamine on at least four occasions when you exceeded the sensory critical limit, even though there were more than [redacted] fish in the lot:

- (1) For a lot (S2) of yellowfin tuna that you received from the [REDACTED] Vessel (trip [REDACTED]), 12.1% of the lot were found decomposed. As a corrective action, you sampled [REDACTED] composites ([REDACTED] fish per composite) for histamine analysis, instead of [REDACTED] composites ([REDACTED] fish per composite for a total of [REDACTED] fish). At this time, you had a balance of [REDACTED] tons of yellowfin tuna in your freezer.
- (2) For a lot (P11) of yellowfin tuna that you received from the [REDACTED] Vessel (trip [REDACTED]), 12.2% of the lot were found decomposed. As a corrective action, you sampled [REDACTED] composites ([REDACTED] fish per composite) for histamine analysis, instead of [REDACTED] composites ([REDACTED] fish per composite for a total of [REDACTED] fish). At this time, you had a balance of [REDACTED] tons of yellowfin tuna in your freezer.
- (3) For a lot (S8) of yellowfin tuna that you received from the [REDACTED] Vessel (trip [REDACTED]), 5.2% of the lot were found decomposed. As a corrective action, you sampled [REDACTED] composites ([REDACTED] fish per composite) for histamine analysis, instead of [REDACTED] composites ([REDACTED] fish per composite for a total of [REDACTED] fish). At this time, you had a balance of [REDACTED] tons of yellowfin tuna in your freezer.
- (4) For a lot (S9) of yellowfin tuna that you received from the [REDACTED] Vessel (trip [REDACTED]), 5.3% of the lot were found decomposed. As a corrective action you ran [REDACTED] composites ([REDACTED] fish per composite) for histamine analysis, instead of [REDACTED] composites ([REDACTED] fish per composite for a total of [REDACTED] fish). At this time, you had a balance of [REDACTED] tons of yellowfin tuna in your freezer.

Mr. Mario Piccinin's letter of January 8, 2002 states that the above lots of fish involved large fish and that there were insufficient fish in the sample lot to allow for the [REDACTED]-fish sampling requirement. However, we note in each instance that there were from [REDACTED] to [REDACTED] tons of fish remaining in the freezer. Mr. Piccinin states that procedures have been revised to require additional samples to be pulled from the freezer in order to acquire the [REDACTED] fish sample. The revision should be included in the 5/15/01 proposed plan (page 17, Critical Control Point - 1, Fish Receiving, Test Pack Analysis) to reflect that the random sample of [REDACTED] raw or precooked fish may be selected from the test lot *or the original* lot as needed for histamine analysis. Mr. Piccinin further states that, in each instance noted, the histamine level was less than 0.9 mg%, significantly below the 5.0 mg% DAL. Since you reduced the sample size from [REDACTED] fish to [REDACTED], and [REDACTED] fish, respectively, you reduced the likelihood of detecting fish containing high histamine levels if they were in the lot.

- b You must fully document, in records subject to verification, all corrective actions taken to comply with 21 CFR 123.7(d). However, you did not document that

corrective actions were taken when you deviated from your decomposition critical limit for canned tuna at the Receiving critical control point to control the hazard of histamine formation.

Specifically, whenever you exceeded your decomposition critical limit and performed corrective action by examining all of the fish in the lot, you failed to document that you conducted sensory examination of each fish. While the sensory activities during the examination of the protocol or test lot indeed need to be documented in the monitoring records, your firm also needs to document the sensory accept/reject activities during the corrective action that directs you to control [REDACTED] sensory examination of the remaining fish in the original lot per your 6/26/01 "Incoming Fish/Loin Handling Procedures" (item 4, [REDACTED] Lot), and your 5/16/01 proposed HACCP plan (page 18, Critical Control Point - 1, Fish Receiving, Corrective Action).

- c. Since you chose to include corrective actions 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 Receiving critical control point to control the hazard of histamine formation is not adequate.

In addition to ensuring that injurious product does not enter commerce, according to 21 CFR 123.7(b)(2), an appropriate corrective action plan describes steps to be taken to ensure that the cause of a deviation is corrected. FDA recommends that an appropriate corrective action to address the cause of a critical limit deviation for histamine control at the Receiving critical control point for primary processors is to discontinue use of the supplier until evidence is obtained that their harvesting and handling practices have been improved.

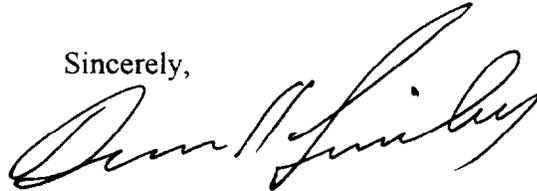
At the conclusion of the inspection, the deviations were listed on Form FDA 483 (Inspectional Observations) and discussed with Mr. Phillip A. Thirkell, General Manager. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. There were many significant deficiencies observed in your HACCP plan and implementation of the plan at the time of the inspection and upon review of the inspectional evidence. However, as a consequence of your promises to implement the new plan as pledged by Mr. Philip A. Thirkell, General Manager, at the time of the inspection and by Mr. Mario Piccinin, Senior Manager of Quality Assurance, in your 1/18/02 response to the Form FDA 483, this warning letter does not cite each of those deficiencies, and rather, focuses on corrections needed to the proposed plan and its implementation. You are responsible for ensuring that your processing facility operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR 110).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you have done to correct these deviations. You may wish to include in your response documentation such as copies of the HACCP plan 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.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,



Dennis K. Linsley  
District Director  
San Francisco District

Enclosures:

Handout on Fish & Fisheries Products Hazards & Controls Guidance, 3<sup>rd</sup> edition,  
June 2001  
Form FDA 483

cc: Barry A. Mills  
V.P. Seafood Operations & Procurement  
Heinz North America Divisional Headquarters  
Heinz 57 Center  
357 - 6<sup>th</sup> Avenue  
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