



MAY 4 2000

Mrs. Fely Layug
President
Mofel's Food International Corporation
Governor's Drive Dasmarinas
Cavite, Philippines

WARNING LETTER

Dear Mrs. Layug:

We inspected your firm, located at Governor's Drive Dasmarinas, Cavite, Philippines on 5/22/99 and found that your firm has serious deviations from the U.S. Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your firm's attention during FDA 483 discussion with management at the close of inspection, cause your firm's **Frozen Vacuum Packed Smoked Fish (Round Scad, Mackerel, Herring)** to be in violation of section 402(a)(4) of the U.S. Federal Food, Drug, and Cosmetic Act. You can find this Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. Your firm failed to implement the monitoring procedures specified in its HACCP plan, as required by 21 CFR 123.6(b).
 - For instance, your firm did not follow the monitoring procedure of checking the temperature at the Vacuum Pack/Sealing critical control point to control pathogen growth listed in your firm's HACCP plan for **Frozen Vacuum Packed Smoked Fish**. Your firm's plan specifies that Q.C. personnel will monitor the temperature of every batch and will record that information on your firm's Process Checklist. Upon reviewing your firm's Process Checklists for 5/15/99 and 5/21/99, we found no temperatures recorded for the Vacuum Packing/Sealing processing step.
 - In addition, your firm did not follow the monitoring procedure of reviewing each lot of labels at the Vacuum Packing/Sealing critical control point to control the hazard of pathogen growth listed in your HACCP plan for **Frozen Vacuum Packed Smoked Fish**. Even though your firm supplied our investigator with an amended HACCP plan, your firm did not follow the specified monitoring procedures at the time of inspection. The Process Checklists dated 5/15/99 and 5/21/99 do not provide a place for noting the

specified label checks. Please provide us with copies of your updated labels and an amended Process Checklist.

2. Your firm did not have a HACCP plan that specifies the critical limits that must be met, as required by 21 CFR 123.6(c)(3). Your firm's HACCP plan for **Frozen Vacuum Packed Smoked Fish** does not specify a critical limit at the Vacuum Packing/Sealing critical control point to control pathogen growth and toxin formation (*Clostridium botulinum*). Your firm's HACCP plan specifies that temperature will be monitored at this step, but does not specify critical limits. Time must also be monitored along with temperature.
3. Your firm did not have a HACCP plan that specifies adequate monitoring procedures for each critical control point, as required by 21 CFR 123.6(c)(4). Your firm's HACCP plan for **Frozen Vacuum Packed Smoked Fish** specifies a monitoring procedure at the Receiving critical control point that is not adequate to control the hazard of histamines. Your Firm's critical limit is listed as "less than 5mg/100g" (50 ppm) and that the histamine content will be monitored by sensory evaluation. Histamine concentrations can only be determined by chemical analysis. Because your firm is the primary processor of some of the fish your firm smokes, your firm must have adequate controls in place to minimize or eliminate the hazard of histamines at Receiving. Chapter 7 of the Fish & Fisheries Products Hazards & Controls Guide: Second Edition can provide your firm with guidance in choosing an adequate method of control.
4. Because your firm chose to include corrective actions in your firm's HACCP plan, your firm's HACCP plan failed to describe appropriate corrective actions as required 21 CFR 123.7(b). Your firm's corrective action plan for **Frozen Vacuum Packed Smoked Fish** at the Receiving critical control point to control the hazard of histamines is not appropriate. Your plan states that the product will undergo a "visual and taste evaluation" if the critical limit of 5 mg/100g (50 ppm) is exceeded. When the product exceeds that critical limit at Receiving, the appropriate corrective action would be to reject the product.
5. Your firm failed to verify that your firm's HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, as required by 21 CFR 123.8(a)(2)(ii). Your firm's HACCP plan does not provide methods or records for the calibration of your firm's thermometers and timers for **Frozen Vacuum Packed Smoked Fish**. Calibration of your firm's monitoring equipment is essential for assuring that your firm's measurements are accurate and must be included as a verification step wherever time and temperatures are monitored.

Please respond in writing within six (6) weeks from your receipt of this letter. Your firm's response should outline the specific things you are doing to correct these deviations. You firm may wish to include, in its response, documentation such amended HACCP plans, copies of corrected forms and labels, production records, or other useful information that

would assist us in evaluating your firm's corrections. If your firm believes the hazards listed above are not reasonably likely to occur in your firm's products, your firm must provide U.S. FDA with adequate, written documentation that clearly supports your firm's reasoning. If you firm cannot complete all corrections before your firm responds, we expect that your firm will explain the reason for the delay and state when your firm will correct any remaining deviations. Failure to provide us evidence of corrections to the deviations may result in your products being placed on "Detention Without Physical Examination."

This letter may not list all the deviations at your facility. Your firm is responsible for ensuring that its processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110).

Your firm also has a responsibility to use procedures to prevent further violations of the U.S. Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your firm's reply to the Food and Drug Administration, Attention: Frank Sikorsky, Consumer Safety Officer, Office of Field Programs, Division of Enforcement, Import Branch HFS-606, 200 C Street S. W., Washington, DC 20204. If you have questions regarding any issue in this letter, please contact Mr. Sikorsky at (202) 205-1922.

Sincerely,



Dennis M. Dignan

Director

Division of Enforcement and Programs

Office of Field Programs

Center for Food Safety

and Applied Nutrition