



5001 Campus Drive
College Park, MD 20740

March 23, 2018

VIA EXPRESS DELIVERY

Mr. Mihails Silovs
Manager
SIA Piejura
Nicas pagasts, Nicas novads
Avoti Liepajas Aprinkis, 3473 Latvia

Reference #548182

Dear Mr. Silovs:

During an inspection by a representative of the United States Food and Drug Administration (FDA) of an importer of seafood products located in the United States, Threeline Imports Inc., located in Brooklyn New York, that was found to be importing canned roasted and smoked sprats from your processing facility, FDA obtained copies of your HACCP plans for "Fried Sprats in Tomato Sauce", "Smoked Sprats in Oil", and "Smoked Sprats in Tomato Sauce", dated January 24, 2017. Our evaluation of the HACCP plans revealed a significant concern, as further described in this letter.

In accordance with 21 CFR 123.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operates in accordance with the requirements of Part 123, renders the fish or 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). You may find the Act, the seafood HACCP regulation and the 4th Edition of the Fish and Fisheries Products Hazards and Controls Guidance (The Hazards Guide) through links in FDA's home page at www.fda.gov.

We have the following concern:

- You must conduct or have conducted for you a hazard analysis for each kind of fish and fishery product that you produce to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan, that at a minimum, lists the food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(a) and (c)(1). 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's HACCP plans entitled "Fried Sprats in Tomato Sauce", "Smoked Sprats in Oil", and "Smoked Sprats in Tomato Sauce" do not list the food safety hazards of scombrototoxin (histamine) formation which is reasonably like to occur from

receipt of the refrigerated fresh sprats until the processed sprats are rendered shelf-stable (i.e., when containers have reached retort temperature).

You should respond in writing within thirty (30) working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct these deviations. More specifically, your response should include documentation reflecting the changes you made, such as a copy of your revised HACCP plans, five (5) consecutive days of completed monitoring records (i.e., records for the production of 5 production date codes of the products) to demonstrate implementation of the plan, and any additional information that you wish to supply that provides assurance of your intent to fully comply now and in the future with the applicable laws and regulations. Submission of the information in English will assist in our review. If you cannot complete all corrections within 30 days, you should explain the reason for your delay and state when you will correct any remaining violations.

Please send your reply to Food and Drug Administration, Attention: Sandra Purnell, Compliance Officer, Food Adulteration Assessment Branch (HFS-607), Division of Enforcement, Office of Compliance, 5001 Campus Drive, College Park, MD 20740 U.S.A. If you have any questions regarding this letter, you may contact Ms. Purnell via email at standra.purnell@fda.hhs.gov. Please reference CMS #548182 on any submissions and within the subject line of any emails to us.

Sincerely,

/s/

Sabina Reilly
Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition