



January 22, 2002

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

**WARNING LETTER**  
**CHI-14-02**

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

Mr. Daniel L. Schwartz  
Chief Operating Officer  
Allavoix Smoked Seafood Company, Ltd.  
8121 Ogden Avenue  
Lyons, IL 60534

Dear Mr. Schwartz:

An investigator from the Food and Drug Administration conducted an inspection at your cold smoked fish processing facility on September 5 and 6, 2001. During the inspection, a sample of packaged smoked salmon fillets labeled in part: "\*\*\*\* Allavoix\*\*\*\*Sliced Atlantique Smoked Salmon\*\*\* 2\*\*LBS. S12490\*\*\*\*" was taken from the daily production on September 6, 2001, and submitted to our laboratory for microanalysis. Our laboratory detected *Listeria monocytogenes* in two of the sub-samples taken. A copy of the laboratory results is attached.

*Listeria monocytogenes* is a pathogenic organism that can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Although healthy individuals may suffer only short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain and diarrhea, *Listeria* infection can cause miscarriages and stillbirths among pregnant women. Therefore, the salmon identified above is adulterated under Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) because it is contaminated with the pathogenic bacteria *Listeria monocytogenes* which may render the product injurious to health. You should review your manufacturing and sanitation processes from incoming raw material to finished product to determine how to control this hazard.

The seafood HACCP regulations, which became effective December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food 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 us, 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 fewer problems generally.

Your products are further adulterated under Section 402(a)(4) of the Act in that you have not met the requirements of 21 CFR 123 as follows:

Because you manufacture vacuum-packaged smoked fishery products, you must include in your HACCP plan how you are controlling the food safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions. However, your HACCP plan for this product covers only refrigerated storage at your facility. Chapter 13 of the Food and Drug Administration's Fish & Fisheries Products Hazard & Controls Guidance: Third Edition provides guidance on control of this hazard.

You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR Part 123.6(c)(3). However, your firm's HACCP plan for vacuum-packaged smoked fishery products lists a critical limit at the cold storage critical control point that is not adequate to control pathogens. Specifically, the cooler storage critical control point lists a temperature of 45°F, which has not been found to be adequate to control pathogen growth for products intended to be held under refrigeration. A temperature limit of 40°F or less is recommended for maintaining the safety of the product.

Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for smoked fishery products at the refrigeration CCP to control pathogens does not ensure that product adulterated as a result of the deviation will not enter commerce.

You must maintain sanitation control records in order to comply with 21 CFR 123.11(c). However, you indicated to our investigator that sanitation control records are not kept.

Among the significant findings described on the Form FDA-483 is the observation that the temperature of your cold storage room was recorded to be 48°F on at least one occasion, which is above the 45°F that according to your HACCP plan requires a corrective action. None was identified or recorded for the incident. Also, there are no documents that show actual temperatures in the cooler, and you do not maintain any standard sanitary operating procedure (SSOP) monitoring records for your smoked fish operation.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Moreover, it is your responsibility to produce safe products. You should take prompt action to prevent further violation of the Act. Further violation of the Act may result in regulatory action without further notice, which can include seizure of your products and/or injunction of your firm.

You should examine your process to determine the source of this contamination so that steps can be taken to correct the condition as well as perform the necessary HACCP operations to be in compliance with Part 123 (HACCP) of Title 21, Code of Federal Regulations. It is essential that you respond to this office concerning this matter within 15 days of receipt of this letter, stating the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 30 days, state the reasons for the delay and the time at which the corrections will be completed.

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Your reply should be directed to Paul Boehmer, Compliance Officer, at the above address.

Sincerely,

\s\  
Arlyn H. Baumgarten  
Acting District Director

Enclosure