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Food and Drug Administration
Kansas City District
Southwest Region
P.O. Box 15905
Lenexa, Kansas 66285-5905
Telephone: (913) 752-2100

October 20, 2000

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER
Ref. KAN 2001-006

Mr. Larry Stoller, President
Stoller Fisheries Division - Progressive Companies, Inc.
1301 18th Street, Box B
Spirit Lake, IA 51360

Dear Mr. Stoller:

We inspected your firm, located at 1301 18th Street, Spirit Lake, Iowa on September 26-28, 2000 and found you have serious deviations from the Seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause your product, salted carp roe, to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the Seafood HACCP regulations on the internet through links on the Food and Drug Administration (FDA) homepage at www.fda.gov.

The deviations were as follows:

1. Your firm's HACCP plan for salted carp roe does not list all the monitoring procedures at the fresh fish receipt critical control point to control chemical contamination. You do not have a procedure that, on at least a quarterly basis, identifies possible drug residues in the fresh water carp that is processed to yield the salted carp roe. [21 CFR 123.6(c)(4)]
2. Your firm did not follow the monitoring procedure of requiring a lot by lot certificate from the supplier showing the fresh water carp was caught in safe waters. Your HACCP plan identifies this critical control point will be performed at the receipt of the fresh water carp to control chemical contamination in your salted carp roe. [21 CFR 123.6(b)]
3. Your firm did not adequately control the following sanitation conditions and practices during the processing of the salted carp roe:
 - The safety of the water used in your processing as evidenced by the lack of water testing records for the past year [21 CFR 123.11(b)(1)]

- the possible cross-contamination of the product as evidenced by employees returning to work without hand washing, the handling of unsanitary objects with gloved hands and then continue processing salted carp roe without sanitizing their gloves [21 CFR 123.11(b)(3)]
- the food contact surfaces are not properly maintained as evidenced by processing tables and scales used in the operation having residue caked on the surfaces [21 CFR 123.11(b)(2)]

We may take further action if you do not promptly correct these violations. Actions that may be taken include seizure of your products and/or injunction of your firm.

This letter does not list all the deviations observed, or that otherwise may be occurring at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please respond in writing within three (3) weeks 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 documentation, 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 your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Ralph J. Gray, Compliance Officer, P.O. Box 15905, Lenexa, KS 66285-5905. If you have any questions regarding any issue in this letter, please contact Compliance Officer Gray at (913) 752-2105.

Sincerely,



for Charles W. Sedgwick
District Director
Kansas City District