IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, v. EUROLINE FOODS, LLC, ROYAL SEAFOOD BAZA, INC., EDUARD SHNAYDER, SYOMA SHNAYDER, ALBERT NIYAZOV, and OLEG POLISCHOUK, Defendants.	Civil Action No. 18-2879 (Cogan, J.)

CONSENT DECREE AND JUDGMENT OF PERMANENT INJUNCTION

WHEREAS, Plaintiff, the United States of America, by its undersigned counsel, commenced this action against Euroline Foods, LLC, a Delaware limited liability company; Royal Seafood Baza, Inc., a New York corporation; and Eduard and Syoma Shnayder, Albert Niyazov (also known as Alex Niyazov), and Oleg Polischouk, individuals (collectively, Defendants), by filing a complaint in this Court (the "Complaint"), a copy of which is annexed hereto as Exhibit A; and

WHEREAS, Defendants operate a business located at 175 Lake Avenue, Staten Island, New York ("Defendants' Facility") that receives, packs, holds, labels, and distributes articles of food within the meaning of 21 U.S.C. § 321(f), including refrigerated and frozen seafood products, and a variety of salt-cured (pickled) fish and fishery products, including herring and caviar, and ready-to-eat whitefish salad; and

WHEREAS, the Complaint, the allegations of which are incorporated by reference herein, states claims for relief under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), by alleging that Defendants engaged in certain violations of the aforementioned acts,

namely, receiving, preparing, processing, packing, holding, labeling, and distributing articles of food from and for transportation in interstate commerce in a manner that causes the food to violate the Act, including by preparing, packing and holding such articles of food in the chronic presence of *Listeria monocytogenes* ("*L. mono*"), the bacterium that causes listeriosis, and under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health; and

WHEREAS, the Complaint seeks to enjoin and restrain Defendants from violating: (a) 21 U.S.C. § 331(k), by causing food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such food is held for sale after shipment of one or more of its components in interstate commerce; and (b) 21 U.S.C. § 331(a), by causing to be introduced or delivered for introduction into interstate commerce food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4); and

WHEREAS, Defendants have answered the Complaint; and

WHEREAS, Defendants agree to waive formal service of a summons; and

WHEREAS, Defendants having appeared and consented to entry of this Consent Judgment and Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree; and

WHEREAS, Defendants have taken certain steps toward ensuring compliance with the Act and its implementing regulations, including by:

(i) disposing of certain equipment used to prepare food articles at Defendants' Facility that was the subject of prior written observations by the government;

(ii) retaining an independent expert in an effort to meet all relevant requirements of the Act and its implementing regulations; and

(iii) ceasing all seafood processing operations, except for receiving, holding, and distributing fish and fishery products that are completely enclosed by a container, and ceasing all other food manufacturing operations.

WHEREAS, the parties wish to settle this action without further litigation and, pursuant thereto, consent to the entry by the Court of the following provisions as judgment in this action.

NOW, THEREFORE, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331 and 1345, 21 U.S.C. § 332, and its inherent equitable authority.

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

3. The Complaint alleges that Defendants violated the Act, 21 U.S.C. § 331(k), by causing articles of food within the meaning of 21 U.S.C. § 321(f), including, but not limited to, fish and fishery products, to become 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, while such articles are held for sale after shipment in interstate commerce.

4. The Complaint alleges that Defendants violated the Act, 21 U.S.C. § 331(a), by causing the introduction or delivery for introduction into interstate commerce of articles of food, within the meaning of 21 U.S.C. § 321(f), including, but not limited to, fish and 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.

5. Defendants represent to the Court that, at the time of entry of this Decree, they are engaged in receiving, packing, labeling, holding, and/or distributing food that is completely enclosed by a container, and that such food remains sealed and enclosed in such container until the time of distribution from Defendants' Facility.

6. Defendants represent to the Court that they do not, and do not intend to, engage in receiving, preparing, processing, packing, labeling, holding, and/or distributing food at Defendants' Facility other than food which is completely enclosed by a container, and which will remain sealed and enclosed in such container until the time of distribution from Defendants' Facility. Defendants also represent to the Court that they do not, and do not intend to, engage in receiving, preparing, processing, packing, labeling, holding, and/or distributing fish or fishery products or any other food that presents a *Listeria monocytogenes* hazard at any other food facility required to register with FDA under section 415 of the Act (21 U.S.C. § 350d) ("Food Facility"), other than that which is completely enclosed by a container, and which will remain sealed and enclosed in such container until the time of distribution from the Food Facility.

7. If, after entry of this Decree, Defendants intend to resume or permit preparation of food, at or from Defendants' Facility or any other Food Facility (collectively, "the Facility"), they must first notify the United States Food and Drug Administration ("FDA") in writing at least ninety (90) calendar days in advance of resuming operations and comply with paragraphs 8(A)-(H) of this Decree. This notice shall identify the type(s) of food Defendants intend to prepare at or from the Facility. Defendants shall not prepare food at Defendants' Facility or any Food Facility until (i) FDA has inspected the Facility and operations pursuant to paragraph 17, (ii) Defendants have paid the costs of such inspection(s) pursuant to paragraph 19, and (iii)

Defendants have received written notice from FDA, as required by paragraph 8(H), and thereafter shall resume operations only to the extent authorized in FDA's written notice.

8. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, affiliates, franchisees, and "doing business as" entities) (hereinafter, collectively referred to as "Associated Persons"), who have received actual notice of this Decree by personal service or otherwise, are hereby permanently restrained and enjoined under 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 any article of food at or from Defendants' Facility, and from directly or indirectly receiving, preparing, processing, packing, labeling, holding, and/or distributing fish or fishery products or any other food that presents a *Listeria monocytogenes* hazard at or from any other Food Facility unless and until:

A. Defendants retain, at their expense, an independent laboratory (the "Laboratory") having no personal or financial ties (other than the retention agreement) to Defendants or their families, that is qualified to analyze product and environmental samples collected at the Facility for the presence of *Listeria*, including *L. mono*, in a manner that is acceptable to FDA. Defendants shall notify FDA in writing within three (3) business days of retaining the Laboratory and shall provide FDA a copy of the service contract and the qualifications of the Laboratory. Such service contract shall contain provisions, acceptable to FDA, for environmental and finished product sample analyses, including how and where to sample, the number and frequency

of samples to be collected, and the methods of analyses, in accordance with the *Listeria* Monitoring Program discussed in paragraph 8(C) below;

B. Defendants retain, at their expense, an independent expert or experts (the "Expert(s)") having no personal or financial ties (other than a retention agreement) to Defendants or their families, and who, by reason of background, education, training, or experience, is qualified to:

(1) Conduct hazard analyses to develop adequate Hazard Analysis Critical Control Point ("HACCP") plans in accordance with the Act and its implementing regulations;

(2) Verify and ensure the adequacy of Defendants' HACCP plans in accordance with paragraphs 8(C)(1-3) below;

(3) Develop adequate written Sanitation Standard Operating Procedures ("SSOPs") in accordance with paragraph 8(C)(4) below;

(4) Develop a *Listeria* Monitoring Program in accordance with paragraph 8(C)(5) below;

(5) Collect product and environmental samples from within the Facility for pathogen testing in accordance with paragraph 8(C) below;

(6) Evaluate Defendants' compliance with the current good manufacturing practice ("CGMP") requirements as required by 21 C.F.R. Part 117;

(7) Develop and conduct employee training programs (in English and any other language necessary to effectively convey the substance of the training) on the SSOPs, HACCP and CGMP requirements, and *Listeria* Monitoring Program;

(8) Supervise and document intensified cleaning and sanitizing of the Facility and equipment followed by environmental sampling before food receiving, preparing, processing, packing, holding, labeling, or distribution resumes; and

(9) Inspect the Facility and determine whether the methods, facilities, and controls are operated and administered in conformity with the Act, its implementing regulations, and this Decree;

Defendants shall notify the FDA in writing of the identity and qualifications of the Expert(s) under paragraph (B) within three (3) business days of retaining such Expert(s);

C. After reviewing all FDA inspectional observations of deficiencies from March 2015 to the present, and after consultation with the Laboratory, Defendants' Expert(s), in conjunction with Defendants:

(1) Conducts hazard analyses and develops, to FDA's satisfaction, an adequate written HACCP plan, as required by 21 C.F.R. 123.6, for each type of fish and/or fishery product received, prepared, processed, packed, held, labeled, and/or distributed by Defendants, that at a minimum, effectively controls food safety hazards, such as (i) those associated with *Clostridium botulinum* ("*C. bot.*") growth and toxin formation likely to occur in reduced oxygen packaging; and (ii) those associated with scombrotoxin (histamine) formation.

(2) Develops and implements, to FDA's satisfaction, written corrective action plans as part of Defendants' HACCP plans to be taken whenever there is a deviation from a critical limit, as described in 21 C.F.R. § 123.7(b);

(3) Develops and implements, to FDA's satisfaction, written verification procedures as part of Defendants' HACCP plans, as described in 21 C.F.R. § 123.8;

(4) Develops and implements, to FDA's satisfaction, written SSOPs specific to Defendants' Facility and operations and that shall conform with the procedures set forth at 21 C.F.R. § 123.11(a) through (d), and ensures, to FDA's satisfaction, that Defendants' operations comply with the Act, including the CGMP requirements under 21 C.F.R. Part 117;

(5) Develops and implements, to FDA's satisfaction, a written *Listeria* Monitoring Program that shall include, at a minimum, the following:

(a) an effective written sanitation control program that establishes adequate methods, facilities, and controls for receiving, preparing, processing, packing, labeling, holding, and distributing articles of food to minimize the risk of introducing *L. mono,* other pathogenic organisms, and filth into Defendants' food, and to ensure that foods are not adulterated within the meaning of 21 U.S.C. § 342(a);

(b) an effective program for environmental monitoring and testing of the Facility to ensure that organisms such as *Listeria* species ("*L. spp.*") are systemically controlled and that pathogenic organisms such as *L. mono* are not present in finished products. Sampling should be conducted using specified frequencies and methods (e.g. including how, where, and when to sample; the number and frequency of samples to be collected; and the methods of analyses) that are acceptable to FDA. Defendants shall ensure that the results of all analyses conducted pursuant to (C)(6)(b) are sent to FDA within two (2) calendar days after receipt by Defendants; and

(c) an adequate written plan for remedial action that Defendants shall implement should *L. spp.* or any pathogenic organism, including *L. mono*, be detected. The remedial action shall include, at a minimum and as relevant, product disposition, intensified

cleaning and sanitizing, intensified sampling measures, and, upon repeat findings, a contamination source determination (root cause analysis), all of which are acceptable to FDA.

(6) Develops and implements, to FDA's satisfaction, employee training programs (in English and any other language necessary to effectively convey the substance of the training) on the HACCP and CGMP regulations, the FDA-approved HACCP plans, SSOPs, and *Listeria* Monitoring Program, and any other control strategies specific to Defendants' fish and fishery products, and documents that Defendants and each of their officers, employees, and any other person(s) who perform duties at the Facility for Defendants have received such training; and

(7) Submits to FDA the written HACCP plans and all associated records (including monitoring records), validation studies, SSOPs, the *Listeria* Monitoring Program, written verification procedures, and training programs developed pursuant to paragraphs 8(C)(1)-(6) above; and documentation demonstrating that the Expert(s) have trained Defendants and each of their officers, employees, and any other persons who perform duties at the Facility as described in paragraph 8(C)(6) above;

D. FDA has approved, in writing, the HACCP plans, validation studies, SSOPs, *Listeria* Monitoring Program, written verification procedures, and employee training programs and documentation developed by the Expert(s) as specified in paragraphs 8(C)(1)-(6) above;

E. Defendants take the following additional actions:

(1) Assign continuing responsibility for implementing and monitoring the FDA-approved SSOPs and *Listeria* Monitoring Program to a person (or persons) who, by reason of background, education, training, or experience, is qualified to maintain the Facility in a sanitary condition, coordinate with the Laboratory and the Expert(s), and implement any

necessary corrective action(s), and Defendants provide such person with the authority to achieve any necessary corrective action;

(2) Ensure that the FDA-approved HACCP plans, *Listeria* Monitoring Program, and SSOPs are available and accessible (in English and any other language necessary to effectively convey the substance of such documents) to their officers, employees, and any other persons who perform duties for Defendants;

(3) Successfully administer an FDA-approved employee training program; and

(4) At their expense, have the Expert(s) supervise and document intensified cleaning and sanitizing of the Facility and equipment followed by environmental sampling as verification of effectiveness therein and make improvements, thereby rendering the Facility and equipment suitable for receiving, preparing, processing, packing, holding, labeling, and distributing articles of food in accordance with this Decree, the Act, and all applicable regulations, and Defendants ensure that the Facility and equipment therein will be continuously maintained in a sanitary condition.

F. The Expert(s) conducts a comprehensive inspection of the Facility and the methods and controls used to receive, prepare, process, pack, hold, label, and distribute food to determine whether Defendants can and will be operating in compliance with this Decree, the Act, and all applicable regulations. The Expert(s) shall verify, with supporting documentation, that (i) Defendants have corrected all of the HACCP and CGMP deficiencies observed by FDA since March 2015, specifying each FDA observation and Defendants' corrections thereof; (ii) the monitoring equipment used to implement Defendants' HACCP plans is suitable and performing adequately; and (iii) the Facility and the methods and controls used to receive, prepare, process, pack, hold, label, and distribute articles of food are, in the Expert's opinion, in compliance with

this Decree, the Act, and its implementing regulations. Defendants shall ensure that the Expert(s) shall submit, in writing, all findings and supporting documentation to Defendants and FDA concurrently, within fifteen (15) business days after completion of the inspection;

G. Defendants have paid and will continue to pay all costs of inspection, analysis, review, investigation, examination, and supervision for FDA's oversight with respect to paragraph 8(A) though (F), at the rates set forth in paragraph 19; and

H. FDA has notified Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 8(A)-(G) of this Decree, the Act, and its implementing regulations. In no circumstance shall FDA's silence be construed as a substitution for written notification.

9. After receiving notice from FDA pursuant to paragraph 8(H), Defendants shall not receive, prepare, process, pack, hold, label, or distribute any food product not identified in a written HACCP plan approved by FDA pursuant to paragraph 8(D) until Defendants submit for FDA's review a written HACCP plan for such food product and receive FDA's written approval for such plan. In no circumstance shall FDA's silence be construed as a substitution for written approval.

10. Immediately upon resuming operations after completing the requirements of paragraph 8, Defendants shall, in consultation with the Expert(s), continuously implement the written HACCP plans, SSOPs, *Listeria* Monitoring Program, written verification procedures, and employee training programs approved by FDA pursuant to paragraph 8(D).

11. Defendants further shall comply with the *Listeria* Monitoring Program as follows:

A. Defendants shall have tested for *L. mono* in the following manner:

(1) A randomly collected, representative sample from every lot of fish or fishery products that they process, except for fish or fishery products that remain completely sealed and enclosed by a container the entire time they are in the Facility, for the first five (5) consecutive production days;

(2) After the completion of testing under paragraph 11(A)(1), Defendants shall have tested a randomly collected, representative sample from one lot of each type of finished fish or fishery products that they process, except for fish or fishery products that remain completely sealed and enclosed by a container the entire time they are in the Facility, each week for the next three (3) months;

(3) After the completion of testing under paragraph 11(A)(2), Defendants shall have tested a randomly collected, representative sample from at least one lot of each type of finished fish or fishery products that they process, except for fish or fishery products that remain completely sealed and enclosed by a container the entire time they are in the Facility, each month for the next twelve (12) months; and

(4) After completion of testing under paragraph 11(A)(3), Defendants shall have tested a randomly collected, representative sample from at least one lot of each type of finished fish or fishery products, except for fish or fishery products that remain completely sealed and enclosed by a container the entire time they are in the Facility, that they process every three (3) months thereafter.

B. Defendants shall send copies of the results of all testing conducted pursuant to paragraphs 8(C) and 11(A) to FDA within two (2) calendar days after receipt by Defendants. If any laboratory test completed pursuant to paragraphs 8(C) and/or 11(A) shows the presence of *L.*

mono in any article of food, then Defendants must immediately cease production and notify FDA of the presence of *L. mono* and that production has ceased. Defendants shall also destroy, at Defendants' expense, under FDA's supervision, and according to a destruction plan submitted to and approved by FDA in writing prior to implementation, all food products manufactured in the Facility that may have been exposed to *L. mono* from the time the Laboratory sample(s) testing positive for *L. mono* was collected. Defendants may resume production only when they have determined and corrected the cause of the contamination and only after FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements of this Decree, the Act, and its implementing regulations. After correcting the cause of the contamination, Defendants shall reinstate the complete sequence of testing under paragraphs 8(C) and 11(A) anew;

C. In the event that Defendants or their Expert(s) determine that the *Listeria* Monitoring Program that FDA approved pursuant to paragraph 8(E) needs to be revised, Defendants shall provide proposed changes to FDA in writing at least twenty (20) calendar days prior to their proposed implementation, and shall not implement their proposed changes until FDA approves those changes in writing. Any such changes shall consist of methods and controls that are shown to FDA's satisfaction to systematically control *L. spp.* and ensure that *L. mono* does not occur in finished products.

D. Defendants receive written notification from FDA that Defendants appear to be in compliance with the requirements set forth in paragraphs 11(A) through 11(C) of this Decree, the Act, and all applicable regulations. In no circumstances shall FDA's silence be construed as substitution for written notification.

12. If, after notifying FDA of the name of the Laboratory retained to conduct sample collection and analyses pursuant to paragraph 8(E), Defendants terminate or in any way alter their service contract with the Laboratory, Defendants shall notify FDA within seven (7) calendar days. If Defendants terminate their service contract, Defendants shall provide a copy of the service contract with the new Laboratory to FDA within five (5) business days after contract execution.

13. Within thirty (30) calendar days after Defendants resume their operations after completing the requirements of paragraph 8 and receiving the notice set forth in paragraph 8(H), the Expert(s) shall conduct a comprehensive inspection of the Facility at or from which Defendants receive, prepare, process, pack, hold, label, or distribute articles of food, and the methods and controls used to receive, prepare, process, pack, hold, label, and distribute foods to determine whether Defendants are operating in compliance with this Decree, the Act, and all applicable regulations. The Expert(s) shall submit a report documenting all findings to Defendants and FDA concurrently, within ten (10) calendar days after completing the inspection. Thereafter, the Expert(s) shall conduct one inspection every three (3) months for one year, and one inspection every six (6) months for the next two (2) years. Beginning in the fourth year after Defendants resume their operations after completing the requirements of paragraph 8, the Expert(s) shall conduct inspections annually unless FDA informs Defendants in writing that more frequent expert inspections and reporting are required. During each inspection conducted by the Expert(s), the Expert(s) shall verify that the Facility and the methods and controls Defendants use to receive, prepare, process, pack, hold, label, and distribute articles of food are in compliance with the requirements of this Decree, the Act, and all applicable regulations, and shall certify compliance in the Expert's report. If the Expert's report contains any observations

indicating that Defendants are not in compliance with this Decree, the Act, or its implementing regulations, Defendants shall make all necessary corrections within ten (10) business days after receipt of the Expert's report, unless FDA notifies Defendants in writing that a shorter time period is necessary.

14. Nothing in paragraph 8 shall prevent Defendants from receiving, holding, and distributing in the United States, from Defendants' Facility or any other Food Facility, any food product completely sealed and enclosed by a container that is in compliance with the Act and its implementing regulations so long as such food product remains sealed and enclosed in such container until it leaves the Facility. Nothing in this Decree shall prevent Defendants from operating retail food establishments that are not a Food Facility.

15. Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, affiliates, franchisees, and "doing business as" entities), 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(k), by causing any article of food within the meaning of 21 U.S.C. § 321(f) to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such article is held for sale after shipment of one or more components in interstate commerce;

B. 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); and/or

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

16. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, name or character of their 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. Defendants 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 after providing a copy of this Decree to a prospective successor or assign.

17. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' Facility, and any other Food Facility at or from which Defendants receive, prepare, process, pack, hold, label, or distribute articles of food 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 such inspections, FDA shall be permitted to: (i) have immediate access to buildings and the contents therein, including equipment, raw ingredients, in-process and finished articles of food, containers and packaging material; (ii) take photographs and make video recordings; (iii) take samples of Defendants' raw ingredients, in-process and finished articles of food, containers, and packaging material; and (iv) examine and copy all records relating to receiving, preparing, processing, packing, holding, labeling, and distributing any and all articles of food and their components. 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.

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

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

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

C. Revise, modify, expand, or continue to submit any reports, plans, procedures, or other records prepared pursuant to this Decree;

D. Submit additional reports or information to FDA as requested;

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

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

G. Issue a safety alert; and/or

H. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

The provisions of this paragraph (18) shall be separate and apart from, and in addition to, any other remedy available to FDA. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses to implement and monitor the remedies set forth in paragraph 18, at the rates specified in paragraph 19.

19. Defendants shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time the costs are incurred. Defendants shall make payment in full to FDA within twenty (20) business 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: $95.39 per hour or fraction thereof per representative for inspection and investigative work; $114.33 per hour or fraction thereof per representative for analytical or review work; $0.545 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

20. Upon receipt of any order issued by FDA pursuant to paragraph 18, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other

action described in paragraph 18 shall be implemented immediately upon notice from FDA and shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. After a cessation of operations, and while determining whether Defendants appear to be in compliance with the Decree, the Act, and its implementing regulations, FDA may require Defendants to re-institute or re-implement any of the requirements of this Decree.

21. Defendants shall promptly provide any information or records to FDA upon request regarding the receiving, preparing, processing, packing, holding, labeling, and/or distributing of Defendants' products. Defendants shall maintain copies of their HACCP plans, along with copies of all records required by such plans, 21 C.F.R. Part 123, or this Decree, at Defendants' Facility, and any other Food Facility at or from which Defendants receive, prepare, process, pack, hold, label, and/or distribute articles of food, in a location where such records are readily available for reference and inspection by FDA. Defendants shall retain all records referred to in this paragraph for at least three (3) years after the date the records are prepared.

22. If any Defendant fails to comply with any provision of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America liquidated damages in the sum of three thousand dollars ($3,000) for each day such violation continues; an additional sum of one thousand dollars ($1,000) in liquidated damages per day for each violation of this Decree, the Act, or its implementing regulations; and an additional sum in liquidated damages equal to twice the retail value of any shipment of articles of food that is adulterated or otherwise in violation of this Decree, the Act, or its implementing regulations. Defendants understand and agree 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 the Court to impose, additional civil or criminal penalties based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

23. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), expert witness fees, travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to such contempt proceedings.

24. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

25. Within five (5) calendar days after entry of this Decree, Defendants shall prominently post a copy of this Decree (in English and any other language necessary to effectively convey the substance of the Decree) in a conspicuous location in an employee common area at Defendants' Facility and shall ensure that the Decree remains posted for as long as the Decree remains in effect. Within fifteen (15) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph.

26. Within ten (10) calendar days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all Associated Persons, at which they shall describe the terms and obligations of this Decree (in English and any other language necessary to effectively convey the substance of the Decree). Within fifteen (15) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

27. Within ten (10) calendar days after entry of this Decree, Defendants shall provide a copy of the Decree by personal service or certified mail (return receipt requested) to each and all of their Associated Persons and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships). Within thirty (30) calendar days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all persons so notified, and attaching a copy of the executed certified mail return receipts, if any.

28. In the event that any Defendant becomes associated with any additional Associated Person(s), 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, Defendants 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 any Defendant becomes associated with any such person, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the

facts stated therein, stating the fact and manner of 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, if any.

29. Defendants shall notify FDA in writing at least ten (10) business days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, lease, sale, or any other change in the structure or identity of Euroline Foods, LLC, or Royal Seafood Baza, Inc., or the assignment, lease, or sale of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

30. If Defendants have maintained a state of continuous compliance with this Decree, the Act, and all applicable regulations, for at least five (5) years following entry of this Decree, Defendants may petition this Court for relief from this Decree and the United States will not oppose such petition.

31. Defendants shall address all communications required under this Decree to the Director, New York District Office, 158-15 Liberty Avenue, Jamaica, NY 11433. All such communications to FDA required by the terms of this Decree shall reference this civil action by case name and civil action number, and shall be prominently marked "Decree Correspondence."

32. Except as provided in the foregoing provisions of this Decree, the parties shall bear their own costs and attorneys' fees in this action.

33. This Court retains jurisdiction over this action and the parties thereto 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, this 16th day of July, 2018.

UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to entry of the foregoing Decree.

FOR DEFENDANTS:

EDUARD SHNAYDER
Individually and on behalf of EUROLINE FOODS, LLC, and ROYAL SEAFOOD BAZA, INC.

SYOMA SHNAYDER
Individually

ALBERT NIYAZOV
Individually

OLEG POLISCHOUK

FOR PLAINTIFF:

RICHARD P. DONOGHUE
United States Attorney
Eastern District of New York
271 Cadman Plaza East
Brooklyn, New York 11201

By:
GAIL A. MATTHEWS
Assistant United States Attorney
(718) 254-6025
gail.matthews@usdoj.gov

CHAD A. READLER
Acting Assistant Attorney General
Civil Division
United States Department of Justice

GUSTAV EYLER
Acting Director
Consumer Protection Branch

Individually

JESSICA P. O'CONNELL
JENNIFER L. SAULINO
Covington & Burling, LLP
850 10th Street NW
Washington, DC 20001
(202) 662-5180
Attorneys for Defendants

By: _____
JAMES T. NELSON
Trial Attorney
Consumer Protection Branch
Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044
(202) 616-2376
james.nelson2@usdoj.gov

OF COUNSEL:
ROBERT P. CHARROW
General Counsel

REBECCA K. WOOD
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation

JENNIFER KANG
Associate Chief Counsel for Enforcement
Food and Drug Division
10903 New Hampshire Avenue
Bldg. 31, Room 4545
Silver Spring, MD 20993-0002
(240) 402-0347
jennifer.kang@fda.hhs.gov