UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

UNITED STATES OF AMERICA, Plaintiff, v. PORTLAND SHELLFISH COMPANY, INC., a corporation, and JEFFREY D. HOLDEN, SATYAVAN SINGH and JOHN A. MALONEY, individuals, Defendants.	)	Civil no. 2:11-cv-00001-JAW CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by Thomas E. Delahanty, II, United States Attorney for the District of Maine, having filed a complaint for injunctive relief against Portland Shellfish Company, Inc. ("Portland Shellfish"), Jeffrey D. Holden, Satyavan Singh, and John A. Maloney (collectively, "Defendants"), and Defendants having appeared and having consented to entry of this Decree without contest and before any testimony has been taken, without admitting any of the allegations in the Complaint and disclaiming any liability herewith, and the United States of America having consented to this Decree:

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The complaint for injunction states a claim for relief against Defendants under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et seq*.

3. Defendants have violated the Act, 21 U.S.C. § 331(a), by introducing into interstate commerce articles of food, as defined by 21 U.S.C. § 321(f), namely ready-to-eat, cooked fish and fishery products, that are adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) and (a)(4); and 21 U.S.C. § 331(k), by causing articles of food, namely ready-to-eat, cooked fish and fishery products, to become adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) and (a)(4) after shipment in interstate commerce.

4. Defendants and each and all of their officers, agents, employees, successors, assigns, attorneys, and those persons in active concert or participation with any of them, are perpetually restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from receiving, processing, preparing, packing, holding, or distributing, at or from their facilities located at 92 Waldron Way, Portland, Maine (the "Waldron facility") and 110 Dartmouth Street, South Portland, Maine (the "Dartmouth facility"), and any other locations at or from which Defendants receive, process, prepare, pack, hold, or distribute food, including any ready-to-eat, cooked fish and fishery products, unless and until:

A. Defendants have thoroughly cleaned and sanitized the facilities and equipment therein and made improvements, thereby rendering the facilities and equipment suitable for receiving, processing, preparing, packing, holding, and distributing articles of food;

B. Defendants have selected a person or persons ("*Listeria* expert"), other than an employee of Portland Shellfish, who by reason of background, experience, and education is qualified to develop a Hazard Analysis Critical Control Point ("HACCP") plan, a finished product testing program, a Sanitation Standard

Operation Procedure ("SSOP"), an employee training program on sanitary food handling techniques and personal hygiene practices, and an environmental microbial monitoring program for all species of the genus *Listeria* ("*L. spp.*") for the processing of ready-to-eat, cooked fish and fishery products;

C. The *Listeria* expert has developed a written finished product testing program for *Listeria monocytogenes* ("*L. mono*"), an SSOP, an employee training program, and an environmental microbial monitoring program for *L. spp.* for the processing of ready-to-eat, cooked fish and fishery products;

D. The United States Food and Drug Administration ("FDA") has reviewed and approved in writing the finished product testing program, SSOP, training program, environmental microbial monitoring program developed by the *Listeria* expert, and an ongoing program of adequate measures to control *L. mono*, as described in paragraph 5. FDA's review of the documents submitted pursuant to this subparagraph shall be completed as soon as is reasonably practicable;

E. Defendants, under the supervision of and in accordance with methods acceptable to FDA, have tested for *L. mono* all ready-to-eat, cooked fish and fishery products on hand at the Defendants' facilities, and any other locations at which Defendants receive, process, prepare, pack, hold, or distribute ready-to-eat, cooked fish and fishery products, before they are released for sale, in the following manner:

i. Defendants shall submit to FDA for approval before testing begins, a sampling plan for product testing which is scientifically based and ensures that the samples are representative of the entire lot and batch of product;

ii. Defendants shall select a competent, independent laboratory acceptable to FDA to perform the testing;

iii. The name of the laboratory shall be submitted to FDA for approval before the testing begins;

iv. All written reports of such examinations shall be submitted to FDA within two (2) calendar days after receipt by Defendants;

v. FDA is authorized to conduct additional analyses and examine the articles of food, as it deems necessary, to evaluate whether the articles contain pathogens; and

vi. All ready-to-eat, cooked fish and fishery products that contain *L. mono* or any other pathogen shall be destroyed by Defendants under FDA's supervision;

F. Defendants, along with their *Listeria* expert, have conducted appropriate hazard analyses and have prepared HACCP plans as required by 21 C.F.R. § 123.6(b) for all foods, including all ready-to-eat, cooked fish and fishery products, received, processed, prepared, packed, held, or distributed at the Waldron and Dartmouth facilities and any other facility at which Defendants conduct their food operations. These analyses must be performed and these plans must be designed to the satisfaction of FDA;

G. Defendants, along with their *Listeria* expert, develop and implement an ongoing program of adequate measures to control *L. mono*, as described in paragraph 5;

H. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of paragraph 4, conducts inspections of the facilities;

I. Portland Shellfish pays the costs of inspections, supervision, analyses, and examination by FDA at the rates specified in paragraph 6; and

J. FDA has notified Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 4(A)-(G) and (I) and with all requirements of 21 C.F.R. Parts 110 and 123.

K. This paragraph shall not prohibit the brokering of seafood that, at the time of entry of this Decree, Portland Shellfish is contractually obligated to purchase, provided that such seafood at no time enters or is held, stored, or processed at any facility owned, operated or controlled by Portland Shellfish.

5. Defendants shall have and implement an ongoing program of adequate measures to control *L. mono* ("*Listeria* program"). The *Listeria* program, consisting of validated methods and controls that are shown to FDA's satisfaction to eliminate *L. mono* in both cooked finished product and in the ready-to-eat areas of the facilities, shall include the following procedures, unless Defendants submit for and receive FDA's written approval for an alternate *L. mono* control program:

A. HACCP Plan Implementation. Implementation of a HACCP plan for ready-to-eat, cooked fish and fishery product, which is satisfactory to FDA, and includes, but is not limited to, critical control points, critical limits, and monitoring and record keeping procedures;

B. Effective and diligent sanitation procedures for cleaning and sanitizing manufacturing equipment and environment to minimize the risk of reintroducing *L.*

mono. These procedures shall consist of the SSOP and the training program developed by the *Listeria* expert pursuant to the provisions of paragraph 4(C) and shall be implemented on a continuous basis. If *L. spp.* is detected within the facilities, Defendants must institute immediate corrective actions to appropriately sanitize the area and further test for *L. mono* contamination;

C. An effective program for environmental monitoring and testing of manufacturing and storage environment to ensure that *L. spp*. is controlled within the ready-to-eat areas of the facilities and *L. mono* does not occur in the finished product.

The ongoing environmental microbial monitoring program shall ensure that the SSOP continues to eliminate the *L. mono* hazard and that the SSOP is consistently being followed. Environmental monitoring shall include collecting swab samples from food-contact surfaces, equipment, and other environmental sites throughout the facilities (where the fish or fishery products are received, prepared, packed, and held, up to and including final packaging, and common areas that could be reservoirs for cross-contamination), and analyzing such samples for the presence of *L. spp*. Environmental testing for *L. spp.* shall be performed in accordance with timetables and methods submitted to and approved in writing by FDA before testing begins. Defendants shall select a competent, independent laboratory to perform the testing and submit the name of the laboratory to FDA before testing begins. Defendants shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) calendar days after receipt by Defendants;

D. Cooked finished product testing. To demonstrate compliance with the requirements described in 5(A)-(C), Defendants shall conduct finished testing of cooked product produced at the Waldron facility as follows:

i. immediately upon resumption of operations after completion of the requirements in paragraph 4, Defendants shall test for *L. mono* for each type of finished product produced for at least five consecutive production days;

ii. immediately after the completion of testing under paragraph 5(D)(i), Defendants shall test at least one lot per day for at least the next 20 production days;

iii. immediately after the completion of testing under paragraph 5(D)(ii), Defendants shall test at least one lot per every five production days for the next three months; and

iv. immediately after the completion of testing under paragraph 5(D)(iii), Defendants shall test at least one lot during each three month period thereafter.

If any laboratory test listed in subparagraphs 5(D)(i)-(iv) show the presence of *L. mono* in any product, Defendants must stop production and, before resuming any food production, determine and correct the cause of the microbial contamination and start the complete sequence of testing again. Results from all laboratory tests listed in subparagraphs 5(D)(i)-(iv) shall be forwarded to FDA within two (2) calendar days after receipt by Defendants.

6. Portland Shellfish shall pay the costs of FDA's supervision, inspection, review, examination, and analyses conducted pursuant to this Decree at the standard rates prevailing at the time the activities are accomplished. As of the date this Decree is signed by the parties, these rates are: $87.57 per hour and fraction thereof per

representative for inspection and supervision work other than laboratory and analytical work; $104.96 per hour and fraction thereof per representative for laboratory and analytical work; $0.50 per mile for travel by automobile; the government rate or equivalent for travel by air; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day per representative for subsistence expenses, where necessary. In the event that the standard rates generally applicable to FDA supervision, inspection, review, examination, or analysis are modified, these rates shall be increased or decreased without further order of the Court.

7. Duly authorized representatives of FDA shall be permitted, as FDA deems necessary and without prior notice, to make inspections of the Defendants' facilities, including any new locations, and all equipment, finished and unfinished materials and products, containers, and labeling; to take photographs and make videotape recordings; to collect samples of any finished and unfinished materials and products, containers, environmental surfaces, and labeling; and to examine and copy all records relating to the receipt, processing, packing, labeling, holding, and distribution of any and all of the Defendants' products to ensure continuing compliance with the terms of this Decree. During inspections, Defendants shall cooperate fully with FDA, by, among other things, promptly providing FDA investigators with requested documents and materials. The costs of all such inspections, supervision, review, examination, and analyses are to be borne by Portland Shellfish at the rates specified in paragraph 6. The inspections shall be permitted upon presentation of a copy of this Decree and

appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

8. After the requirements of paragraph 4 are met, Defendants and each and all of their officers, agents, employees, successors, assigns, attorneys, and those persons in active concert or participation with any of them, are permanently restrained and enjoined from doing or causing to be done, directly or indirectly, any act that violates: (1) 21 U.S.C. § 331(a), by causing the introduction into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) or (a)(4); and (2) 21 U.S.C. § 331(k), by causing articles of food to become adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) or (a)(4) after shipment in interstate commerce. If, and for so long as, Defendant Satyavan Singh ceases to be employed by or act on behalf of Portland Shellfish, then that Defendant shall not be subject to the terms of this Decree except as to such individual's act(s) or failure(s) to act under this Decree prior to the time such individual ceased to be employed by or to act on behalf of Portland Shellfish.

9. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analysis of a sample or samples, or other information, that the Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the regulations, or the Act, FDA may, as and when it deems necessary, notify the Defendants in writing of the noncompliance and order the Defendants to take appropriate action, including, but not limited to, ordering the Defendants to immediately take one or more of the following actions:

A. Cease receiving, processing, preparing, packing, holding, or distributing any article of food;

B. Recall all articles of food that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers; or

C. Take any other corrective actions as FDA deems necessary to bring the Defendants into compliance with this Decree, FDA regulations, and the Act.

Portland Shellfish shall pay all costs of such recalls and corrective actions, including the costs of FDA supervision, inspections, analyses, examinations, review, travel, and subsistence expenses to implement recalls and other corrective actions, at the rates specified in paragraph 6 of this Decree. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

10. Any cessation of operations as described in paragraph 9 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Decree, the Act, and its implementing regulations. After a cessation of operations, and while determining whether Defendants are in compliance with the Decree, the Act, and its regulations, FDA may require that Defendants re-institute or re-implement any of the requirements of this Decree.

11. Defendants shall maintain copies of their HACCP plans, along with copies of any HACCP records required by the plans and by 21 C.F.R. Part 123, at their facilities in a location where they are readily available for reference and inspection by FDA officials. All records required to be kept by the HACCP plans and by the regulations shall be retained for at least three (3) years after the date the records are prepared.

12. All decisions specified in this Decree shall be vested in the discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based on the written record before FDA at the time the decision was made. No discovery shall be had by either party.

13. Defendants shall provide a copy of this Decree to each of Defendants' directors, officers, and employees within ten (10) calendar days from the date of entry of this Decree by the Court, and shall provide to FDA, within thirty (30) calendar days of the date of entry of this Decree, an affidavit of compliance with this paragraph stating the fact and manner of compliance and identifying the names and positions of all persons so notified.

14. Defendants shall, in writing, notify FDA at least thirty (30) calendar days before any change in ownership, character, or name of its business, including reorganization, relocation, dissolution, assignment, or sale resulting in the emergence of a successor entity or corporation; the creation or dissolution of subsidiaries or any other change in the corporate structure or identity of Portland Shellfish; or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect obligations arising out of this Decree. Defendants shall serve a copy of this Decree on any prospective successor or assign no later than thirty (30) calendar days prior to such sale or change in business and shall furnish the United States with an affidavit of compliance with this paragraph within fifteen (15) calendar days of such service on a prospective successor or assign.

15. Defendants shall post a copy of this Decree on a bulletin board in an employee common area at their facilities within ten (10) calendar days of the entry of this Decree and shall ensure that the Decree remains posted for a period of six (6) months.

16. Defendants shall, within ten (10) calendar days of the entry of this Decree, hold a general meeting or series of smaller meetings for employees of their facilities, at which they shall describe the terms and obligations of this Decree.

17. Any notices, test results or other information this Decree requires Defendants to give to FDA shall be given in writing to the District Director, FDA New England District Office, One Montvale Avenue, Stoneham, MA 02180.

18. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants agree to pay attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses, court costs, expert witness fees, and investigational and analytical expenses incurred in bringing such action.

19. This Court shall retain jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

20. No sooner than five (5) years after entry of this Decree, Defendants may petition this Court for an order dissolving the Decree. If Defendants have maintained to FDA's satisfaction a state of continuous compliance with this Decree, the Act, and all applicable regulations during the five (5) years preceding Defendants' petition, the United States of America will not oppose such petition.

SO ORDERED:

Dated this 20th day of January, 2011.

/s/John A. Woodcock, Jr.
JOHN A. WOODCOCK, JR.
CHIEF UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of the foregoing Decree:

/s/ Meredith Manning
Meredith Manning
Counsel for Portland
Shellfish Co., Inc.

/s/ Thimi R. Mina
Thimi R. Mina, Counsel for Jeffrey D. Holden, Satyavan Singh, and John A. Maloney

THOMAS E. DELAHANTY, III
United States Attorney
District of Maine

/s/ Evan Roth
Evan Roth
Assistant U.S. Attorney
District of Maine

/s/ Gerald C. Kell
Gerald C. Kell
Trial Attorney
Office of Consumer Litigation
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044

Of Counsel:

MARK B. CHILDRESS
Acting General Counsel

Ralph S. Tyler
Associate General Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel, Litigation

VERÓNICA A. WONG
Assistant Chief Counsel
U.S. Department of Health and Human Services
Office of the General Counsel
10903 New Hampshire, WO32
Silver Spring, MD 20993