



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
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Bothell, WA 98021-4421

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January 12, 2004

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-14

Robert C. Jackson, President
Quality Plus Products, Inc.
3977 Hoff Road
Bellingham, Washington 98225

WARNING LETTER

Dear Mr. Jackson:

On September 2-3, 2003, we inspected your seafood processing facility, located at 3977 Hoff Road, Bellingham, Washington. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or to 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-packaged hot smoked salmon, smoked salmon spread, and pickled salmon are adulterated, in that these products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find this Act and the seafood HACCP regulation through links in FDA's homepage at www.fda.gov.

The deviations are as follows:

Refrigerated, vacuum-packaged hot smoked salmon

1. You must implement the record keeping system that you listed in your HACCP plan to comply with 21 CFR 123.6(b). Your firm did not record monitoring observations at the brining and cooling (after hot smoking) control points to control the *Clostridium botulinum* hazard listed in your HACCP plan. You have no monitoring records for these critical control points.

2. You must implement the monitoring procedures that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). Your firm did not follow the monitoring procedures at the brining critical control point as listed in your plan. Specifically, your plan lists that you will monitor salinity at [REDACTED] using a salometer. Discussions during the inspection of your facility revealed that you do not use a salometer and, in fact, do not measure salinity at all.
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(a) and (c)(3). A critical limit is defined in 21 CFR Part 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."
 - Your firm's HACCP plan lists a critical limit of [REDACTED]°F that is not adequate to control the hazard of *Clostridium botulinum* at the storage/distribution critical control point. FDA recommends that you maintain refrigerated temperatures at or below 40°F to prevent the growth and potential toxin formation from pathogenic organisms.
 - Additionally, your firm's HACCP plan for hot smoked salmon lists a critical limit at the cooling after smoking critical control point that is not adequate to control pathogen growth. Your critical limit lists that your smoked fish will be placed under refrigeration within [REDACTED] hours from the finish of your smoking process. Once product temperature has been reduced to 140°F, cooling should occur rapidly. FDA recommends that the temperature be reduced to below 70°F within 2 hours. After that, the temperature should continue to be reduced to below 40°F within the next 4 hours.
4. You must have a HACCP plan that, at a minimum, lists the monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). Your firm's HACCP plan does not list monitoring procedures at the smoking/drying and storage/distribution critical control points that are not adequate to control *Clostridium botulinum*.
 - Specifically, your monitoring procedures at the smoking/drying critical control point list that you conduct a visual check of internal temperature of fish with a probe for each batch. Your listed monitoring procedures are insufficient to show that your critical limits have been met. Our investigator reports that you insert dial thermometers into [REDACTED] of the thickest portions of fish to monitor internal temperatures. This procedure cannot assure that your critical limits are achieved. Given that your smoking/drying procedures include both time and internal temperature critical limits, we recommend using temperature probes that provide

a method of continuously monitoring/recording the internal temperature for the duration of the process.

- Your monitoring procedures at the storage/distribution critical control point state that temperature-monitoring frequency will be "daily." FDA recommends that, in order to adequately ensure that safe temperatures are consistently maintained during storage, monitoring should be conducted on a continuous basis with a visual check of the equipment once per day. For more information on monitoring procedures for control of *Clostridium botulinum* in smoked fish, please refer to *Chapter 13 of the Fish and Fisheries Products and Hazards and Controls Guidance 3rd Edition (the Hazard Guide)*.
5. You must verify that your HACCP plan is adequate to control the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.8(a). Your firm did not verify the adequacy of the critical limits at the brining critical control point to control *Clostridium botulinum*.

Our investigator collected a sample of refrigerated, vacuum-packaged hot smoked salmon on September 3, 2003. FDA then analyzed ten 0.5 lb. packages for percent water phase salt. Two out of ten packages had water phase salt levels below 3.5%. The results of the original analysis for the two packages were 3.1% and 3.4%, and for the check analysis the results were 3.0% and 3.3%, respectively. Our evaluation of that sample (date coded 8/30/03) determined a wide range of water phase salt levels from 3.0 to 6.9. Two of the subsamples collected had water phase salt levels below the recommended safety level of 3.5. If your process had been properly validated, the variation in water phase salt would be less and all of your processed products would have achieved a consistently safe water phase level. FDA has determined that your verification of your process was flawed or not conducted.

Refrigerated smoked salmon spread in a plastic tub with snap on lid

1. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point to comply with 123.6(c)(4). Your firm's HACCP plan for smoked salmon spread does not list monitoring procedures at the storage critical control point to control pathogen growth and toxin formation.

Refrigerated pickled salmon in glass jar

1. You must implement the record keeping system that you listed in your HACCP plans to comply with 21 CFR 123.6(b) and 21 CFR 123.9. Your firm did not record monitoring observations at the salting, brining and pickling, and refrigerated storage critical control points listed in your HACCP plan for Pickled Salmon. Your firm was

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unable to produce records showing monitoring observations for these critical control points during our investigation.

2. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for refrigerated pickled salmon in glass jars does not list monitoring procedures at the salting, primary brining/pickling, and refrigerated storage critical control points.

Sanitation

1. You must maintain sanitation control records that, at a minimum, document monitoring and corrections, to comply with 21 CFR 123.11(c). As of August 5, 2003, your firm has not maintained sanitation monitoring records for the eight areas of sanitation required for the processing of refrigerated vacuum-packaged hot smoked salmon, refrigerated smoked salmon spread in a plastic tub with snap on lid, and refrigerated pickled salmon in glass jar.

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 in your response documentation such as your revised HACCP plan and copies of your 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 your delay and state when you will correct any remaining deviations.

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

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Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact CO Elrand at (425) 483-4913.

Sincerely,

Kristy B. Dues
for Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: WSDA with disclosure statement