



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

g44760

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Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781)596-7896

WARNING LETTER

NWE-16-04W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 30, 2003

Sunja Hayden
President
Sunja's Oriental Food Inc.
40 Foundry Street
Waterbury, VT 05676

Dear Ms. Hayden:

We inspected your seafood processing facility, located at 40 Foundry Street, Waterbury, VT on November 6, 13 and 17, 2003 to determine your compliance with FDA's Seafood Hazard Analysis Critical Control Point (HACCP) Regulations 21 CFR Part 123, "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products", and the Good Manufacturing Practices (GMP) requirements for foods, 21 CFR Part 110.

The Seafood HACCP Regulations were issued pursuant to Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). Seafood that is processed in violation of the HACCP regulations is adulterated, according to the Act, because it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or may have been rendered injurious to health. You can find this Act and the Seafood HACCP Regulations through links in FDA's home page at <http://www.fda.gov>.

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as HACCP. HACCP involves:

(1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and

(2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.

Prudent processors already take these kinds of measures. HACCP provides a systematic way of taking those measures that demonstrates to FDA, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have been fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During our inspection, the investigator provided you with the form FDA 483, which presents her evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. Upon further review, we found that you have a serious deviation from the HACCP Regulations. 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 processed there 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, your ready-to-eat sushi rolls are adulterated, in that the product has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health.

The serious deviation observed was as follows:

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 does not maintain sanitation monitoring records for the eight areas of sanitation required for the processing of sushi rolls, a ready-to-eat product.

We may take further action if you do not promptly correct this above violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

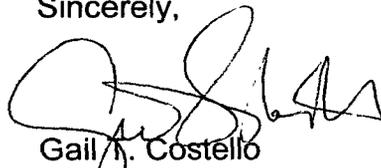
Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. You should include in your response any documentation, such as your HACCP plan, or other useful information that would 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 deficiencies.

This letter does 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.

Additionally, we understand that you have updated your HACCP plan to include thawing as a CCP. Please provide us with a copy of your revised plan. Also, you should note that the food safety hazard of pathogens, which is associated with your sushi rolls, may be controlled by ensuring that the product is not exposed to times and temperatures which may be conducive to the growth of pathogenic microorganisms. You may control pathogen growth by monitoring your storage temperatures using any continuous logging method, or by using a high temperature alarm. You may wish to refer to Chapter 12 of the Fish and Fisheries Products Hazards and Controls Guidance for examples of some of the FDA recommended controls and critical limits.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,



Gail A. Costello
District Director
New England District Office