



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

54183d

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

VIA FEDERAL EXPRESS

Our Reference: 3001032796

July 30, 2003

Henry T. Ichinose, Co-owner
Christopher C. Kondo, Co-owner
ABS Seafood Company
1600 Evans Street
San Francisco, California 94124

WARNING LETTER

Dear Mssrs. Ichinose and Kondo:

On May 9 and 12, 2003, we inspected your seafood processing facility, located at 1600 Evans Street, San Francisco, CA. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, 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), 21 U.S.C. § 342(a)(4). Accordingly the following products are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or rendered injurious to health:

- Tuna Small (Katsuo/Aku)
- Tuna (Large), Mahi-Mahi, Wahoo-Ono, Sardines and Escolar
- Yellowtail, Amberjack (Hamachi)
- Mackerel, Atka Mackerel, Chub Mackerel, Jack Mackerel, Spanish Mackerel

You may find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). However, your firm's HACCP plan for

Yellowtail does not list the food safety hazard of *Clostridium botulinum* toxin at the “Receiving” Critical Control Point to cover this product when it is received vacuum-packaged. FDA recommends that you ascertain and document that a time/temperature indicator is present in a vacuum-packaged refrigerated raw seafood product, that the time/temperature threshold has not been exceeded and that there is an adequate amount of coolant present at the time of receipt.

2. You must conduct a hazard analysis 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 critical control points, to comply with 21 CFR 123.6(a) and (c)(2). A critical control point (CCP) is defined in 21 CFR 123.3(b) as a “point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.” Your hazard analysis indicates that since the product will be held at 40°F there is no need for a CCP at the “finished product cooling/storage” step. However, because holding the product at 40°F or less will prevent, eliminate, or reduce the hazards of histamine and pathogen growth to an acceptable level, “finished product cooling/storage” is by definition a CCP. Accordingly, your firm’s HACCP plans for small tuna, large tuna, Yellowtail, and mackerel need a CCP at the “finished product cooling/storage step for controlling the food safety hazards of histamine and pathogen growth.
3. 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 plans for the small tuna, large tuna, Yellowtail, and mackerel products:
 - do not list a critical limit at the “Receiving” CCP that is adequate to control histamine formation and pathogen growth. Your monitoring records indicate that your firm is routinely checking the adequacy of the cooling media upon receipt. FDA recommends you change your HACCP plans’ critical limits to reflect the critical limit and monitoring procedure. FDA considers monitoring the adequacy of the cooling media upon receipt an appropriate control.
 - lists a critical limit of 40 degrees Fahrenheit internal temperature at the Raw Material Storage Critical Control Point that is not adequate to control parasites. FDA recommends freezing for the control of parasites of fish that are to be consumed raw. Please see the Fish & Fisheries Products Hazards & Controls Guidance, Chapter 5, for guidance.
4. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your

firm's HACCP plans for small tuna and mackerel products list a monitoring frequency at the Raw Material Storage CCP of "beginning of operations, end of operations" and your HACCP plans for large tuna and Yellowtail products list "beginning of operations, [REDACTED] into operations and end of operations" as the monitoring frequencies. These monitoring frequencies are inadequate to control the food safety hazards of histamine formation and pathogen growth in your histamine-forming and ready-to-eat products. FDA has determined that continuous monitoring of the temperature by means of a temperature data recorder or alarm system, with a visual check at least once per day is adequate to control the hazards of histamine formation and pathogen growth.

5. You must maintain sanitation control records that, at a minimum, document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records for condition and cleanliness of food contact surfaces, prevention of cross-contamination, maintenance of hand washing, hand sanitizing, and toilet facilities, and exclusion of pests from the facility required for the processing of small tuna, large tuna, Yellowtail, and mackerel products on May 7, 8, and 9, 2003.
6. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor two sanitation areas with sufficient frequency to ensure control as evidenced by:
 - Prevention of cross contamination: Your firm placed a cardboard container from an unsanitary pallet on the filleting table and then cut a tuna loin on the same table without sanitizing the table.
 - Exclusion of Pests: After a fly walked on the filleting table, your firm placed a tuna loin on the same spot without sanitizing the table.

At the conclusion of the inspection, the deviations were listed on Form FDA 483 and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. 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 are doing to correct these deviations. You should include in your response documentation 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.

Please send your reply 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,

Charles D. Moss, Acting DD

for

Dennis K. Linsley
District Director
San Francisco District

Enclosure:

Form FDA 483