



DEPARTMENT OF HEALTH AND HUMAN SERVICES

9/6/29d
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

August 16, 2001

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-76
Katsukichi Chikamatsu, President
Mayco Fish Company, Ltd.
2535 Jefferson Avenue
Tacoma, Washington 98402

WARNING LETTER

Dear Mr. Chikamatsu:

We inspected your firm located at 2534 Jefferson Avenue, Tacoma, Washington, on May 15 & 17, 2001, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations, some of which were previously brought to your attention, was presented to Christopher R. Langley, Plant Foreman, cause your herring and pollock roe to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations are as follows:

1. 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(b). Your firm does not have a HACCP plan for your herring roe to control the food safety hazard of histamine development. Your herring roe is held for up to two days after thawing at temperatures up to 12°C (54°F).
2. 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(b). Your firm does not have a HACCP plan for your pollock roe to control the food safety hazard of pathogen growth during the "cure" stage where product is held at ambient temperature overnight.
3. You must adequately monitor and keep records for sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b) and (c). Your firm did not monitor five of the eight areas of sanitation listed below:
 - Prevention of cross contamination
 - Handwashing facilities

Katsukichi Chikamatsu, President
Mayco Fish Company, Ltd., Tacoma, WA
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- Prevention of cross contamination
- Handwashing facilities
- Protection of products from adulteration
- Labeling, storage, and use of toxic chemicals
- Employee health

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 the Good Manufacturing Practice regulations (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.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your 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.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Lisa Elrand at (425) 483-4913.

Sincerely,



for Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: WSDA with disclosure statement