



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Minneapolis District Office  
Central Region  
212 Third Avenue South  
Minneapolis, MN 55401  
Telephone: (612) 334-4100  
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September 23, 2003

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 03 - 36

Daniel W. Schwarz  
President  
International Fine Foods  
4399 Highway 57  
Sturgeon Bay, Wisconsin 54235

Dear Mr. Schwarz:

We inspected your firm located at 4399 Hwy 57, Sturgeon Bay, WI, on April 9, 2003, and found that you have serious deviations from the seafood HACCP regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). 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 sausage is adulterated, in that the product has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You can find this Act, the seafood HACCP regulations, and *FDA's Fish and Fisheries Products Hazards and Controls Guidance: Third Edition* through links on FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations of most concern to us are as follows:

1. You must have a HACCP plan that, at a minimum lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for smoked fish sausage lists a critical limit, "Maximum cooler

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temp of [REDACTED] degrees," at the Product Receiving critical control point that is not adequate to control pathogen growth and toxin formation.

When you receive your smoked fish sausage from the smoking facility, Schwarz, it is considered a ready-to-eat item by FDA. FDA recommends that you assure that your sausage has been transported at safe temperatures. Since the transport times between your firms appear to be less than four hours, we recommend that you monitor the internal temperatures of a representative sample of the shipment upon receipt. An example of an appropriate critical limit is "Internal temperature of sausages will not exceed 40 degrees F." Your monitoring procedures and corrective actions should be adjusted appropriately.

2. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for smoked fish sausage lists a monitoring frequency at the Cooler Storage critical control point that is not adequate to control pathogen growth and toxin formation in your ready-to-eat smoked fish sausage.

You have listed that you will monitor the temperature of the cooler [REDACTED] a day. When you are storing ready-to-eat seafood, FDA recommends that you use a monitoring method that will assure that safe temperatures are maintained continuously. This may be done by installing a method of recording the temperature of your cooler continuously and performing a daily visual check or by installing a high temperature alarm set to alert you when your critical limit is exceeded. Another option is to surround your product in ice and monitor the adequacy of the ice twice a day.

If you do not promptly correct these violations we may take further action to seize your product(s) 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.

Moreover, your existing HACCP plan must be signed and dated upon initial acceptance and after any modifications. A reassessment of the adequacy of your HACCP plan must be made whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually (21 CFR 123.10).

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 may wish to include in your response a copy of your current HACCP Plan that is signed and dated per 21 CFR 123.6(d)(2) or other useful

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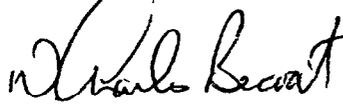
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information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

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 regulation and the Current Good Manufacturing Practice regulation (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 Compliance Officer Jane E. Nelson at the address on the letterhead. If you have questions regarding any issue in this letter, please contact Ms. Nelson at (612)758-7119.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Charles Becoat". The signature is written in a cursive style with a large initial "W".

W. Charles Becoat  
Director  
Minneapolis District