IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**Case No. 3:17-CV-1005-NJR-RJD**
	)	
MARY E. PARRISH, an individual, doing business as FORT MASSAC FISH MARKET,	)	
	)	
Defendant.	)	

CONSENT ORDER

DECISION BY THE COURT.

Plaintiff, the United States of America (the "United States"), by its undersigned attorneys, having filed a complaint for injunctive relief (the "Complaint") against Mary E. Parrish, in her individual capacity and doing business as the Fort Massac Fish Market ("Defendant"), and Defendant having consented to entry of this Consent Decree of Permanent Injunction ("Decree") without contest[1] and before any testimony has been taken, and the United States having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

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

2. The Complaint states a cause of action against Defendant under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* (the "Act").

[1] The Court notes that Defendant has not formally entered an appearance, but she has signed the Consent Decree, and thus it appears she has appeared and consented to the Court 's jurisdiction.

3. Defendant violates the Act, 21 U.S.C. § 331(a), by causing to be introduced or delivered for introduction into interstate commerce food, within the meaning of 21 U.S.C. § 321(f), namely fish or fishery products, that are adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or may have been rendered injurious to health.

4. Defendant represents to the Court that, at the time of the entry of this Decree, she is not directly or indirectly receiving, preparing, processing, manufacturing, packing, holding, or distributing any type of food at or from any location.

5. If Defendant intends to resume, directly or indirectly, receiving, preparing, processing, manufacturing, packing, holding, or distributing food at or from any location, Defendant (a) shall first notify the United States Food and Drug Administration ("FDA") in writing at the address specified in paragraph 26 at least ninety (90) calendar days in advance of the commencement of any such food-related operations and (b) shall not, directly or indirectly, receive, prepare, process, manufacture, prepare, pack, hold, and/or distribute any food until and unless the Defendant fully complies with all of the requirements set forth in paragraphs 6(A) through 6(K) of this Decree. Defendant's notice shall identify the type(s) of food that Defendant intends to receive, prepare, process, manufacture, pack, hold, and/or distribute, and the location at which Defendant desires to commence or resume operations. Defendant shall not commence or resume operations until and unless FDA has inspected any and all such facility(ies) and any and all food-related operations to be

located therein pursuant to paragraph 6(I), Defendant has paid the costs of such inspections as required by paragraph 6(J), and Defendant has received written notice from the FDA as required by paragraph 6(K), and then shall resume operations only to the extent authorized in FDA's written notice.

6. Defendant and each and all of her officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships), who received actual notice of this Decree by personal service or otherwise, are hereby permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly receiving, preparing, processing, packing, labeling, holding, and/or distributing articles of food, at or from 1117 E. 2nd Street, Metropolis, Illinois, and/or any other location(s) at or from which Defendant, now or in the future, directly or indirectly receives, prepares, processes, packs, labels, holds, and/or distributes articles of food (the "Facility"), unless and until:

A. Defendant has, at her expense, cleaned and sanitized the Facility and equipment and made improvements, thereby rendering the Facility and equipment suitable for receiving, preparing, processing, packing, holding, and distributing articles of food, and Defendant has ensured that the Facility and equipment will be continuously maintained in a sanitary condition;

B. Defendant, at her expense, has rid the Facility and its premises of pests, as defined in 21 C.F.R. § 110.3(j), and filth contributed by them, and adequately repaired the Facility to prevent the re-entry of such pests;

C. Defendant has retained, at her expense, an independent person (the "Expert") who has no personal or financial ties (other than the retention agreement) to Defendant or her family, and who, by reason of background, education, training, and experience is qualified to assist Defendant in complying with the Hazard Analysis Critical Control Point ("HACCP") regulations for fish and fishery products, 21 C.F.R. Part 123. The Expert's qualifications shall include, but not be limited to: developing procedures to adequately control the hazard of C. botulinum ("*C. bot*") in Defendant's food, including but not limited to procedures for brining or salting raw fish eggs, or roe, to achieve water phase salt levels that adequately control *C. bot* growth and toxin formation in Defendant's ready-to-eat caviar; inspecting the Facility and establishing procedures to ensure that Defendant's methods, facilities, and controls are continuously operated and administered in conformity with this Decree, the Act, and 21 C.F.R. Parts 123 and 110, including but not limited to establishing adequate written Standard Sanitation Operating Procedures ("SSOPs"), as required by 21 C.F.R. § 123.11; and developing and conducting employee training programs on sanitation controls and on complying with this Decree, the Act, and 21 C.F.R. Parts 123 and 110. Defendant shall notify FDA in writing of the name and qualifications of the Expert within five (5) calendar days of retaining such expert;

D. After reviewing all FDA inspectional observation forms ("Forms

FDA-483") issued to Defendant since April 2016, the Expert has, in conjunction with Defendant:

(1) Conducted hazard analyses for each type of fish and fishery product Defendant intends to process to identify all food safety hazards reasonably likely to occur in accordance with 21 C.F.R. § 123.6(a);

(2) Developed and submitted to FDA an adequate written HACCP plan, as described in 21 C.F.R. Part 123, which shall include, for each food safety hazard reasonably likely to occur in Defendant's food, effective critical control points, critical limits, and written corrective action plans addressing deviations from such critical limits. The HACCP plan shall effectively control for all food safety hazards reasonably likely to occur for each type of fish and fishery product that Defendant intends to process in accordance with 21 C.F.R. Part 123, including, but not limited to, *C. bot* growth and toxin formation in Defendant's ready-to-eat caviar. The submission under this subparagraph shall also include all monitoring records required under 21 C.F.R. § 123.6(c)(7);

(3) Provided evidence of the adequacy of the critical limits listed in Defendant's HACCP plan to control for all food safety hazards reasonably likely to occur for each type of fish and fishery product that Defendant intends to process including, but not limited to, *C. bot.* growth and toxin formation in Defendant's ready-to-eat caviar. Such evidence shall include, at a minimum, scientific evidence that the critical limits listed in Defendant's HACCP plan for shovelnose sturgeon (hackleback) and paddlefish (spoon bill) roe are adequate to

ensure that Defendant's ready-to-eat caviar achieves a water phase salt level of 5.0% or higher;

(4) Developed and submitted to FDA adequate written SSOPs, as required by 21 C.F.R. § 123.11, that, at a minimum, ensure on an ongoing basis that the Facility and all equipment contained therein is clean, sanitized, and suitable for receiving, preparing, processing, packing, holding, and distributing articles of food, and that Defendant's operations comply with the Act and its implementing regulations;

(5) Developed and submitted to FDA, prior to implementation, employee training programs on Defendant's HACCP plan and SSOPs;

E. FDA has approved, in writing, the HACCP plan, SSOPs, and employee training programs developed by the Expert, as specified in Paragraphs 6.D;

F. Defendant has successfully implemented and personally completed the employee training programs developed by the Expert and approved by FDA according to Paragraph 6.E;

G. Defendant has reported to FDA, in writing, the actions she has taken to bring her operations into compliance with this Decree, the Act, and all applicable regulations, including the specific measures Defendant has taken to address each of the deficiencies documented by FDA since April 2016;

H. The Expert has conducted a comprehensive inspection of the Facility and the methods and controls used to receive, prepare, process, pack, hold, and distribute food to determine whether the Facility is sanitary, and Defendant is fully

prepared to operate in compliance with this Decree, the Act, and all applicable regulations. The Expert shall verify that Defendant has corrected all of the observations listed on Forms FDA-483 since April 2016. The Expert shall submit all findings, in writing, to Defendant and FDA concurrently, within ten (10) business days of completion of the inspection;

I. FDA, in order to evaluate Defendant's compliance with the terms of this Decree, the Act, and all applicable regulations, has inspected the Facility, including the building, sanitation-related systems, equipment, utensils, articles of food, and relevant records contained therein;

J. Defendant has paid all costs of inspection, analyses, review, investigations, examination, and supervision for FDA's oversight with respect to Paragraphs 6.A through 6.I, at the rates set forth in Paragraph 15 below; and

K. FDA notifies Defendant in writing that Defendant appears to be in compliance with the requirements set forth in Paragraphs 6.A through H and J of this Decree, the Act, and its implementing regulations.

7. Within thirty (30) calendar days after entry of this Decree, Defendant shall destroy, under FDA's supervision and pursuant to a destruction plan approved in writing by FDA, all in-process and finished fish and fishery products in Defendant's custody, control, and/or possession as of the date this Decree is signed by both parties.

8. Immediately upon resuming operations after completing the requirements of Paragraph 6, Defendant shall:

A. In consultation with the Expert, continuously implement the FDA-

approved HACCP plan and SSOPs.

B. Retain an independent laboratory having no personal or financial ties (other than the retention agreement) to Defendant or her family ("the Laboratory") to conduct the sample collection, testing, and analysis described in Paragraphs 8.C-D. Defendant shall ensure that the Laboratory will perform its sample collection, testing, and analysis in a manner acceptable to FDA.

C. Have tested a randomly-collected, representative sample from every lot of ready-to-eat caviar that Defendant processes for the first five (5) consecutive production days, and all such samples shall have a water phase salt level of 5.0% or higher. If any of such samples does not achieve a water phase salt level of 5.0% or higher, Defendant must take corrective actions as specified in her approved HACCP plan under FDA's supervision and repeat the testing specified in this Subparagraph until all representative samples achieve a water phase salt level of 5.0% or higher;

D. In addition to the testing requirement in Paragraph 8.C, have a randomly-collected, representative sample from one lot of ready-to-eat caviar that she processes for each month in the first three (3) months tested to ensure a water phase salt level of 5.0% or higher. If any sample does not achieve a water phase salt level of 5.0% or higher, Defendant must take corrective actions as specified in her approved HACCP plan under FDA's supervision, and repeat the testing specified in this Subparagraph until all representative samples achieve a water phase salt level of 5.0% or higher; and

E. Defendant shall send copies of the results of tests conducted pursuant to Paragraphs 8.C-D to FDA within two (2) calendar days after receipt by Defendant.

9. If, after notifying FDA of the name of the Laboratory retained to conduct sample collection and analyses, as required by Paragraph 8.B, Defendant terminates or in any way alters her service contract with the Laboratory, Defendant shall notify FDA within seven (7) calendar days. If Defendant terminates the service contract, Defendant shall provide a copy of the service contract with a new Laboratory to FDA within five (5) business days of execution. At all times while this Decree is in effect, Defendant shall have in place a service agreement with a laboratory to institute the testing required by Paragraph 8.

10. After receiving notice from FDA pursuant to Paragraph 6.K, Defendant shall not receive, prepare, process, pack, hold, label, or distribute any fish or fishery product not identified in a written HACCP plan approved by FDA until Defendant submits for FDA's review a written HACCP plan for such fish or fishery product and receives FDA's written approval. In no circumstances shall FDA's silence be construed as a substitute for written approval.

11. Within thirty (30) calendar days after receiving FDA's notification under Paragraph 6.K, the Expert shall conduct a comprehensive inspection of the Facility and the methods and controls used to receive, prepare, process, pack, label, hold, and distribute foods to determine whether Defendant is operating in compliance with this Decree, the Act, and all applicable regulations. The Expert shall submit a report

documenting all findings to Defendant and FDA concurrently, within ten (10) calendar days after completing the inspection. Thereafter, the Expert shall conduct two audits during each operating season for three (3) years (with the first audit occurring in the first half of the season and the second audit occurring in the latter half of the operating season), and then one audit during each operating season for the next two (2) years, unless FDA informs Defendant in writing that more frequent expert inspections and reporting are required.

A. During each inspection conducted by the Expert, the Expert shall verify that the Facility and the methods and controls Defendant uses to receive, prepare, process, pack, label, hold, and distribute articles of food are in compliance with the requirements of this Decree, the Act, and its implementing regulations, and shall certify such verification in the Expert's report submitted to Defendant and FDA concurrently, as described in this Paragraph.

B. If the Audit Report contains any observations indicating that Defendant is not in compliance with this Decree, the Act, or its implementing regulations, Defendant shall, within fifteen (15) business days after receipt of the Expert's report, make all necessary corrections, unless FDA notifies Defendant in writing that a shorter timeframe is required or that a longer timeframe is appropriate.

12. Defendant, and each and all of her officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of this Decree, are

permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

A. Violates the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce, any article of food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4);

B. Results in the failure to implement and continuously maintain the requirements of this Decree.

13. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the Facility and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During the inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process, and finished articles of food, containers, and packaging material; to take photographs and make video recordings; to take samples of Defendant's in-process and finished articles of food, containers, and packaging material; and to examine and copy all records related to receiving, processing, manufacturing, preparing, packing, holding, and/or distributing any and all articles of food. 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.

14. Defendant shall notify FDA in writing at least fifteen (15) calendar days

before any change in ownership, name, or character of her business, including reorganization, relocation, dissolution, assignment, or lease or sale of the business or any assets of the business, such as buildings, equipment, or inventory, that may affect compliance with the obligations arising from this Decree. Defendant shall provide any prospective successor or assign with a copy of this Decree at least ten (10) calendar days before the assignment or change in business and shall provide FDA with an affidavit of compliance with this Paragraph within ten (10) calendar days of providing a copy of this Decree to a prospective successor or assign.

15. Defendant shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendant's compliance with this Decree, at the standard rates prevailing at the time costs are incurred, and Defendant shall make payment in full to FDA within thirty (30) calendar days of receiving written notification from FDA of the costs. As of the date that this Decree is signed by the parties, these rates are (i) $93.26 per hour and fraction thereof per representative inspection work, (ii) $111.77 per hour or fraction thereof per representative analytical or review work, (iii) $0.535 per mile for travel by automobile, (iv) the government rate or the equivalent for travel by air or other means, and (v) the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates for FDA supervision of Court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

16. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, audit, analysis of a sample, report submitted by the Expert(s), or other information, that Defendant has 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 Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendant in writing and order Defendant to take appropriate action, including, but not limited to, ordering Defendant immediately to take one or more of the following actions:

A. Cease receiving, preparing, processing, packing, labeling, holding, and distributing any articles of food;

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

C. Submit additional samples to a qualified laboratory for analysis;

D. Institute or re-implement any of the requirements set forth in this Decree; and

E. Take any other corrective actions as FDA deems necessary to protect the public health or bring Defendant into compliance with this Decree, the Act, and its implementing regulations.

The provisions of this Paragraph shall be separate and apart from, and in addition to, all other remedies available to FDA. Defendant shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections,

investigations, analyses, examinations, review, travel, and subsistence expenses to implement and monitor recalls and other actions, at the rates specified in Paragraph 15 of this Decree.

17. Upon receipt of any order issued by FDA pursuant to Paragraph 16, Defendant shall immediately and fully comply with the terms of the order. Any cessation of operations or other action as described in Paragraph 16 shall be implemented immediately upon notice from FDA and shall continue until Defendant receives written notification from FDA that Defendant appears to be in compliance with the Decree, the Act, and its implementing regulations and that Defendant may resume operations. After a cessation of operations, and while determining whether Defendant is in compliance with this Decree, the Act, and its implementing regulations, FDA may require Defendant to re-institute or re-implement any of the requirements of this Decree.

18. Defendant shall maintain copies of her HACCP plan, along with copies of all records required by such plans, 21 C.F.R. Part 123, and this Decree, at the Facility in a location where they are readily available for reference and inspection by FDA. All records required to be kept by Defendant's HACCP plan, FDA regulations, and this Decree shall be retained for at least three (3) years after the date the records are prepared and shall be presented immediately to FDA investigators upon request.

19. If Defendant fails to comply with the provisions of the Act, its implementing regulations, or this Decree, then Defendant shall pay to the United States of America liquidated damages in the sum of three hundred dollars ($300) for each day

that such violation continues; an additional sum of three hundred dollars ($300) in liquidated damages per day for each violation of the Act, its implementing regulations, or this Decree; and a further sum equal to twice the retail value of each shipment of food that is adulterated or otherwise in violation of the Act, its implementing regulations, or this Decree. Defendant understands and agrees that the liquidated damages specified in this Paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and this Court to impose, additional civil or criminal penalties based on the conduct that may also be the basis for payment of liquidated damages pursuant to this Paragraph.

20. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendant shall, in addition to other remedies, reimburse the United States for its attorneys' fees, travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to the contempt proceedings.

21. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. If contested, FDA's decisions under this Decree 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 exclusively on the written record before the FDA at the time the decision was made. No discovery shall be taken by either party.

22. Within ten (10) calendar days after entry of this Decree, Defendant shall provide a copy of this Decree by personal service or certified mail (return receipt

requested) to each and all of her officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships), and including but not limited to Paramount Caviar, located at 38-15 24th Street, Long Island City, NY 11101. Defendant shall provide to FDA, within thirty (30) calendar days after entry of this Decree, an affidavit stating the fact and manner of compliance with this Paragraph and identifying the names and positions of all persons notified and attaching copies of the executed certified mail return receipts or other proof of service if the Decree was delivered by personal service.

23. Defendant shall prominently post a copy of this Decree in any employee common areas at the Facility within ten (10) calendar days after entry of this Decree and shall ensure that the Decree remains posted for as long as the Decree remains in effect.

24. Defendant shall, within ten (10) calendar days after entry of this Decree, hold a general meeting or a series of smaller meetings for employees of the Facility, at which she shall describe the terms and obligations of this Decree. Defendant shall provide to FDA, within thirty (30) calendar days after entry of this Decree, an affidavit stating the fact and manner of compliance with this Paragraph and identifying the names and positions of all meeting attendees and attaching a copy of the meeting sign-in sheet(s).

25. In the event that Defendant becomes associated with any additional officers, agents, employees, representatives, successors, assigns, attorneys, or any additional persons in active concert or participation with any of them (including

individuals, directors, corporations, subsidiaries, affiliates, and partnerships) at any time after entry of this Decree, Defendant shall immediately provide a copy of this Decree, by personal service or certified mail (return receipt requested), to such persons. Within ten (10) calendar days after each instance that Defendant becomes associated with any such person, Defendant shall provide to the FDA an affidavit stating the fact and manner of Defendant's compliance with this Paragraph, identifying the names, addresses, and positions of all persons who received a copy of this Decree pursuant to this Paragraph and attaching a copy of the executed certified mail return receipts.

26. Defendant shall address all communications required under this Decree to the Director, U.S. Food and Drug Administration, 550 W. Jackson Blvd, 15th Floor, Chicago, Illinois 60661, and shall reference this civil action by case name and civil action number and shall prominently mark "Decree Correspondence" in all such communications.

27. This Court retains jurisdiction of this action and the parties hereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

Dated this 27th day of September, 2017.

Nancy J. Rosenstengel

NANCY J. ROSENSTENGEL
United States District Judge

The undersigned hereby consent to entry of the foregoing Decree.

FOR DEFENDANT:

Mary E. Parrish

MARY E. PARRISH,
Individually and
d/b/a Fort Massac Fish Market

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