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SUMMARY

The comprehensive inspection of this manufacturer and distributor of salmon was conducted in accordance with C.P. 7303.842, Domestic Fish and Fishery Products, C.P. 7303.842H, Seafood HACCP under FACTS Assignment #934564, OP ID #3653673.

The previous FDA inspection of Cultivadora De Salmones Linao Ltda was conducted on September 12, 2006 by Frank Sedzielarz. Observations noted during the inspection included: HACCP plan did not list the food safety hazard reasonably likely to occur and no verification procedures at receiving. An FDA 483, Inspectional Observations, was issued to Gustavo Quiroz, Processing Manager, on September 12, 2006. The inspection was classified VAI.

The current inspection was conducted on April 23, 24, and 25, 2008. It focused on fresh trim D skin-on salmon fillets and covered the firm's HACCP Plan and Hazard Analysis, warehouse

operation, individual responsibility, manufacturing, sanitation, shipping/receiving, product storage and distribution, pest control, and the structural conditions of the building. The firm processed and packaged the product covered during the inspection.

We issued an FDA 483 to Ruben Molina, Processing Director, on April 25, 2008. Observations listed in the FDA 483, included: critical limits do not ensure control of the aquaculture drugs hazard and sanitation monitoring records did not accurately documented conditions observed in the firm. Mr. Molina agreed to review the observations and respond accordingly. We verified that observations listed in the last FDA 483 issued to the firm on September 12, 2006 were corrected.

No reconciliation exam was performed, no labels or samples were collected, and no refusals were encountered during the current inspection.

ADMINISTRATIVE DATA

Inspected firm:	Cultivadora De Salmones Linao Ltda
Location:	Ruta 226, Km 8 Camino El Tepual Puerto Montt, Chile
Phone:	56 65 221701
FAX:	56 65 221402
Mailing address:	P.O. Box 56-D Puerto Montt, Chile
Dates of inspection:	4/23/2008, 4/24/2008, 4/25/2008
Days in the facility:	3
Participants:	Tania K. Mercado, Investigator Mary M. Finn, Investigator

We displayed credentials to Ruben Molina, Processing Manager, and most responsible person on-site, on April 23, 2008. The actual dates in the plant were April 23, 24, and 25, 2008. An FDA 483 was issued to Mr. Molina on April 25, 2008. Mr. Molina participated during the General Discussion with Management.

The firm is also regulated by Servicio Nacional de Pesca (Sernapesca), a Chilean Regulatory Agency. Sernapesca certifies fish and fishery product firms that want to export products as part of the requirements, Sernapesca conducts annual inspections to validate the firms' HACCP plan and the

firms' quality control system. The firms' quality control system is inspected [redacted] Firms are rated based on observations. If a firm rates between 1 and 3, they can export their products.

Investigator, Mary Finn and I wrote all the sections in this establishment inspection report (EIR).

HISTORY

Firm's history has not changed since the last inspection on September 12, 2006, unless otherwise stated below.

According to Berta Contreras, Food Safety & Quality Manager, there was a merger with Marine Harvest on January 2007 and was finalized on June 2007. A list of all the firms affiliated to Cultivadora De Salmones Linao Ltda (Marine Harvest) is attached (Exhibit #1). Cultivadora de Salmones does business as Marine Harvest.

The previous FDA inspection of Cultivadora De Salmones Linao Ltda was conducted on September 12, 2006 by Frank Sedzielarz. Observations noted during the inspection included: HACCP plan did not list the food safety hazard reasonably likely to occur and no verification procedures at receiving. An FDA 483, Inspectional Observations, was issued to Gustavo Quiroz on September 12, 2006. The inspection was classified VAI.

The firm operates Monday through Saturday [redacted]

All correspondence should be sent to:

Mr. Ruben Molina
Processing Director
Marine Harvest Chile
Camino Chinquihue, Km. 12
Casilla 35-D
Puerto Montt, Chile

INTERSTATE COMMERCE

Exhibit #2 shows customers in the US. Product arrives in New York, Florida, and California. [redacted]

All the salmon processed on-site is supplied by firms that are part of Marine Harvest. Approximately [redacted] of the fish processed on-site comes from [redacted] It takes anywhere from [redacted] for fish to arrive from the primary plant to Marine Harvest. All feed for fish from Marine Harvest is supplied by [redacted]

JURISDICTION

A list of products processed on-site, including products distributed in the US (Exhibit #3), technical sheets for products distributed in the US (Exhibit #4), and labels for products distributed in the US (Exhibit #5) were collected during this inspection. Enrique Silva, Tepual Factory Manager, stated that the last shipment of Coho salmon was last January.

Labeling agreements were not covered during this inspection. Marine Harvest is the brand name used for products distributed in the US.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Ruben Molina, Processing Manager, is the most responsible person on-site. He has production's overall duty, power, and responsibility. He was present during the initial meeting and the general discussion with management.

Berta Contreras, Food Safety & Quality Manager, Enrique Silva, Tepual Factory Manager, and Hector Ojeda, Chief of Processing Plant Quality, accompanied us during the inspection, answered most of the questions, and provided most of the documents.

Adriana Mendoza, Veterinarian, answered most of the questions regarding the process prior to receiving, feed, and drugs used in salmon.

Exhibit #6 includes Marine Harvest's management structure and identifies key personnel.

FIRM'S TRAINING PROGRAM

The following employees have completed the HACCP training and Sernapesca has certified them (Exhibit #7) in HACCP:

Berta Castillo in August 25, 2007
Berta Contreras in June 30, 2003
Carolina Ruz on December 9, 2003

All employees are trained in general HACCP principles [redacted] (Exhibit #7).

MANUFACTURING/DESIGN OPERATIONS

I verified that the manufacturing process has not changed since the last inspection on September 12, 2006. The same process is used for all the fresh seafood products manufactured on-site. Process is discussed in this EIR to include more details. Trim D skin-on Atlantic salmon was processed during our visit (Exhibit #8).

Processing of trim D skin-on fresh Atlantic salmon fillets

Ms. Mendoza stated that Marine Harvest owns brood stock and chooses salmon for reproduction. Eggs can also be imported from Ireland and Norway. The smolts are grown in the hatcheries until they weight approximately [redacted]. Growth is controlled with temperature and light. Then, they're transported in trucks to a lake until they weight approximately [redacted]. Finally, they are brought to the sea where they grow in cages until they are big enough for processing. There is approximately [redacted] salmon per cage and approximately [redacted] This growing process takes approximately [redacted] from egg to production. Ms. Contreras stated that a salmon cage can not be released until it is sampled for drug residues and Sernapesca approves it. Therefore, each cage is analyzed once it is opened. Temperature is used to make the salmon dormant and is killed by knocking them on the head with a hammer using a machine.

Ms. Mendoza stated that Astaxanthin is used for color in the fish. Astaxanthin is added to the feed and the fish ingest it. We collected a copy of the feed's formula during the inspection (Exhibit #9).

Ms. Contreras stated that a salmon cage can not be realeased until it is sampled for drug residues and Sernapesca approves it. Therefore, each cage is analyzed before it is harvested. During transport from the sea to the slaughtering plant, cold temperature is used to make the salmon dormant. The salmon are killed by mechanically knocking them on the head with a hammer.

Bins with ice are sent to the slaughtering plant to pick up the salmon. Sealed bins return with salmon in iced slurry. After the records are verified, the seals are broken. The bins are removed from the truck and a visual inspection of the salmon in each bin is conducted and recorded. If the salmon passes the visual inspection, the bin is labeled and placed in the Raw Material Area.

Bins are dumped on the evisceration line, where a conveyor belt moves the salmon through a wash and a mechanical scaler. Then, one person makes an incision in the belly, another pulls the viscera, another cuts the liver, and finally all the residue is sucked out using a suction nozzle.

Then, the salmon is conveyed through a spray tunnel to rinse off any remaining residue and it is graded for quality by [redacted] employees. Next a machine sorts the salmon by size in bins. The graded, eviscerated, cleaned, salmon are put into bins, covered with ice, the bins are labeled, and the salmon is held in the bin until it is dumped onto [redacted] filleting lines. Mr. Silva stated that the line [redacted] is usually used to process trout. Salmon to be distributed whole is transported in bins directly to packaging (Exhibit #10).

A Trim D fillet means that the salmon's head, gills, fat, and tail are cut manually. Also, bones, hematomas, and melanosis are manually removed. Machines fillet the fish and remove most of the bones. Finally, fillets are graded again and bagged. Bagged fillets on trays are placed on pallets and the pallets are labeled. According to Ms. Contreras, rejected salmon and scraps are sold to an independent company to be used for pet food, not for salmon feed manufacturers, as required by Chilean regulations.

Fillets are stored in a cooler until they are ready for packaging. Once they arrive in the Packaging Area, they go through a metal detector. Fillets are packaged in Styrofoam coolers. Then, the coolers are weight and approximately [redacted] ice bags are placed on top of the fillets. The coolers are labeled and close with tape. Coolers are packed in boxes and stored in another cooler until they are ready for shipment.

Processing of frozen Atlantic salmon bits and pieces

We briefly covered this product that was also processed during the inspection. Broken trim D skin-on fresh Atlantic salmon fillets are sold as bits and pieces. A machine removes the pieces' skin. The fat is further cut and the pieces are cut into smaller pieces manually. Then, they are packed in vacuum sealed bags and frozen in the blast freezer. Salmon not used in this product is sold to another company to be used in preserves.

Sanitation

The truck and the bins' outside are disinfected with [redacted] After receiving the salmon, the plastic bags inside the bins are rinsed with chlorinated water and sanitizer. The bins are rinsed with

chlorinated water. Sanitized bags and bins are returned to the primary plant. Ice is made at two locations on-site using well water (Exhibit #11). Ice made near the Raw Materials Area is used in the bins sent to the primary plant and ice made in the second location is used for on-site production.

Production areas are cleaned between shifts and a deeper cleaning is performed at the end of the [redacted] shift. Quality control is in charge of verifying that cleaning is adequate with visual checks and concentration measuring strips. A [redacted] verification is done by swabbing and the swabs are sent to an outside laboratory for microbiological analyses.

There are only two ways for production employees to suit up and enter the production area, one for men and the other for women. Employees suit up with dedicated clothes provided and cleaned by the firm. The employees we observed wore jump suits, boots, plastic aprons that appeared to be clean, gloves, face masks, and hair nets. They appeared to be in good health with no visible cuts or open wounds. The entrance has boot scrubbers, foot bath, sinks with soaps, paper towels, and sanitizers.

The toilet facilities were equipped with water, soap, paper towels, toilet tissue, trash receptacle, and working toilet and sinks during the inspection.

A list of chemicals used on-site was collected during the inspection (Exhibit #12). Quaternary ammonia is used for foot baths, a general detergent is used for overall cleaning, chlorine is used for sanitation, and acetic acid is used on surfaces.

No signs of pests were observed during the inspection. Mouse traps are located around the property's perimeter and around the buildings' perimeters.

Seafood HACCP

The seafood HACCP plan on-site at the time of the inspection (Exhibit #13) was last revised on April 21, 2008. The firm's HACCP manual contains process descriptions, hazard analyses, HACCP plans for products manufactured on-site. A copy of the firm's sanitation standard operation procedures (SSOP) (Exhibit #14) was collected during the inspection.

Ms. Mendoza stated that all aquaculture drugs need to be approved by Chile's "Servicio Agricola y Ganadero" (SAG) (Agricultural and Livestock Service) before they can be used in salmon. Dosage periods can be [redacted] depending on the drug. Marine Harvest started to use a vaccine for infectious salmon anemia (ISA) this year. Sernapesca requires [redacted] samples for prohibited and unauthorized substances by site and drug residues of each cage before harvesting. The [redacted] samples include random species and substances selected by Sernapesca and they change [redacted]

The following documents accompany the bins when they arrived at the plant: bill of lading, sanitation records, route sheet (one per cage), supplier's certificate, and a sworn declaration (Exhibit #15). The supplier's certificate states that fish had no signs of disease at harvesting, withdrawal periods were maintained, were harvested from not contaminated waters, and free of prohibited and unauthorized substances.

Laboratory reports are attached with the certificate and are performed by third party laboratories (Exhibit #15). Marine Harvest only uses laboratories approved by Sernapesca (Exhibit #16). There is no laboratory on-site.

We randomly selected different lots processed on April 24, 2008, December 26, 2007, and June 20, 2007 and reviewed the critical control point (CCP) monitoring records of receiving and metal detection. We also reviewed verification records, such as sanitation monitoring records, supplier's certificates, and laboratory results. Overall, the required records are maintained by the firm.

MANUFACTURING CODES

A lot number is assigned at receiving and it is assigned per harvest (Exhibit #17). A harvest can consist of more than one truck.

COMPLAINTS

Complaints were not covered during this inspection.

RECALL PROCEDURES

Recall procedures have not changed since the last inspection on September 12, 2006.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

Your HACCP plan does not list a critical limit that ensures control of one or more hazards.

Specifically, your HACCP plan lists a critical limit of aquaculture drugs at the receiving critical control point that does not ensure the control of drug residues. Product information records for salmon used in the April 24, 2008 production, lab reports dated January 18, 2008, January 21, 2008, February 1, 2008, July 9, 2007, and May 12, 2007, show that fish was treated with unapproved drugs, such as Emmamectin.

Reference: 21 CFR 123.6(c)(3)

Supporting Evidence and Relevance: According to the Fish and Fisheries Products Hazards and Controls Guidance: *Third Edition* June 2001, "Unregulated/unapproved drugs administered to aquaculture fish pose a potential human health hazard. These substances may be carcinogenic, allergenic, and/or may cause antibiotic resistance in man. To control this hazard in food animals, all drugs, whether for direct medication or for addition to feed, must be approved by FDA. Under certain conditions authorized by FDA, unapproved new animal drugs may be used in conformance with the terms of an Investigational New Animal Drug (INAD) application." Emmamectin benzoate and flumequine are not listed as approved drugs by FDA. Therefore, they pose a potential human health hazard. Also, the firm has not submitted any INAD application for these drugs nor was they are conducting clinical studies for any other firms.

Chile allows the use of oxolinic acid, emmamectin, and flumequine (Exhibit #18). A list of pharmaceutical veterinary medicines used by Marine Harvest in salmonids included: oxolinic acid and flumequine as antibiotics and emmamectin benzoate as an anti-parasite (Exhibit #19). Product information records for salmon from the Quinchao site cage # 211 used in the April 24, 2008 production shows that the salmon was treated with emmamectin until January 17, 2008 (Exhibit #15). The following laboratory results showed that traces of unapproved drugs were detected on salmon:

January 18, 2008 - emmamectin was detected on salmon from Quinchao site cage #211 (Exhibit #15)

January 21, 2008 - oxolinic acid, flumequine, and emmamectin (Exhibit #20)

November 21, 2007 - oxolinic acid and flumequine (Exhibit #21)

November 27, 2007 – emmamectin (Exhibit #21)

February 1, 2008 – emmamectin (Exhibit #22)

July 9, 2007 – emmamectin (Exhibit #22)

May 12, 2007 - emmamectin (Exhibit #21)

Discussion with Management: Ms. Contreras stated that Marine Harvest responded to an FDA warning letter dated August 14, 2003 on November 12, 2003 (Exhibit #23). FDA responded on a letter dated January 14, 2004 stating that: "With reference to the use of aquaculture drugs, specifically, oxolinic acid and flumequine, the control methods implemented by your firm appear adequate." (Exhibit #24) The firm continued to use these drugs, but has a program to keep them under control and has worked on reducing the amounts used each year (Exhibit #25).

OBSERVATION 2

Your sanitation control records do not accurately document the conditions or practices observed at your firm.

Specifically, we observed chipped concrete, flaking paint, and brown residue spots in the pass through to Filleting Line #3, where operators were beheading salmon. Also, we observed a rough weld in the ice maker's chute in the Gutting Area; a gap approximately 3/4" under a docking door in the Cold Storage Area; gaps on the walls in the Main Packaging Warehouse; and the chlorine concentration in the sanitizer solution bin in the Cart Washing Room was over 200 ppm on April 24, 2008. Sanitation monitoring records for that day did not reflect these observations.

Reference: 21 CFR 123.11(b)

Supporting Evidence and Relevance: Sanitation monitoring records must reflect actual conditions to ensure that sanitation problems are adequately identified and corrected. Sanitation records for April 24, 2008 showed that areas stated above were in good and acceptable conditions (Exhibit #15).

We observed chipped concrete, flaking paint, and brown residue spots in the pass through to Filleting Line #3, where operators were beheading salmon (Exhibit #26). Also, we observed a rough weld in the ice maker's chute in the Gutting Area (Exhibit #27); a gap approximately 3/4" under a docking door in the Cold Storage Area (Exhibit #28); gaps on the walls in the Main Packaging Warehouse; and the chlorine concentration in the sanitizer solution bin in the Cart Washing Room was over 200 ppm on April 24, 2008.

Discussion with Management: Management agreed with the observations and corrected some before the end of the inspection. Details of corrections verified during the inspection are included in the Voluntary Corrections Section of this EIR.

REFUSALS

No refusals were encountered during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

Mr. Molina, Ms. Contreras, Mr. Silva, Mr. Ojeda, Andres Perez, Chief of Receiving and Hygene, Levi Rivera, Chief of Maintenance, Patricio Acuna, Shift Manager, and Bernandita Utevoron, Shift Manager, were present during the discussion with management. We issued an FDA 483 to Mr. Molina during this discussion on April 25, 2008. Details of the observations listed in the FDA 483 and its discussion are included in the Objectionable Conditions and Management's Response Section of this EIR.

Metal detection was identified as a critical control point (CCP) for vacuum packed products only. We stated that it must be identified as a CCP for all products since they are processed very similarly and it is a hazard that is reasonably likely to occur.

Ms. Mercado suggested more specific verification procedures for drug and chemical residues in the receiving CCP.

Then, we explained the process after the inspection and that we're not in charge of deciding what the next action is, but if they show that they are correcting the issues noted during the inspection, it may be taken under consideration by the people in charge of making future decisions regarding this inspection.

ADDITIONAL INFORMATION

No additional information was noted during this inspection.

SAMPLES COLLECTED

No samples were collected during this inspection.

VOLUNTARY CORRECTIONS

Observations listed in the FDA 483 issued during the last inspection on September 12, 2006, included: HACCP plan did not list the food safety hazard reasonably likely to occur and no

verification procedures at receiving. We verified that all observations were corrected during the current inspection.

During the walk-through, we observed chipped concrete, flaking paint, and brown residue spots in the pass through to Filleting Line #3, where operators were beheading salmon. Also, we observed a gap approximately 3/4" under a docking door in the Cold Storage Area; and gaps on the walls in the Main Packaging Warehouse. Ms. Finn verified on April 25, 2008 that residue was cleaned off the ceiling above pass through to the filleting line and that the biggest gaps in the Main Packaging Warehouse were closed.

EXHIBITS COLLECTED

Exhibit #1	List of firms affiliated to Cultivadora de Salmones Linao Ltda.
Exhibit #2	List of customers in the US
Exhibit #3	List of products manufactured on-site including products distributed in the US
Exhibit #4	Technical sheets for products manufactured on-site
Exhibit #5	Labels collected during the inspection
Exhibit #6	Management structure and key personnel
Exhibit #7	Firm's Quality Assurance Program
Exhibit #8	Trim D skin-on fresh Atlantic salmon fillets flow diagram
Exhibit #9	Basic feed formula
Exhibit #10	Whole salmon flow diagram
Exhibit #11	On-site well information
Exhibit #12	List of chemicals used on-site
Exhibit #13	Trim D skin-on fresh Atlantic salmon fillets HACCP plan
Exhibit #14	SSOP
Exhibit #15	Production records for April 24, 2008, including sanitation and raw material records
Exhibit #16	Third party laboratory information
Exhibit #17	Explanation of the manufacturing code used on-site
Exhibit #18	Table with drug allowances in different markets, including Chile
Exhibit #19	Drugs treatments used by the firm
Exhibit #20	Some receiving records for February 14, 2008
Exhibit #21	Some receiving records for December 26, 2007
Exhibit #22	Laboratory results showing emmamectin
Exhibit #23	Firm's response to a warning letter dated November 12, 2003
Exhibit #24	FDA letter dated January 14, 2004
Exhibit #25	Outline of the firm's Drug Usage Program

Exhibit #26 Photographs of wall on top of Filleting Line #3
Exhibit #27 Photograph of rough weld on ice machine
Exhibit #28 Photograph of gap under docking door in the Cold Storage Area
Exhibit #29 FDA 525 – Sample Package Identification containing CD-R with inspection's photographs

ATTACHMENTS

Attachment #1 FDA 483 Inspectional Observations

Tania K. Mercado, Investigator

Mary M. Finn, Investigator

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SUMMARY

The comprehensive inspection of this manufacturer and distributor of cooked salmon products was conducted in accordance with C.P. 7303.842, Domestic Fish and Fishery Products, C.P. 7303.842H, Seafood HACCP under FACTS Assignment #934564, OP ID #3653672.

The previous FDA inspection of Cuisine Solutions was conducted on September 8, 2006 by Frank Sedzielarz. Observations noted during the inspection included: HACCP plan not specific to the kind of fish or fishery product processed, no critical control point for allergens, no time identified in the critical limits for pasteurization, no temperature device calibration for the cooking critical control point, and no sanitation records for cross-contamination and food contact surfaces. An FDA 483, Inspectional Observations, was issued to Alex Miquel on September 8, 2006. The inspection was classified OAI.

The current inspection was conducted on April 28, 29, and 30, 2008. It focused on grilled salmon teriyaki and covered the firm's HACCP Plan and Hazard Analysis, warehouse operation, individual responsibility, manufacturing, sanitation, shipping/receiving, product storage and distribution, pest control, and the structural conditions of the building. The firm processed and packaged the product covered during the inspection.

An FDA 483, Inspectional Observations, was issued to Alex Miquel, Chief Operating Officer, on April 30, 2008. Observations listed in the FDA 483, included: critical limits do not ensure control of the aquaculture drugs hazard, [redacted] and [redacted] critical control points not listed in the HACCP plan, lack of verification procedures and frequencies for cooking, and HACCP plan not specific to the kind of fish or fishery product processed. Mr. Miquel agreed to review the observations and respond accordingly. We verified that observations listed in the last FDA 483 issued to the firm on September 12, 2006 were corrected, except for HACCP plan not specific to the kind of fish or fishery product processed, even though it applied to a different product.

No reconciliation exam was performed, no labels or samples were collected, and no refusals were encountered during the current inspection.

ADMINISTRATIVE DATA

Inspected firm:	Alimentos Cuisine Solutions
Location:	Ruta 5 Sur - km. 1029 Pto Monte, Chile
Phone:	56 65 277 900
FAX:	
Mailing address:	61 Sta Teresa Pto Monte, Chile
Dates of inspection:	4/28/2008, 4/29/2008, 4/30/2008
Days in the facility:	3
Participants:	Tania K. Mercado, Investigator Mary M. Finn, Investigator

We displayed credentials to Alex Miquel, Chief Operating Officer, and most responsible person on-site. The actual dates in the plant were April 28, 29, and 30, 2008. An FDA 483 was issued to Mr.

Miquel on April 30, 2008. Mr. Miquel participated during the General Discussion with Management.

The firm is also regulated by Servicio Nacional de Pesca (Sernapesca), a Chilean Regulatory Agency. Sernapesca certifies fish and fishery product firms that want to export products as part of the requirements, Sernapesca conducts [redacted] inspections to validate the firms' HACCP plan and the firms' quality control system. The firms' quality control system is inspected [redacted] Firms are rated based on observations. If a firm rates between 1 and 3, they can export their products. The last Sernapesca's inspection was conducted on March 26, 2008 and was classified as 1.

The United States sister company of Alimentos Cuisine Solutions (Cuisine Solutions) audits this site [redacted]. Customers, including [redacted] conduct audits of this site as well.

Investigator, Mary Finn and I wrote all the sections in this establishment inspection report (EIR).

HISTORY

Firm's history has not changed since the last inspection on September 8, 2006, unless otherwise stated below. The parent company is Inverciones Estefal Limitada in Germany and the Cuisine Solutions headquarters are Alimentos Cuisine Solutions Chile S.A. located in Santiago, Chile (Exhibit #1).

[redacted] is the primary processing plant that raises and harvests the salmon. [redacted] is affiliated with Cuisine Solutions. Other plants affiliated to these two firms can be found in Exhibit #1.

The previous FDA inspection of Cuisine Solutions was conducted on September 8, 2006 by Frank Sedzielarz. Observations noted during the inspection included: HACCP plan not specific to the kind of fish or fishery product processed, no critical control point for allergens, no time identified in the critical limits for pasteurization, no temperature device calibration for the cooking critical control point, and no sanitation records for cross-contamination and food contact surfaces. An FDA 483, Inspectional Observations, was issued to Alex Miquel on September 8, 2006. The inspection was classified official action indicated (OAI).

The firm operates Monday through Saturday [redacted] It has approximately [redacted] employees on-site and approximately [redacted] employees work in production.

All correspondence should be sent to:

Alex Miquel
Chief Operating Officer
Alimentos Cuisine Solutions
Ruta 5 Sur - km. 1029
Pto Monte, Chile

INTERSTATE COMMERCE

Products are shipped by sea, except for samples. [redacted] serves as the broker and they keep HACCP plans for all the products manufactured at the Chilean site. The contact is [redacted] QA Manager. Her phone number is [redacted] and the email address is [redacted]

Liquid smoke used in Seared Peppered Smoked Salmon is supplied by [redacted] and [redacted]

JURISDICTION

All products manufactured on-site are distributed frozen and vacuum packed. The firm processes approximately [redacted] of raw fish [redacted]. Product for distribution in the US are primarily oven-ready salmon with sauce and is partially cooked at this plant. The only other product distributed in the US is a ready to eat crab product.

The process observed during the inspection consisted of salmon portions in teriyaki sauce. The teriyaki sauce's ingredients are light soy sauce, sake, sake vinegar, sugar, water, and starch.

A list of products processed at this plant, including products distributed in the US (Exhibit #1) and technical sheets, including labels, for products distributed in the US (Exhibit #2) were collected during this inspection. The product code that starts with [redacted] is for product to be distributed to the US.

Labeling agreements were not covered during this inspection. [redacted] is the brand name used for products distributed in the US.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Mr. Alex Miquel, Mr. Claudio Pavez, Mr. Juan Petersen's responsibilities have not changed since the last inspection on September 8, 2006. Other corporate and administrative officers and key plant personnel are included in Exhibit #1.

Ms. Marcia Fernandez, Quality Control Assistant, assists Mr. Petersen. All the people mentioned in this section accompanied us during various periods of the inspection, answered questions, and provided documents.

FIRM'S TRAINING PROGRAM

The firm's written training program states that operators will be trained annually in good manufacturing practices (GMPs) and HACCP concepts (Exhibit #3). HACCP training certificates for members of the firm's HACCP team were collected during the inspection (Exhibit #4).

MANUFACTURING/DESIGN OPERATIONS

I verified that the manufacturing process has not changed since the last inspection on September 8, 2006. The process is discussed in this EIR to include more details. Trim E salmon portions in teriyaki sauce were processed during our visit (Exhibit #5).

Mr. Miquel stated that Cuisine owns the salmon eggs. The salmon processing prior to arriving at the production plant has three stages. Stage 1 is the fresh water cycle, where smolts are kept in cages in rivers, approximately 200 km north of the plant in Puerto Montt, until they weight approximately [redacted] This stage takes approximately [redacted]. When this stage is completed, the smolts are transported in trucks and boats to the sea. Stage 2 consists of [redacted] in the Rio Negro Region where salmon are kept in cages in the sea. Atlantic and Koho salmon and trout are grown in these sites. There is only one species per site. They are kept in these cages for approximately [redacted] Stage 3 is performed at the primary plant where slaughtering is done. Feed composition was collected during the inspection (Exhibit #6).

Ms. Contreras stated that a salmon cage can not be released until it is sampled for drug residues and Sernapesca approves it. Therefore, each cage is analyzed once it is opened. Temperature is used to make the salmon dormant and the salmon are killed by knocking them on the head with a mechanically operated hammer.

Processing of grilled salmon teriyaki

The teriyaki sauce is usually prepared the day before salmon arrives. All the ingredients are weighed in Preparation Room #3A (Exhibit #7) and cooked in a steam jacketed kettle at approximately [redacted]. Then, the sauce is cooled to [redacted]. Finally, it is pumped to a cooling mixer until it reaches [redacted]. It takes approximately [redacted] for the sauce to cool down from [redacted] and a dial thermometer is used to monitor the temperature. The cold sauce is stored in a cooler until it is ready to be mixed with the salmon.

Ms. Finn observed rough welds inside the steam jacketed kettle (Exhibit #8) where the teriyaki sauce is prepared, during the inspection. She pointed out the observation to Mr. Miquel.

The salmon are received from [redacted] the same day it is harvested. The [redacted] facility is approximately 50 miles south of Cuisine Solution's plant. The salmon are unpacked in the Salmon Storage Room, where it is labeled, visually inspected, and the temperature is measured. According to Mr. Petersen, salmon are not stored in this room for [redacted]

Other ingredients are opened in the Unpacking Room and they are stored in the Dry Storage Cooler, except for frozen ingredients that are stored in the Frozen Storage, until they are used in production. Temperature in the Frozen Storage is recorded digitally [redacted].

Allergens are identified with a green sticker and segregated inside the cooler. The list of products containing allergens is posted at various locations throughout the firm (Exhibit #9).

Salmon is portioned on-site. It is kept cold through the process to prevent decomposition and dehydration. Salmon is salted with approximately [redacted] salt for taste.

Then, salmon is transferred to the Kitchen, where it is cooked enough to produce grill marks on one side. After grilling, the salmon's temperature is [redacted] inside blast cooler #8.

The cold salmon are weighed, mixed with the teriyaki sauce (Exhibit #10), and vacuum packed in the Pack Sealing Area. Technical sheets for the films used to vacuum pack products on-site were collected during the inspection (Exhibit #11). The film used depends on product's specifications, the film used for the teriyaki salmon is [redacted] After the teriyaki salmon is packed, it is placed in trays.

The vacuum packed teriyaki salmon is stored in the [redacted] Cooler #13 prior to pasteurization. Teriyaki salmon can be stored in this cooler for a day.

Pasteurization is performed in the [redacted] (Exhibit #12). This process consists of five phases. Phase 1: the tank is loaded with [redacted] of packaged product, hot water is pumped into the tank, the water temperature [redacted] and held at [redacted]. Phase 2: The temperature is allowed to [redacted] and held at that temperature for [redacted] Phase 3: This phase is listed as a critical limit for the Cooking CCP in the Cooked Fish HACCP Plan. The critical limit is a product temperature of [redacted]. Phase 4: The hot water is pumped out and cold water from a different tank is pumped in to [redacted]. Phase 5: The temperature is [redacted] by pumping in refrigerated water, this process takes roughly [redacted] (Exhibit #13). Studies perform on the [redacted] (Exhibit #14) were used to develop cooking specifications for the teriyaki salmon. [redacted] depending on the product scheduled to be cooked and the [redacted] cooks the product depending on [redacted] specifications. Temperature inside the [redacted] is monitored by inserting a probe in one of the packs on the top of the tank. According to Mr. Petersen, heat distribution studies showed that the top is the coldest spot in the tank, since water is pumped from the bottom. There is a second probe in the bottom of the tank that is used to measure the water temperature inside the tank.

The teriyaki salmon finishes cooling at the [redacted] Cooler #15. It can be stored in this cooler for a day. It is finally frozen in the Freezing Tunnel #30 and stored in Freezer #18 until it is ready for packaging. The teriyaki salmon is then weighed, passed through a metal detector, labeled, and palletized in the Packaging Area.

Freezer #19 is used to store finish product. Product can not be stored in this freezer for more than one day. The freezer has two sections used for sorting product prior to shipping.

Smoked flavored salmon process

Smoked flavored salmon process was briefly covered during the inspection (Exhibit #15). Mr. Miquel stated that customers requested the name Seared Peppered Smoked Salmon even though the salmon is not technically smoked, but smoke is only used for flavor. [redacted] the liquid smoke that diluted in water is used for flavoring in Inversion Chamber #3B.

Portioned salmon is immersed in a tank with diluted smoke for [redacted] at room temperature approximately [redacted]. Then, it is seared cooked in the Kitchen, cooled, seasoned with pepper, and vacuum pack. The rest of the process is the same as the teriyaki salmon.

Sanitation

Mr. Miquel stated that the shift's last hour is dedicated to cleaning. There is a central sanitation system that dispenses water, detergent, and sanitizer throughout the plant. The system alternates the use of sanitizers between quaternary ammonia and acetic acid. Mr. Petersen stated that there is a person in charge of drying the condensation in the plant.

Trays, utensils, carts, cutting boards, and conveyer belts were being washed in Tray Washing Area #20 at the time of the inspection. First, they are washed by hand and then they are placed in a machine that rinses, sanitizes with chlorine, and rinses again.

Water used on-site comes from a [redacted] deep well located on the property. The last [redacted] test prior to the inspection was performed on March 26, 2008 and the last [redacted] test was on September 10, 2007 (Exhibit #16). Chlorine is tested on-site [redacted] by an outside laboratory, and more in depth annually (Exhibit #17). Water is not reused on-site, but it is treated with a degreaser prior to be discarded.

The toilet facilities were equipped with water, soap, paper towels, toilet tissue, trash receptacle, and working toilet and sinks during the inspection.

A list of chemicals used on-site was collected during the inspection (Exhibit #18). Quaternary ammonia is used for foot baths, a general detergent is used for overall cleaning, chlorine is used for sanitation, and acetic acid is used on surfaces.

No signs of pests were observed during the inspection. Rodent bait stations are located around the exterior of the building (Exhibit #7) and property perimeters.

Seafood HACCP

The seafood HACCP plan on-site at the time of the inspection was last revised on April 20, 2008. The firm's HACCP manual contains process descriptions, hazard analyses, and HACCP plans for products manufactured on-site (Exhibit #19). Final product verification procedures are included in separate document (Exhibit #20). The firm also maintains detailed sanitation standard operation procedures (SSOPs) (Exhibit #21)

[redacted] probes are calibrated [redacted] (Exhibit #22) using a standard thermometer (Exhibit #23). Probes located in cold storage areas and [redacted] hand held thermometers are calibrated [redacted] (Exhibit #24).

The harvest salmon laboratory reports are sent electronically by third party laboratories. [redacted] uses only the following laboratories which are approved by Sernapesca (Laboratorio de Farmacologia Veterinaria de la Facultad de Ciencias Veterinarias y Pecuarias de la Universidad de Chile, SGS Aquatic Health Chile Ltda., BioQuality S.A., Corthorn Quality (Chile) S.A., Laboratorio del Pacifico, and Laboratorio Inspectorate Chile Ltda). [redacted] is used by [redacted] (Exhibit #25). There is no laboratory on-site.

We randomly selected different lots processed on April 29, 2008, February 22, 2008, and October 8, 2007 and reviewed critical control point monitoring records of receiving, pasteurization, and metal detection. We also reviewed verification records, such as sanitation monitoring records, supplier's certificates, and laboratory results. Overall, the required records are maintained by the firm.

MANUFACTURING CODES

Lot numbers are consecutive numbers assigned per product, production date (PO), and batch number. The production date is defined as the date salmon is received and the batch number is a consecutive number per cooking batch starting with the first batch in the PO. The lot number can change if any of the ingredients' lots changes or the production dates changes. Processing of Lot #15761 was observed during the inspection. Batch numbers 01 through 07 were used, since seven batches were cooked on April 29, 2008. Lot #4045 was assigned to the salmon used in Lot #15761 when it received on-site.

COMPLAINTS

The firm has a complaint procedure (Exhibit #26). In summary, costumers call the number on the product label, which connects them to the office located in [redacted] This office sends an email to the firm in Puerto Montt describing the complaint. Quality Control enters the information in the Claim/Comment Document and conducts an investigation. Investigation conclusions and corrective actions are also included in the document.

RECALL PROCEDURES

The firm maintains a written recall procedure on-site (Exhibit #27).

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

Your HACCP plan lists a critical limit that does not ensure control of one or more hazards.

Specifically, your HACCP plan lists a critical limit of aquaculture drugs at the receiving critical control point that does not ensure the control of the use of unapproved drugs. Levels of emmamectin, oxolinic acid, and flumequine were detected in salmon and reported on laboratory reports dated March 31, 2008. Levels of emmamectin were reported on September 13, 2007, September 8, 2007, and August 7, 2007. Product information reports from your salmon supplier showed that salmon was treated with emmamectin benzoate, oxolinic acid, and flumequine at different periods of time between October 2006 and January 2008. These reports were provided for salmon used in products distributed or in-process to be distributed to the US.

Also, the cooking critical control point in your HACCP plan does not list the time intended for pasteurizing salmon products to be shipped to the US.

Reference: 21 CFR 123.6(c)(3)

Supporting Evidence and Relevance: According to the Fish and Fisheries Products Hazards and Controls Guidance: *Third Edition* June 2001, "Unregulated/unapproved drugs administered to aquaculture fish pose a potential human health hazard. These substances may be carcinogenic, allergenic, and/or may cause antibiotic resistance in man. FDA must approve all drugs, whether for direct medication or for addition to feed to control this hazard in food animals. Under certain conditions authorized by FDA, unapproved new animal drugs may be used in conformance with the terms of an Investigational New Animal Drug (INAD) application."

Emmamectin benzoate, oxolinic acid, and flumequine are not listed as approved drugs by FDA. Therefore, they pose a potential human health hazard. Also, the firm has not submitted any INAD application for these drugs nor was they are conducting clinical studies for any other firms.

Records for salmon used to produce teriyaki salmon on April 29, 2008 contained a report of analysis dated March 31, 2008 documenting that emmamectin, oxolinic acid, and flumequine were detected in salmon portions sampled on March 27, 2008 (Exhibit #28). Also, the Product Information Superior Marine Reports for the salmon from cage Ica – 02 showed dates when salmon was treated with emmamectin benzoate, oxolinic acid, and flumequine. Emmamectin was detected, according to the analysis reports dated August 17, 2007 (Exhibit #29) for the salmon used in the October 8, 2008 production. The final product verification dated September 13, 2007 (Exhibit #30) and analysis reports dated September 8, 2007 for salmon used on February 22, 2008 production (Exhibit #31) also showed emmamectin was detected.

Discussion with Management: We provided the list of approved drugs located on the Center for Veterinary Medicine's (CVM) website. We explained to them that if the drug is not listed in the approved drugs list or if it is listed in 21 CFR 530.41, they are not allowed to use the drug to treat salmon destined to be distributed in the US, not even if they meet withdrawal periods and no tissue residue can be detected. Also, we suggested they contact the Center for Food Safety & Applied Nutrition (CFSAN) for further clarification and discuss the use of these drugs. Mr. Miquel stated that they were going to contact Sernapesca and CFSAN.

OBSERVATION 2

Your HACCP plan does not list one or more critical control points that are necessary for each of the identified food safety hazards.

Specifically, your HACCP plan for does not list the cooked fish critical control point(s) at [redacted] processing steps necessary to control growth of Clostridium botulinum in vacuum packed containers.

Reference: 21 CFR 123.6(c)(2)

Supporting Evidence and Relevance: Due to the amount of time that the vacuum packaged product spends in these coolers, we considered that they need to be identified as critical control points (CCPs). Mr. Miquel stated that the product can be stored vacuum packed for up to [redacted] before freezing. Even though the descriptions for these processing steps state that the product can not be stored in the [redacted] coolers for [redacted]. The firm monitors these processing steps' temperatures at by reading the probe readout and recording it [redacted], if product is stored in the cooler (Exhibit #29, Pages #10 and 11), but they are not calibrating the probes.

Discussion with Management: Mr. Miquel agreed with the observation and stated that they would probably continuously monitor the temperature in the pre and post-Thermix coolers. Mr. Miquel also stated that management will discuss alternatives on how to resolve these issues.

OBSERVATION 3

Your HACCP plan lists verification procedures and frequencies that have not been developed in accordance with 21 CFR 123.8(a) to ensure that your HACCP plan is adequate to control food safety hazards, and is being effectively implemented.

Specifically, your HACCP plan for cooked fish does not include verification procedures and frequencies for the monitoring and record review of any of the critical control points listed in the plan.

Reference: 21 CFR 123.6(c)(6)

Supporting Evidence and Relevance: Verification procedures and frequencies are included in the plan as a reminder that the firm needs to confirm that HACCP based controls implemented in the process are working adequately. The HACCP plan for cooked fish does not include verification procedures and frequencies for any of the CCPs identified by the firm, including instrument calibration, finish product testing, and records review (Exhibit #19).

Discussion with Management: Finish product verification tests (Exhibit #20) and calibration procedures (Exhibit #22) are included in separate procedures. Ms. Mercado suggested that they should be included in the HACCP plan or make reference to the procedures in the plan's verification column.

Mr. Pavez stated that on-site visits are conducted to monitor [redacted] processes prior to receiving and Mr. Miquel is also a manager at [redacted] but there are no procedures or records for the visits. Ms. Mercado stated that they should take credit and have documentation, especially if they are already doing it. Mr. Miquel agreed with the observation and stated that they are going to discuss alternatives on how to resolve these issues.

OBSERVATION 4

Your HACCP plan is not specific to the kind of fish or fishery product processed.

Specifically, your firm does not have a specific HACCP plan for stuffed salmon with crab, since the process has additional steps with microbiological hazards.

Reference: 21 CFR 123.6(b)

Supporting Evidence and Relevance: Every firm that process fish or fishery products needs to develop a HACCP plan if necessary from the conclusions of the hazard analysis. If products have the same hazards, they can be groped in the same plan. The firm needs to demonstrate, which products are included in the plan and that they have the same hazards.

Even though we did not covered the crab stuffed salmon process during the inspection, Mr. Pavez stated that the product is cooked with the crab inside. Therefore, the process and the critical limits for the cooking CCP are different (Exhibit #32).

Also, this observation was listed in the FDA 483 issued to the firm on September 8, 2006, but the observation referred to other products.

Discussion with Management: Mr. Miquel agreed with the observation and stated that they are going to discuss alternatives on how to resolve these issues.

REFUSALS

No refusals were encountered during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

Mr. Miquel, Mr. Pavez, Mr. Petersen, Mr. Carlos Menen, Chief of Personnel; Mr. Mario Molina, Maintenance Assistant; and Ms. Fernandez were present during the discussion with management. We issued an FDA 483 to Mr. Miquel during this discussion on April 30, 2008. Details of the observations listed in the FDA 483 and its discussion are included in the Objectionable Conditions and Management's Response Section of this EIR.

Ms. Finn suggested Mr. Miquel to use another thermometer to measure the temperature in the [redacted] because according to the "Calibracion [redacted] Reporte Digital" ([redacted] Calibration Digital Report) (Exhibit #33) the [redacted] probes were reading higher than the standard thermometer. The standard thermometer has a +/- 2° C acceptable range (Exhibit #23), but the critical limit for the product is [redacted] If the thermometer is reading higher, there is a possibility of having undercooked product in such short amount of time and since they calibrate the [redacted] there is a possibility that the product manufactured in the whole month could be undercooked. Mr. Miquel agreed with the observation. He stated that they could calibrate the [redacted] more often and will look study the alternatives to resolve the issue.

Cooking was identified as an optional processing step. Ms. Finn stated that they should not identify it as optional since it is one of the CCPs. Mr. Miquel agreed and will correct the plan.

Salmon is immersed for [redacted] in a liquid smoke solution (Exhibit #15) during the seared pepper smoked salmon proess. Ms. Mercado suggested that the salmon's internal temperature or the bath temperature should be monitored, due to the amount of time it remains immersed in the solution. Mr. Miquel stated that he thinks that water maintains the temperature, since the room temperature is controlled, but he is going to monitored to verify how cold it is.

During the walk-though outside the building, we observed beams stored near the receiving area (Exhibit #34). Mr. Petersen stated that they were removed during this discussion.

ADDITIONAL INFORMATION

Ceviche was imported to the US for a convention on October 2007. There was also another shipment of hake on August 2007. Mr. Pavez stated that the ceviche and hake were shipped frozen and were sent as samples. Also, they are planning to send a shipment in September 2008 for another convention. We saw records for the ceviche shipment, which stated that it was a sample.

SAMPLES COLLECTED

No samples were collected during this inspection.

VOLUNTARY CORRECTIONS

The previous FDA inspection of Cuisine Solutions was conducted on September 8, 2006 by Frank Sedzielarz. Observations noted during the inspection included: HACCP plan not specific to the kind of fish or fishery product processed, no critical control point for allergens, no time identified in the critical limits for pasteurization, no temperature device calibration for the cooking critical control point, and no sanitation records for cross-contamination and food contact surfaces. An FDA 483, Inspectional Observations, was issued to Alex Miquel on September 8, 2006. We verified that observations listed in the last FDA 483 issued to the firm on September 12, 2006 were corrected, except for HACCP plan not specific to the kind of fish or fishery product processed, even though it applied to a different product.

EXHIBITS COLLECTED

Exhibit #1	Cuisine Solutions general business information collected during the inspection
Exhibit #2	Product technical sheets including labels
Exhibit #3	Training procedures
Exhibit #4	Training certificates from members of the HACCP Team
Exhibit #5	Teriyaki salmon work instructions
Exhibit #6	Feed composition used by [redacted] to feed salmon
Exhibit #7	Floor plan
Exhibit #8	Photographs of kettle used to process teriyaki sauce
Exhibit #9	List of allergens used on-site
Exhibit #10	Abbreviated teriyaki salmon work instructions
Exhibit #11	Specifications for film used in vacuum packs
Exhibit #12	[redacted] photographs

Exhibit #13	Sample of a [redacted] cooking record
Exhibit #14	Teriyaki salmon cooking studies
Exhibit #15	Seared peppered smoked salmon work instructions
Exhibit #16	Last well tests prior to the inspection
Exhibit #17	Water tests procedure
Exhibit #18	List of chemicals used on-site
Exhibit #19	HACCP plan for cooked fish
Exhibit #20	Finish product verification procedure
Exhibit #21	SSOP
Exhibit #22	Calibration procedure
Exhibit #23	Certificate of calibration of the standard thermometer
Exhibit #24	[redacted] thermometer specifications and sample of a calibration log
Exhibit #25	List of third party laboratories used by the firm
Exhibit #26	Complaints procedure
Exhibit #27	Recall procedure
Exhibit #28	Records for teriyaki salmon manufactured on April 29, 2008
Exhibit #29	Records for teriyaki salmon manufactured on October 8, 2007
Exhibit #30	Analysis report dated September 13, 2007
Exhibit #31	Sworn declaration and analysis report of salmon used on February 22, 2008
Exhibit #32	Crab stuffed salmon cooking curves
Exhibit #33	[redacted] calibration digital report
Exhibit #34	Photograph of beams stored near the receiving area
Exhibit #35	FDA 525 – Sample Package Identification containing CD-R with inspection's photographs

ATTACHMENTS

Attachment #1	FDA 483	Inspectional Observations

Tania K. Mercado, Investigator

Mary M. Finn, Investigator

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SUMMARY

The comprehensive inspection of this manufacturer and distributor of salmon was conducted in accordance with C.P. 7303.842, Domestic Fish and Fishery Products, C.P. 7303.842H, Seafood HACCP under FACTS Assignment #934564, Operation ID #3653671.

The previous FDA inspection of Empresas Aquachile S.A. was conducted on September 6, 2006 by Frank Sedzielarz and Nancy Doyle. Observations noted during the inspection included: HACCP plan not specific per fish product, failure to list hazards, no record keeping system for monitoring, no monitoring frequencies, and no verification procedures for record review. An FDA 483, Inspectional Observations, was issued. The inspection was classified VAI.

The current inspection was conducted on April 21, 22, and 23, 2008. It focused on trim D scales off salmon fillets and covered the firm's HACCP Plan and Hazard Analysis,

warehouse operation, individual responsibility, manufacturing, sanitation, shipping/receiving, product storage and distribution, pest control, and the structural conditions of the building. During the inspection, the firm processed and packaged the product covered during the inspection.

We issued an FDA 483 to Rodrigo Cancino, Process Manager, on April 23, 2008. Observations listed in the FDA 483, included: critical limits do not ensure control of the aquaculture drugs hazard, verification procedures and frequencies not listed in the plan, and sanitation monitoring records did not accurately documented conditions observed in the firm. Mr. Cancino agreed to review the observations and respond accordingly. We verified that observations listed in the last FDA 483 issued to the firm on September 6, 2006 were corrected except for verification procedures not included in the HACCP plan.

No reconciliation exam was performed, no labels or samples were collected, and no refusals were encountered during the current inspection.

ADMINISTRATIVE DATA

Inspected firm:	Empresas Aquachile S.A.
Location:	Cardonal S/N, Lote B, Casilla 30-D Puerto Montt, Chile
Phone:	56 65 433 660
FAX:	
Mailing address:	Cardonal S/N, Lote B, Casilla 30-D Puerto Montt, Chile
Email:	N/A
Dates of inspection:	4/21/08, 4/22/08, 4/23/08
Days in the facility:	3
Participants:	Tania K. Mercado, Investigator, Mary Finn, Investigator

I displayed credentials to Gerardo Crot, Plant Manager and most responsible person on-site, on April 21, 2008. The actual dates in the plant were April 21, 22, and 23, 2008. An FDA 483 was issued to Mr. Cancino on April 23, 2008. Mr. Cancino participated during the General Discussion with Management.

The firm is also regulated by Servicio Nacional de Pesca (Sernapesca), a Chilean Regulatory Agency. Sernapesca certifies fish and fishery product firms that want to export products. As part of their requirements, Sernapesca conducts annual inspections to validate the firms' HACCP plan and the firms' quality control system. The firms' quality control system is inspected [redacted] Firms are rated based on observations. If a firm rates between 1 and 3, they can export their products. The last inspection was on March 27, 2008 and the firm received a rating of 1. Luis Cayo, Sernapesca's Veterinarian, briefly met with us on April 21, 2008 to introduce himself and welcome us to Chile.

The firm is also audited by customers, International Organization for Standardization (ISO), and IFS.

Investigator, Mary Finn and I wrote all the sections in this establishment inspection report (EIR).

HISTORY

Firm's history has not changed since the last inspection on September 6, 2006, unless otherwise stated below.

AquaChile, Inc. is the parent company and it is located at Empresas Aquachile's property. Other companies' part of AquaChile, Inc. includes:

Pesquera Antares (Reproduction Department)
Aquachile S.A. (Freshwater Stage)
Salmones Cailin S.A. (Slaughter and Frozen Products) located at Riquelme 165, Quellon, Chile, Manager: Julio Aravena
Empresas Aquachile S.A. (Seawater Processing)
Aguas Claras (Atlantic salmon and Rainbow Trout Fillets) located at Camino Caicaen SN, Calbuco, Chile, Manager: Jorge Albarran
Salmones Maullin located at Camino a Chinquihue, Km. 7, Puerto Montt, Chile, Manager: Cesar Hidalgo
Salmones Chiloe
Antarfood S.A. located at Camino a Huicha, Km.12, Chonchi, Chile, Manager: Francisco Mozo
Procesadora Huenocoihue Ltda. located at Sector Huenocoihue, Km. 1.5, Dalcahue, Chine, Manager: Marcelo Rivas

The previous FDA inspection was conducted on September 6, 2006 by Investigators Frank Sedzielarz and Nancy Doyle. Observations noted during the inspection included: HACCP plan not specific per fish product, failure to list hazards, no record keeping system for monitoring, no monitoring frequencies, and no verification procedures for record review. An FDA 483, Inspectional Observations, was issued. The inspection was classified voluntary action indicated (VAI).

The firm operates on Saturday [redacted]. It has approximately [redacted] employees on-site and approximately [redacted] employees work in production.

All correspondence should be sent to:

Mr. Rodrigo Cancino
Empresas Aquachile S.A.
Cardonal S/N, Lote B, Casilla 30-D
Puerto Montt, Chile

INTERSTATE COMMERCE

Approximately [redacted] of the firm's total production is distributed in the US (Exhibit #1). Product arrives in New York, Florida, and California. [redacted] is the firm's broker company in the US. The contact person is [redacted] and his phone number is [redacted].

All the salmon processed on-site is supplied by firms that are part of AquaChile, Inc. All feed for fish from AquaChile, Inc. is supplied by [redacted].

JURISDICTION

Mr. Felipe Espinosa, Environmental and Quality Manager, stated that the salmon is packed in boxes except for frozen that can be packed in vacuum sealed bags. They have not packed any modified atmosphere packaged (MAP), frozen marinated portions products, or have exported trout to the US [redacted] A list of products processed on-site (Exhibit #2), list of products distributed in the US (Exhibits #1 and 3), and labels for products distributed in the US (Exhibit #4) were collected during this inspection.

Labeling agreements were not covered during this inspection. [redacted] are the brand names used for products distributed in the US.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Changes to the individual responsibility since the last inspection on September 6, 2006, include:

Rodrigo Cancino, Process Manager, is in charge of several plants, including Empresas Aquachile.

Gerardo Crot, Plant Manager, is in charge of the Empresas Aquachile's plant.

Ulises Jara, Health Chief, answered questions regarding fish treatments and process before they arrive to Empresas Aquachile.

Stephen Gunther, Nutrition Quality Manager, answered most of the questions regarding feed used by AquaChile, Inc. for salmon.

Felipe Espinosa, Environmental and Quality Manager, and Claudia Aburto accompanied us during the inspection, answered most of the questions, and provided most of the documents.

FIRM'S TRAINING PROGRAM

There are no changes to report since the last inspection on September 6, 2006.

MANUFACTURING/DESIGN OPERATIONS

I have verified that the manufacturing process has not changed since the last inspection on September 6, 2006. The same process is used for all the seafood products manufactured on-site. Process is discussed in this EIR to include more details. Trim D scales-off Atlantic salmon was processed during our visit (Exhibit #5).

Processing of trim D scales-off fresh Atlantic salmon fillets

Ulises Jara, Health Chief, stated that AquaChile, Inc. owns and selects specific salmon families for reproduction. Eggs and smolts are grown in the hatcheries until the smolts weight approximately [redacted] This process takes approximately [redacted]. Then, they're transported in trucks to a lake until they weight approximately [redacted] Finally, they are brought to the sea where they grow in cages until they are big enough for production.

Mr. Jara stated that Astaxanthin is used for color in the fish. Astaxanthin is added to the feed and the fish ingest it. The feed consists of poultry and vegetable derivatives, fish meal, and oils (Exhibit #6). Fish meal consists mostly of anchovies and other small fish from South America that are too small for human consumption. It can't contain salmon, as required by Chilean regulations. Empresas Aquachile conducts on-site inspections of feed suppliers [redacted].

Once fish are big enough to be used by Empresas Aquachile, they are slaughter at [redacted]. or on-site at the salmon farm. Entrails and fish scraps are sold to another company to be used for pet food and fish oil. We did not see any salmon at receiving during this inspection, but according to Mr. Espinosa, salmon are shipped to the plant in bins immersed in seawater and ice slurry. At receiving, fish are washed in a high pressure spray water tunnel. According to Ms. Aburto, the salmon's internal temperature is measured at receiving.

Salmon are transported on a conveyor belt that passes them through a scale to [redacted] grading machines that sort the salmon in bins by weight. The bins are labeled with the firm's name, weighting date and time, grader machine, machine's basket, lot number, product name, description, and specie, site name and cage number, quality, size, total number of units, net weight, bin number, gutted or not, and a color sticker to identified day of the week. Quality can be premium or industrial. Premium salmon can be used for any product, but industrial can only be used for whole frozen fish. Salmon's internal temperature is measured at this step, according to Ms. Aburto.

Ice is added to the bins and they are transported to another conveyor belt through the filleting processing step. There are [redacted] filleting lines. A Trim D fillet means that the fish' gills, fat, and tail are cut manually. Also, bones and melanosis are manually removed. Machines fillet the fish and remove most of the bones. Fish scraps are placed in blue bins that are sent to [redacted] to be used as pulp and to be exported [redacted] Finally, fillets are graded again and bagged. Bags are left open on one end. The temperature in this processing area was approximately [redacted] at the time of the walk-through. This processing step takes approximately [redacted] from beginning to end and they process approximately [redacted].

Bagged fillets are transported to a cooling tunnel on a conveyor belt, where they are placed manually in the tunnel. Fillets are cooled in the tunnel for approximately [redacted] and the tunnel is approximately [redacted].

Another conveyor belt transports the fillets from the tunnel through a metal detector to the Packaging Area. Approximately [redacted] of fillets are packaged in each Styrofoam cooler. Coolers are marked with the number of units and trim type. Then, they are weight; approximately [redacted] are placed on top of the fillets. The coolers are labeled and sealed with plastic wrap (Exhibit #7) on the outside. Packed coolers are stored in a cooler until they are ready for shipment. According to Ms. Aburto, the temperature in the packaging area and the storage coolers is monitored [redacted].

Finished product destined for the US is shipped in contracted refrigerated trucks. The trip is approximately [redacted], where it is shipped by plane to the US. The flight from [redacted]

Processing of cured salmon fillets

We briefly covered this process (Exhibit #8) during the inspection. Fillets are placed in bins and cured with brine, the send to [redacted] for smoking. The temperature of the room where the fillets were stored in brine was [redacted] at the time of the inspection. Fillets are stored at the Pre-Cooler Area between the Coolers and the Curing Room (Exhibit #9).

Sanitation

A list of chemicals used on-site was collected during the inspection (Exhibit #10). Ms. Aburto stated the following:

Acetic acid [redacted]
Sodium metabisulfite [redacted]
Sodium nitrate and "eritorbato de sodio" [redacted]
Calcium hydroxide [redacted]

VQ-ROD Blue is quaternary ammonia [redacted]
DF-100 [redacted]
Ethyl alcohol [redacted]
Sodium hypochlorite [redacted]
Caustic soda [redacted]
Guardian green tea and nisaplin [redacted]

Mr. Espinosa stated that production areas are cleaned at lunch, between shifts, and a deeper cleaner is performed at the end of the second shift. A low pressure cleaning system delivers water, soap, and sanitizer at various locations throughout the production areas. Also, each work station at the filleting lines has a hose to be used during cutting. Indentations were observed on metal work stations where bones are removed manually during the walk-through on April 21, 2008 (Exhibit #11).

The firm's employees appear to be in good health with no visible cuts or open wounds. They wore disposable aprons that appeared to be clean, gloves, face masks, and hair nets. The toilet facility was equipped with water, soap, paper towels, toilet tissue, trash receptacle, and working toilet and sink. It did not have hot water, but the employees need to go through a controlled entrance to come in and out of the production area to use the bathrooms. The entrance has two foot baths, sinks with soaps, and paper towels.

No signs of pests were observed during the inspection. Rodent bait stations are located around the property and buildings' perimeters.

Seafood HACCP

The seafood HACCP plan on-site at the time of the inspection (Exhibit #12) was signed on September 23, 2005. A hazard analysis for products manufactured on-site (Exhibit #13), HACCP plans for all products manufactured on-site to be distributed to the US (Exhibit #14), sanitation standard operation procedures (SSOP) (Exhibit #15), and water analyses (Exhibit #16) were collected during the inspection.

Mr. Espinosa stated that harvesting areas are sampled [redacted] by Sernapesca for environmental and chemical contaminants, but the samples include only salmon not soil or water. Another third party company analyses the bottom sediments annually.

All salmon received on-site are accompanied with the supplier's certificate stating that fish is free of unapproved drugs and that withdrawal periods were maintained. Laboratory reports are attached with the certificate and are performed by third party laboratories (Exhibit #17). Empresas Aquachile uses only the following laboratories which are approved by Sernapesca (Laboratorio de Farmacologia Veterinaria de la Facultad de Ciencias Veterinarias y Pecuarias de la Universidad de Chile, BioQuality S.A., Corthorn Quality (Chile) S.A., Laboratorio Biovac, Laboratorio Cetecsal S.A., and

Laboratorio Inspectorate Chile Ltda) (Exhibit #18) and methods used by those laboratories were collected during the inspection (Exhibit #19).

The metal detector is calibrated [redacted] using iron and stainless steel standards.

We randomly selected different lots processed on April 21, 2008, February 2, 2008, and December 1, 2007 and reviewed receiving, and metal detector monitoring and verification records, such as sanitation monitoring records, supplier's certificates, and laboratory analysis. Overall, the required records are maintained by the firm.

MANUFACTURING CODES

Manufacturing codes have not changed since the last inspection on September 6, 2006.

COMPLAINTS

Complaints were not covered during this inspection.

RECALL PROCEDURES

Recall procedures have not changed since the last inspection on September 6, 2006.

FOOD AND COSMETICS SECURITY

Food and cosmetics security was not covered during this inspection.

RECONCILIATION EXAMINATION

No reconciliation exam was performed during this inspection.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

Your HACCP plan does not list a critical limit that ensures control of one or more hazards.

Specifically, the firm's plan for fresh salmon scales off does not states zero as the limit for drugs not approved by FDA. The Product Information Superior Marine Report for the salmon used to produce fresh salmon scales off on April 21, 2008 states that the salmon was treated with emamectin benzoate and flumiquine.

Reference: 21 CFR 123.6(c)(3)

Supporting Evidence and Relevance: According to the Fish and Fisheries Products Hazards and Controls Guidance: *Third Edition* June 2001, "Unregulated/unapproved drugs administered to aquaculture fish pose a potential human health hazard. These substances may be carcinogenic, allergenic, and/or may cause antibiotic resistance in man. To control this hazard in food animals, all drugs, whether for direct medication or for addition to feed, must be approved by FDA. Under certain conditions authorized by FDA, unapproved new animal drugs may be used in conformance with the terms of an Investigational New Animal Drug (INAD) application." Emmamectin benzoate and flumequine are not listed as approved drugs by FDA. Therefore, they pose a potential human health hazard. Also, the firm has not submitted any INAD application for these drugs nor was they are conducting clinical studies for any other firms.

Chile allows the use of emmamectin benzoate and flumequine as stated in the "Programa de Control de Farmacos, Manual de Procedimientos Seccion 1" (Pharmaceutical Control Program, Procedures Manual Section 1) published by the Gobierno de Chile Servicio Nacional de Pesca (Chilean Government Sernapesca) (Exhibit #20). A list of pharmaceutical products authorized to be used by Aquachile S.A. included: oxolinic acid and flumequine as antibiotics and emmamectin benzoate as an anti-parasite (Exhibit #21). A report of analysis dated January 3, 2008 showed emmamectin detected in salmon's skin and muscle sampled on December 14, 2007 (Exhibit #22). Product Information Superior Marine Reports for the salmon used to produce fresh salmon scales off on April 21, 2008 show dates when fish was treated with emmamectin benzoate and flumequine.

Discussion with Management: We provided the list of approved drugs located on the Center for Veterinary Medicine's (CVM) website and a photocopy of 21 CFR 530.41, Drugs prohibited for extra label use in animals. We explained to them that if the drug is not listed in the approved drugs list or if it is listed in 21 CFR 530.41, they are not allowed to use the drug to treat salmon destined to be distributed in the US, not even if they meet withdrawal periods and no tissue residue can be detected. Also, we suggested they contact the Center for Food Safety & Applied Nutrition (CFSAN) for further clarification and discuss the use of these drugs. Mr. Cancino stated that they were going to contact Sernapesca and CFSAN. Mr. Espinosa stated that he was going to research the use of these drugs because he believes there is evidence that the drugs are safe. Ms. Mercado suggested that they submit any documentation that supports their argument to CFSAN.

OBSERVATION 2

Your HACCP plan does not list verification procedures and frequencies that have been developed to ensure that the HACCP plan is adequate to control food safety hazards, and is being effectively implemented.

Specifically, verification procedures and frequencies for the receiving critical control point to control chemical contaminants and aquaculture drugs in your HACCP plan form for fresh salmon scales off were not listed in the plan. Also, verification procedures and frequencies for all the critical control points in you HACCP plan form for fresh salmon scales off do not include a review of monitoring, verification, and corrective action records within one week of preparation.

Reference: 21 CFR 123.6(c)(6)

Supporting Evidence and Relevance: Verification procedures and frequencies are included in the plan as a reminder that the firm needs to confirm that HACCP based controls implemented in the process are working adequately. The HACCP plan for fresh salmon and trout fillet, scales on or scales off, skin on or skin off does not include the collection of raw material, in-process product, or finished product at least quarterly and analyze for drug residues and chemical and environmental contaminants (Exhibit #12).

Also, the HACCP plan did not include the review of HACCP required records within one week of preparation (Exhibit #12). This observation was included in the FDA 483 issued to the firm during the last inspection on September 6, 2006.

Discussion with Management: Ms. Aburto provided a copy of the verification procedures that are part of the firm's HACCP manual in Spanish. The procedures state that [redacted] samples will be collected [redacted] and will be sent to the University of Chile's laboratory for drug residues, contaminants, and prohibited substances analyses and records will be reviewed daily (Exhibit #23). Also, Mr. Espinosa stated that Sernapesca requires them to send [redacted] samples of the raw material to be analyzed for the parameters above, but the parameters and species are rotated [redacted] Ms. Mercado stated that they need to include these procedures and frequencies to their English version of the HACCP plan and ensure that raw material or finished product is analyzed [redacted] for each parameter.

OBSERVATION 3

Your sanitation control records do not accurately document the conditions or practices observed at your firm.

Specifically, your sanitation control records for April 21, 2008 stated that conditions in the Receiving, Grading, Filleting, and Portion Sealing areas and the Packaging Warehouse were good and acceptable. During the plant's walk-through, we observed high chlorine concentration in the sanitizing bin in the Receiving Area; holes in the ceiling above and unsmooth surfaces on one of the grading machines in the Grading Area and production lines in the Filleting Are; approximately five holes in the ceiling above

filleting lines over 3/4" in diameter, no hot water in employee's bathrooms; rough welds on food contact areas of grading machines/drain bins; items both of the handwashing sinks in the production area; and insufficient space to inspect around materials and openings under the dock door/exterior walls in the Packaging Warehouse.

Reference: 21 CFR 123.11(b)

Supporting Evidence and Relevance: Sanitation monitoring records must reflect actual conditions to ensure that sanitation problems are adequately identified and corrected. Sanitation records for April 21, 2008 showed that areas stated above were in good and acceptable conditions (Exhibit #17).

A bin in the receiving area had a sign stating that the chlorine concentration was 100 ppm, but when the concentration was measured with a chlorine strip, it was 200 ppm.

The following observations were photographed during the walk-through: holes in the ceiling above and unsmooth surfaces on one of the grading machines in the Grading Area; indentations in metal work stations in the Filleting Area (Exhibit #11); approximately five holes in the ceiling above filleting lines over 3/4" in diameter; and insufficient space to inspect around materials and openings under the dock door/exterior walls in the Packaging Warehouse (Exhibit #24).

Discussion with Management: Management agreed with the observations and corrected some before the end of the inspection. Details of corrections verified during the inspection are included in the Voluntary Corrections Section of this EIR.

REFUSALS

No refusals were encountered during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

Mr. Cancino, Mr. Crot, Mr. Espinosa, and Ms. Aburto were present during the discussion with management. We issued an FDA 483 to Mr. Cancino during this discussion on April 23, 2008. Details of the observations listed in the FDA 483 and its discussion are included in the Objectionable Conditions and Management's Response Section of this EIR.

We explained that we only considered receiving and metal detection as critical control points (CCPs) and we only review records for these steps due to time constrains. Also, we explained that the firm can identify as many CCPs as they consider necessary, but that means that they have to maintain all the required records.

Ms. Finn suggested that the firm should monitor the cooler temperature, where the fillets in brine for smoking were stored [redacted] instead of [redacted]

[redacted] Mr. Cancino stated that they could monitor the brine's temperature instead of the room temperature.

Then, we explained the process after the inspection and that we're not in charge of deciding what the next action is, but if they show that they are correcting the issues noted during the inspection, it may be taken under consideration by the people in charge of making future decisions regarding this inspection.

ADDITIONAL INFORMATION

Ms. Finn suggested that the statement for storage conditions included in the label of the finished product for the US should include temperature in both degrees Celsius and Fahrenheit rather than just degrees Celsius.

SAMPLES COLLECTED

No samples were collected during this inspection.

VOLUNTARY CORRECTIONS

Observations listed in the FDA 483 issued during the last inspection on September 6, 2006, included: HACCP plan not specific per fish product, failure to list hazards, no record keeping system for monitoring, no monitoring frequencies, and no verification procedures for record review. We verified that all observations were corrected during the current inspection, except for the review of HACCP required records within one week of preparation.

During the walk-through, Ms. Finn observed two hand-washing stations in the Production Area that had gloves and other items placed in them in them and there were holes in the ceiling above a grading machine. Overall observations in the Packaging Warehouse included not enough space to inspect between aisles and a gap between the docking door and floor (Exhibit #24). On April 23, 2008, Ms. Finn verified that these observations were corrected.

EXHIBITS COLLECTED

Exhibit #1	Amount of firm's products distributed in the US
Exhibit #2	List of products manufactured on-site
Exhibit #3	Technical sheets for products distributed in the US
Exhibit #4	Labels for products distributed in the US
Exhibit #5	Trim D skin-off scales-off salmon process flow diagram
Exhibit #6	Basic feed formula
Exhibit #7	Photographs of packaging step
Exhibit #8	Cured products process flow diagram
Exhibit #9	Site's floor plan

Exhibit #10	List of chemicals used on-site
Exhibit #11	Photograph of indentations on metal work station
Exhibit #12	Trim D skin-off scales-off salmon HACCP plan
Exhibit #13	Hazard analysis for products manufactured on-site
Exhibit #14	HACCP plans for other products manufactured on-site
Exhibit #15	Firm's SSOPs
Exhibit #16	Water analyses
Exhibit #17	Production and sanitation records for April 21, 2008
Exhibit #18	List of laboratories approved by Sernapesca
Exhibit #19	Methods used in laboratories approved by Sernapesca
Exhibit #20	Sernapesca's Pharmaceutical Control Program
Exhibit #21	List of drugs used by AquaChile, Inc. and their technical sheets
Exhibit #22	Laboratory results dated January 3, 2008
Exhibit #23	Verification procedures from the Spanish version of the firm's HACCP manual
Exhibit #24	Photographs of some of the sanitation observations noted during the plant's walk-through
Exhibit #25	FDA 525 - Sample Package Identification containing CD-R with inspection's photographs

ATTACHMENTS

Attachment #1 FDA 483 Inspectional Observations

Tania K. Mercado, Investigator

Mary M. Finn, Investigator