



HFI-35

Mr. Jung Sik Kim  
Sam Jin Trading Company Ltd.  
481 Shinpyong-Dong, Saha-Gu  
Pusan, South Korea

NOV 29 2001

### Warning Letter

Dear Mr. Kim:

This is to acknowledge receipt of your correspondence dated June 9, 2001, in response to our letter dated May 3, 2001, concerning the serious deviations from the U.S. Seafood HACCP regulations (21 CFR Part 123) that we found during our inspection of your firm on October 20, 2000. We want to also acknowledge receipt of your revised HACCP plan and supporting information received January 10, 2001.

We reviewed your updated HACCP plan and supporting documents and made the following determinations:

1. You revised your HACCP plan for frozen salted vacuum packaged mackerel to include histamine development as a hazard at receiving. Your monitoring procedures at receiving are inadequate. Specifically, your monitoring procedures do not include a sensory evaluation. In addition, you should also provide a sampling plan for both the histamine testing and the sensory evaluation. Please refer to chapter 7 The Fish and Fisheries Products Hazards and Controls Guide (3<sup>rd</sup> Edition, June 2001) "Scombrotoxin (Histamine) Formation" for additional information. You do not need to include internal and transport temperatures in your plan, since you receive the product already frozen.
2. You must identify all the critical control points in your HACCP plan to control excessive histamine development resulting from time/temperature abuse. Your hazard analysis appears to indicate the "thawing" and "brining" steps may result in excessive histamine development if left uncontrolled, and should be included as critical control points with critical limits for time and temperature. Your analysis indicates that filleting and vacuum packaging may also need to be included as critical control points. You may want to combine these processing steps when revising your plan, since each step cumulatively adds to the time/temperature exposure. The recommended time/temperature exposures (listed below) take into account all processing steps that could potentially lead to histamine development.

According to the Guide:

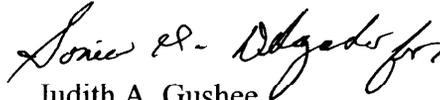
- Previously frozen scombrotoxin forming species of fish should not be exposed to ambient temperature above 40° F (4.4° C) for more than 12 hours, cumulatively if any portion of that time is at temperatures above 70° F (21° C).
  - Fish should not be exposed to ambient temperatures above 40°F (4.4°C) for more than 24 hours, cumulatively, if no portion of that time is above 70°F (21°C) at any time. Your processing description indicates that thawing of the frozen mackerel can take 15 to 24 hours depending on the time of year. No ambient air temperatures are noted. These times appear excessive considering that further processing, such as filleting and brining, will add 2-3 hours more to the exposure time before freezing.
3. You have successfully revised your labels to include the statement “Important, keep frozen until used, thaw under refrigeration.”

Please respond in writing within six weeks from 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 copies of monitoring records or other useful information that would assist us in evaluating your corrections. If you can't 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. 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. 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.

Please send your reply to the Food and Drug Administration, Attention: Frank Sikorsky, Consumer Safety Officer, Office of Field Programs, Division of Enforcement and Programs, 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. Landesberg at (202) 205-5247.

Sincerely,

A handwritten signature in cursive script, appearing to read "Judith A. Gushee".

Judith A. Gushee

Director

Division of Enforcement and Programs

Office of Field Programs

Center for Food Safety

and Applied Nutrition