



Telephone (973)

526-6006

New Jersey District  
Waterview Corporate Center  
10 Waterview Blvd., 3<sup>rd</sup> Floor  
Parsippany, NJ 07054

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

February 2, 2004

**WARNING LETTER**

Mr. Alexander Mogilever, President  
Amros The Second, U.S.A. Inc.  
69 Veronica Avenue  
Somerset, NJ 08873

04-NWJ-07

Dear Mr. Mogilever:

We inspected your firm, Amros The Second, U.S.A. Inc., located at 69 Veronica Avenue, Somerset, New Jersey on December 8, and 10, 2003 and found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), the 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 vacuum packed smoked mackerel, vacuum packed smoked sprats and herring in oil are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

You can find seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov). You should also refer to the FDA guidance document, "Fish and Fisheries Product Hazards & Controls Guide, Third Edition," for recommended critical control points (CCPs), critical limits and monitoring procedures for the manufacture and storage of seafood products. This guide is also available online through the aforementioned link.

The deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have written HACCP plan(s) to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical or physical property that may cause a food

to be unsafe for human consumption.” However, your firm does not have written HACCP plan(s) for the receipt and refrigerated storage of vacuum packed smoked mackerel, vacuum packed smoked sprats and herring in oil. HACCP plan(s) for the above mentioned products are necessary in order to control the food safety hazards of histamine and Clostridium botulinum growth. Your lack of written HACCP plan(s) to control the potential food safety hazards inherent in these products was previously brought to your attention during the inspection conducted on November 18, 20, and 26, 2002, by the New Jersey Department of Health and Senior Services, which was performed under FDA contract.

2. You must have written HACCP plan(s) that identify the appropriate CCPs needed to control the food safety hazards identified in item # 1 above for your refrigerated vacuum packed smoked mackerel, vacuum packed smoked sprats and herring in oil. You must then implement an effective record keeping and monitoring system of the CCPs identified in your HACCP plan(s) in order to comply with 21 CFR 123.6(c)(4). However, your firm does not monitor the storage of potentially hazardous fish and fishery products and does not have a procedure in place that provides assurance that these products are continuously maintained at or below 40 °F.
3. In order to comply with 21 CFR 123.10, you must have an individual who has successfully completed appropriate HACCP training or who is otherwise qualified through job experience to develop your HACCP plan and perform the record reviews required by 21 CFR 123.8(a)(3). Your firm does not employ or otherwise engage an appropriately trained individual to perform these functions. This deviation was previously brought to your attention during the inspection conducted on November 18, 20, and 26, 2002.
4. 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 did not maintain sanitation monitoring records for the eight areas of sanitation specified in 21 CFR 123.11(b). This was previously brought to your attention during the inspection conducted on November 18, 20, and 26, 2002.

In addition to the violations of 21 CFR Part 123 identified above, the inspection also found that you failed to comply with the Current Good Manufacturing Practice requirements for foods (21 CFR Part 110). Specifically, 21 CFR 110.35(c) requires you to take effective measures to exclude pests from the processing areas and protect against the contamination of food in your facility. However, during the inspection, live birds were observed flying in the candy manufacturing area and the rice, dry beans, and grains repacking warehouse area. This was previously brought to your attention during the inspection conducted on November 18, 20, and 26, 2002.

This letter may not list all the deviations observed at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations and the Current Good Manufacturing Practice regulations. You also

**Amros The Second, U.S.A. Inc.  
Somerset, NJ 08873**

**Warning Letter 04-NWJ-07  
February 2, 2004**

have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) 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 may wish to include your written HACCP plan(s), monitoring procedures, copies of monitoring records 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 the delay and provide a deadline by which the corrections will be completed.

Your response should be directed to the New Jersey District, FDA, 10 Waterview Blvd., 3<sup>rd</sup> Floor, Parsippany, New Jersey 07054, Attn: Robert J. Maffei, Compliance Officer.

Sincerely,



Douglas I Ellsworth  
District Director  
New Jersey District