



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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July 19, 2001

VIA CERTIFIED MAIL

In reply refer to Warning Letter SEA 01-70

Terry Gardiner, President
Norquest Seafoods, Inc.
4225 23rd Avenue West
Seattle, Washington 98199

WARNING LETTER

Dear Mr. Gardiner:

On April 11, 2001, Investigator James I. Vik inspected Norquest Seafoods, Inc., 301 Harbor Way, Petersburg, Alaska, and found that you have serious deviations from the Seafood HACCP regulations [21 Code of Federal Regulations (CFR) 123]. These deviations, some of which were previously brought to your attention, cause three products (cooked and peeled shrimp, whole cooked shrimp, and cooked crab sections) to be in violation of section 402(a)(4) of the 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. You must take appropriate action when a deviation from a critical control limit occurs in order to comply with 21 CFR 123.7(a), Corrective Actions. However, your firm did not take a corrective action to control pathogen survival when your process for cooked Tanner crab deviated from your critical limit at the cook control point. Specifically, on February 19, 2001, your Tanner Crab Cooker Log listed [redacted] batches of crab portions that were cooked for [redacted] minutes, which did not meet your listed critical limit of [redacted] minutes. When a deviation occurs from your critical limit, you must take steps to regain control of your process. The insufficient cook times occurred over a period of seven hours. Although your product internal temperatures appeared adequate, your records should have shown that control of your process was regained and your critical limits were being met after the initial deviation occurred.
2. You must have a HACCP plan that lists the monitoring procedures for each critical control point in order to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for Cooked and Peeled Shrimp lists a monitoring frequency of every two hours at the cook

Terry Gardiner, President
Norquest Seafoods, Inc., Seattle, WA
Re: Warning Letter SEA 01-70

critical control point that is not adequate to control the hazard of pathogen survival. Your cooking process is considered "continuous". In addition to your visual temperature checks, cooker temperatures must be monitored by use of a temperature recording device or a digital time/temperature data logger. That log is considered a necessary part of your monitoring records. Intermittent temperature checks do not provide the necessary safety assurances for continuous cooking systems.

Moreover, your firm's HACCP plans for cooked crab portions and cooked whole shrimp list monitoring procedures at the cook critical control point that are not adequate to control the hazard of pathogen survival through cooking. Your temperature critical limit is listed as [REDACTED] degrees. If your "batch" cook is not performed at the boiling point, you must monitor your cook time and temperature with a temperature recording device or digital time/temperature logger. If your cook is performed at the boiling point, an appropriate monitoring procedure would be to visually observe the time the product is boiling. Your plan must state when you will begin timing your cook cycle and your cook temperature must be corrected.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products 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 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 documents 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.

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 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: Thomas S. Piekarski, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter please contact him at 425-483-4975.

Sincerely,



Charles M. Breen
District Director

Terry Gardiner, President
Norquest Seafoods, Inc., Seattle, WA
Re: Warning Letter SEA 01-70

cc:

David N. Ohmer, Plant Manager
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ADEC with disclosure statement