



DEPARTMENT OF HEALTH & HUMAN SERVICES

HF1-35
Public Health Service
Food and Drug Administration

M25240

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

April 9, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Kuwashi Shimizu, President
Totoya-Seizaburo Shoten Corporation
535 South Stanford Avenue
Los Angeles, CA 90013

W/L 27-9

Dear Mr. Shimizu:

On January 6 - 7, 1999, an Investigator from the Food & Drug Administration (FDA) conducted an inspection of Totoya Seafoods, located at 535 So. Stanford Avenue, Los Angeles, California. At the conclusion of the inspection, Mr. Kiyashi Takaizumi, Vice President, was presented with Form FDA 483 listing significant deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products Regulation. A copy of that Form FDA 483 is enclosed for your review. By virtue of these deficiencies, the products processed at your facility are adulterated within the meaning of Section 402 (a) (4) of the Food, Drug and Cosmetic Act (the Act).

Specifically, our investigator found the following deficiencies, related to filleted tuna, intended for raw consumption, and stored and sold as refrigerated product:

1. The HACCP plan created by your firm is inadequate to address the hazards associated with fresh tuna. Specifically, your plan addresses only one Critical Control Point (CCP), namely "Butchering." The hazard of elevated histamine levels in the tuna upon receipt (receiving step) has not been addressed by your firm, and is not identified as a CCP in your HACCP plan for fresh tuna. Your firm must assure that the tuna you receive has not been temperature abused prior to your receipt of the fish (i.e. during transport from your vendor(s)) whereby it may contain high histamine levels. Some sort of temperature assessment of the tuna upon

receipt would be prudent by your firm, and this monitoring should be included in your HACCP plan and documented.

In addition, storage temperatures for your fresh tuna held overnight or longer have not been addressed in your HACCP plan for fresh tuna. Again, we feel that this processing step should be included in your HACCP plan as a CCP, and any monitoring of this cooler should be part of the HACCP plan. These monitoring documents would then be subject to record review, per 21 CFR 123.8(a)(3)(i).

2. Your firm is not implementing your HACCP plan as written. Your HACCP plan for fresh tuna identifies one CCP, "Butchering." Your prescribed critical limits for this CCP are cumulative times of no more than 12 hours for fresh frozen tuna, and no more than 4 hours for (not previously frozen) tuna. Our Investigator found that you were not monitoring these times as written in your plan. In addition, the critical limits for this CCP do not appear adequate to address the safety hazards at this processing step. Temperature of the exposed tuna loins during butchering is not addressed, and would be necessary to establish the adequacy of your "cumulative time" critical limits. Furthermore, the hazard of pathogen introduction through cross contamination (i.e. poor food handling practices) are not addressed at the "Butchering" CCP for fresh tuna, which is intended for sashimi (raw) consumption. Since no further processing of this product is intended, we feel that it would be prudent to address cross contamination as a hazard, and set critical limits, monitoring, etc. to address this hazard. Your firm could address this hazard through the implementation of a Sanitation Standard Operating Procedure (SSOP) and appropriate sanitation monitoring, however, it was noted that your firm does not have these. Please refer to 21 CFR 123.11(d) for further clarification on how sanitation control records can relate to a HACCP plan.

21 CFR 123.6 (b) requires that you have and implement a HACCP plan. 21 CFR Part 123(c)(4) requires you to list the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits. 21 CFR Part 123.6(c)(7) requires you to provide for a record keeping system that documents the monitoring of critical control points.

3. Your firm is not monitoring sanitation conditions and practices in your processing facility as required in 21 CFR 123.11 (b), and recording the results of those monitoring activities per 21 CFR 123.11 (c).

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

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Your reply relating to these concerns should be directed to the Food & Drug Administration, Los Angeles District, Attention: Robert B. McNab, Consumer Safety Officer, 19900 MacArthur Blvd, Ste. 300, Irvine, CA 92612-2445.

Sincerely,

A handwritten signature in black ink, appearing to read "Elaine C. Messa". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Elaine C. Messa
Los Angeles District Director

Enclosures:

FORM FDA 483

cc: CADHS/FDB