



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 2915097

May 14, 2002

Dennis C. Mussel, President  
Chicken of the Sea International  
4510 Executive Drive, Suite 300  
San Diego, California 92121-3029

WARNING LETTER

Dear Mr. Mussel:

On December 4, 5, 6, 7, and 10, 2001, we inspected your seafood processing facility, COS Samoa Packing Company, located at Pago Pago, American Samoa and found that you have serious deviations from the Seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause your canned tuna to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, and held under insanitary conditions whereby they may be 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). We listed the deviations on a Form FDA 483 (Inspectional Observations) and discussed them with Mr. Herman T. Gebauer, General Manager, at the conclusion of the inspection. We are providing a copy of the FDA 483 for your reference. Your serious HACCP deficiencies were as follows:

1. 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 corrective actions when your process for canned tuna deviated from your critical limit at the Receiving critical control point (CCP) that

were not adequate to control histamine formation. Specifically, as examples:

- a. Initial testing of lot L2, from a shipment of yellowfin tuna received from the purse seiner [REDACTED] (Trip Code [REDACTED]) on or about 09/06/01, showed odors of decomposition in 40.9% of the sampled fish and histamine levels as high as 1598 ppm (scombrotoxic). Lot L2 consisted of sub lots A, B, D, E, and F. Your firm rejected sub lots A, D, E, and F after corrective action testing procedures confirmed the presence of elevated histamine levels. However, the HACCP records provided to FDA did not show that the corrective actions listed in your HACCP plan were followed on sub lot L2B and it was subsequently processed and released for distribution.

In your firm's December 19, 2001 response to the FDA 483 inspectional observations, Mr. Gebauer stated that a more thorough review of your records associated with lot L2B showed that histamines were low. Mr. Gebauer also stated in his response that the results of further sensory examination of the lot showed less than 5% decomposed fish. Based on these findings, sub lot L2B was released for processing. The corrective action taken was not adequate to ensure acceptability of the lot prior to its release. Your HACCP plan shows that at the Receiving CCP, when a deviation to a critical limit occurs (whether due to histamine or sensory findings), the corrective action is to reject the lot or conduct histamine tests on [REDACTED] fish in the lot and reject the lot if the level of histamine exceeds [REDACTED] mg%. If the lot is divided into sub lots, your corrective action plan calls for [REDACTED] fish per sub lot to be tested for histamine. You provided no records to show that additional histamine tests were performed on sub lot L2B.

- b. During receipt of fish from the harvest vessel [REDACTED] on or about 10/1/01, your firm conducted sensory examination on a sample of albacore tuna from well #3, representing sub lots A, B, C, and D. Your firm found 18.3% decomposed fish in the sample. You resampled each sub lot individually by sensory examination, which was not part of your HACCP plan. (Your conclusion that none of the sub lots contained any decomposed fish when the original combined sample detected 18% decomposed fish

in the lot was inconsistent in of itself.) The product was subsequently released for processing.

The seafood HACCP regulations also require that all corrective actions are to be fully documented in your records per 21 CFR 123.7(d). In your December 19, 2001, response to the FDA 483 inspectional observations, you indicated your firm implemented a "Special Handling Monitoring Report" that is "used to record [REDACTED] % sensory evaluation results on lots for which initial or **resample** test lot sensory evaluation results showed that [REDACTED] % or more of the fish were rejected for characteristics associated with decomposition". Development of a record to document corrective actions is appropriate. However, as pointed out in the deficiencies above, your written corrective action approach does **not** include a sensory-based **resampling** test and such a corrective action approach may not be appropriate. A more appropriate corrective action, as stated in your HACCP plan, is to conduct histamine testing on any lots initially found to contain [REDACTED] % or more decomposition. Your newly developed reporting system may be appropriate for corrective action situations described in your plan where the initial sensory critical limit is exceeded but appropriate histamine testing determines that none of the [REDACTED]-fish samples contain elevated histamine levels in the fish and, hence, the further corrective action is to cull [REDACTED] % of the remainder of the lot for decomposition during butchering. This latter activity should indeed be documented.

2. 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 CCP does not have provisions for correction of the cause of the deviation. FDA recommends discontinuing use of the supplier until evidence is obtained that harvesting and onboard handling practices have been improved.

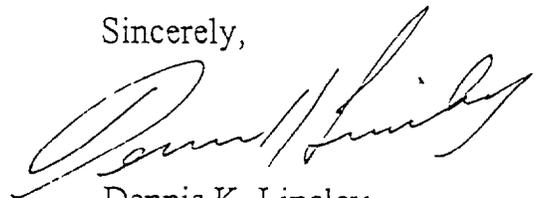
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Sufficient time has passed since our inspection of December 2001 and our presentation of the FDA-483 Inspectional Observations to Mr. Gebauer, to correct the violations at your facility. We acknowledge Mr. Gebauer's response of December 19, 2001 to the inspectional observations presented to him at the close of the inspection. Although the corrections described appear to correct some of the deficiencies, the corrections are incomplete and Mr. Gebauer's response did not provide a mechanism to ensure that the instructions given are followed. Failure to correct these deviations may result in regulatory action without further notice. 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 the other issues raised in this letter. You may wish to include in your response documentation such as HACCP monitoring records, 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. Erlinda N. Figueroa, 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. Figueroa at (510) 337-6795.

Sincerely,



Dennis K. Linsley  
District Director  
San Francisco District

Enclosure: Form FDA 483

cc: VIA CERTIFIED MAIL  
Herman T. Gebauer, General Manager  
COS Samoa Packing Company  
P.O. Box 957  
Pago Pago, American Samoa 96799