DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD

January 19, 2012

Mr. Andre Proulx
President/Owner
C/o Les Aliments Trans Gras/Drummond Export
2825 Rue Power
Drummondville, Q.C.
Canada J2C626

Dear Mr. Proulx:

We inspected your seafood processing facility, Drummond Export, located at 1175 Rue Bergeron, Drummondville, Q.C., Canada, on July 14-18, 2011. We found that you have serious violations of the Seafood Hazard Analysis and Critical Control Point (HACCP) Regulation, Title 21, Code of Federal Regulations, Part 123.

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 operate 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). Accordingly, your firm's pickled mackerel and herring; and dried Pollock appear to be adulterated, in that the products have been prepared, packed, or held under conditions whereby they may have been rendered injurious to health. At the conclusion of the inspection, the FDA investigator issued a FDA-483, Inspectional Observations, listing the deviations found at your firm.

The seafood HACCP regulation requires that you implement a preventative system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP involves:

- Identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and
- Having controls at each "critical control point" in the processing operation to eliminate or minimize the likelihood that the identified hazard will occur.

HACCP provides a systematic way to identify, implement, and document those measures that demonstrate to FDA, to your customers, and to consumers that you are routinely practicing food safety by design. During our review of your plan, we found shortcomings that are violations of the seafood HACCP regulation.

We acknowledge your firm's response received via email on July, 22 2011, to that FDA-483 issued to your firm. However our review revealed that the response was not adequate, as further described in this letter.

You may find the Act and the Seafood HACCP regulation through links in FDA's home page at www.fda.gov.

Additionally, for information regarding FDA's recommended controls for the hazards as discussed below, please refer to the Fish and Fisheries Products Hazards and Controls Guidance: Fourth Edition, which can be found on FDA's web site at: http://www.fda.gov/Food/GuidanceComplianceRegulatorylnformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/index.htm.

Your firm submitted with your July 22nd response a single HACCP plan entitled "semi-dry, ordinary cured and Mackerel". This one plan appears to cover all of your firm's fish and fishery products, including pickled mackerel and herring; and dried Pollock. This HACCP plan identifies several hazards, including but not limited to histamine, microorganism proliferation, and low salinity with various corresponding control points, critical limits, etc. However, the products handled by your firm do not pose the same food safety hazards; do not require identical critical control points; do not require identical critical limits; and do not require the same production methods. Consequently, you can not, in accordance with 21 CFR Part 123.6(b)(2), group these fish and fishery products in the same plan.

As such, taking into consideration that the products require separate plans, and that your firm currently has only one plan, we note the following serious deviations from the requirements of the Seafood HACCP regulation:

1. 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 plan does not list the significant hazard of undeclared allergens.

   FDA requires that the common and usual name of the fish species be listed on the product label. We recommend that firms include a critical control point to visually check each lot of labels to ensure that the allergenic substance (i.e., the fish species) is accurately declared on the labels. Please refer to Chapter 19 of the 4th Edition of the Fishery and Fishery Products Hazards and Control Guidance for additional information.

2. You must have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6(c)(2). A critical control point is defined in 21 CFR 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan "semi-dry, ordinary cured and Mackerel":

- does not list a critical control point for storage of raw material for controlling the food safety hazard of scombrotoxin (histamine) formation in your pickled mackerel and herring products. Specifically, your firm's hazard analysis states that raw materials are held in storage at between (b)(4)°C and (b)(4)°C ((b)(4)°F and (b)(4)°F). Since some products are held in storage at refrigeration temperatures, your firm should be controlling temperatures to control the hazard of scombrotoxin formation. In general, products such as your pickled mackerel and herring, which are received by your firm from a previous processor (i.e., already pickled and packed) and then stored at your facility before shipping, and where your firm does not conduct any additional processing, would require critical control points for receiving and any refrigerated storage steps, to ensure that the products are maintained at or below 4.4°C (40°F) (i.e., during transit to your facility and during any subsequent storage at your facility) to control histamine.

3. 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 "semi-dry, ordinary cured and Mackerel" lists critical limits:

    - At the "Raw Material Reception" critical control point that are not adequate to control scombrotoxin (histamine) formation for your pickled mackerel and herring products, during transit from the previous processor to your facility. Specifically, our investigator noted that the incoming fish are (b)(4) [redacted]. However, your firm does not list this procedure in your HACCP plan, in association with the pickled mackerel and herring products. Please be advised, again, that your firm needs to develop a separate plan for these products. Additionally, FDA's recommendations for transit controls for secondary processors may be found on pages 137-141 of the Fishery and Fishery Products Hazards and Control Guidance, 4th Edition.

    - At the "Drying of fish" critical control point that is not adequate to control *Staphylococcus aureus* growth and toxin formation for your dried Pollock product. Specifically, our investigator observed during the inspection that your firm (b)(4) [redacted]. However, this procedure is not included in the HACCP plan. Moreover, your HACCP plan does not list a final water phase salt level in the finished food (i.e., to be achieved as a result of drying). FDA recommends for dried, shelf stable products such as your dried Pollock (i.e., intended to be held at ambient temperatures, without refrigeration or freezing) that the products

achieve a water phase salt level of at least 20%. In addition, FDA recommends that the 20% level be reached within three (3) hours of drying to ensure control of *Staphylococcus aureus* toxin formation because your firm is conducting the drying process at elevated temperatures, listed in your plan as (b)(4) [redacted]. These temperatures increase the likelihood for growth and toxin formation. Additionally, because of the extended drying times, your firm may need to include in your HACCP plan additional process related critical limits during the drying step such as humidity, fish size/flesh thickness, air velocity, and the initial salt concentration in the fish flesh all of which may affect the end product results. Please refer to Chapters 14 and 15 of the Fishery and Fishery Products Hazards and Control Guidance, 4th Edition for additional information regarding drying and the hazard of *Staphylococcus aureus* growth and toxin formation.

4. Because you chose to include a corrective action plan in your HACCP plan, your described corrective action must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan at the "Raw Material Reception", "Drying of the Fish", "Metal Detection", and "Labeling" critical control points are not adequate. Specifically, the corrective actions listed in your plan do not:

    - ensure that an unsafe product does not reach the consumer and
    - correct the problem that caused the critical limit deviation.

You should respond in writing within thirty (30) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You should include in your response documentation such as a copy of any revised HACCP plans, at least five (5) product days worth of monitoring records to demonstrate that you have implemented the revised plan and other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before the 30 days, you should explain the reason for your delay and state when you will correct any remaining violations.

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 Good Manufacturing Practice regulation (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Food and Drug Administration, Attention: Standra Purnell, Consumer Safety Officer, Office of Compliance, Division of Enforcement, Manufacturing and Storage Adulteration Branch HFS-607, 5100 Paint Branch Parkway, College Park, MD 20740 U.S.A. If you have any questions regarding this letter, you may contact Standra Purnell via email at standra.purnell@fda.hhs.gov.

Sincerely,

/s/

Kathleen Lewis, J.D.
Acting Division Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition