



April 2 2004

WARNING LETTER

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 - 21

Vernon V. Knoespel
President
Vern's Cheese, Inc.
312 West Main Street
Chilton, Wisconsin 53014

Dear Mr. Knoespel:

On February 19, 2004, we inspected your seafood processing facility located in Chilton, Wisconsin. The inspection was conducted to determine your firm's compliance with FDA's Seafood Hazard Analysis Critical Control Point (HACCP) Regulations, 21 CFR 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 demonstrate 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.

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During our inspection, the investigator provided you with the form FDA 483, which presents his evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. Upon further review, we found that you have serious deviations from the seafood 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 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 smoked fish and pickled herring are adulterated in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby it may have been rendered injurious to health. The deviation noted on the issued form FDA-483, Inspectional Observations, of most concern is as follows:

You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and 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(a), and (b). However, your firm does not have a HACCP plan for smoked fish and pickled herring to control the food safety hazard[s] of pathogen growth and toxin formation.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation 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 Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

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For information regarding recommended control strategies for pathogen growth and toxin formation, please refer to the *FDA Fish and Fishery Products Hazards and Controls Guidance, Third Edition*, Chapter 12 (Pathogen Growth & Toxin Formation as a Result of Time/Temperature Abuse), found at <http://www.cfsan.fda.gov/~comm/haccp4.html>.

Please send your reply to the Food and Drug Administration, Attention: Tyra S. Wisecup, Compliance Officer, at the address in the letterhead. If you have questions regarding any issue in this letter, please contact Compliance Officer Wisecup at (612) 758-7114.

Sincerely,

A handwritten signature in black ink that reads "W. Charles Becoat". The signature is written in a cursive style with a large initial "W".

W. Charles Becoat
Director
Minneapolis District