IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. IRVINGTON SEAGOOD, INC., a corporation, KEVIN S. SAKPRASIT, HELEN NOU, and KAMMIE C. RICHARDSON, individuals, Defendants.	Case No. 23-CV-144-B

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint for Permanent Injunction against Irvington Seafood, Inc., an Alabama corporation, and Kevin S. Sakprasit, Helene Nou, and Kammie C. Richardson, individuals (collectively, "Defendants"), and Defendants having appeared and consented to entry of this Consent 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;

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 violate 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), namely seafood and seafood 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. The Complaint also alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of food within the meaning of 21 U.S.C. § 321(f), namely seafood and seafood 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. 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 their facility located at 11125 Beverly Road, Irvington, Alabama, or any other location(s) at which Defendants now or in the future directly or indirectly receive, prepare, process, pack, label, hold, and/or distribute articles of food (referred to as "Defendants' Facility" or "the 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, and that is qualified to analyze product and environmental samples collected at the facility for the presence of *Listeria monocytogenes* ("*Listeria mono*"), in a manner that is acceptable to the United States Food and Drug Administration ("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. Such service contract shall contain provisions, acceptable to FDA, for environmental and finished product sample analyses; and

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 an adequate Hazard Analysis Critical Control Point ("HACCP") plan for Defendants' seafood and seafood products—including crabmeat, as required by 21 C.F.R. § 123.6;

(2) Verify and ensure the adequacy of Defendants' HACCP plans in accordance with paragraphs 4(C)(1-3) below ;

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

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

(5) Collect product and environmental samples from within the facility for pathogen testing in accordance with paragraph (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 Sanitation Standard Operating Procedures ("SSOPs"), seafood HACCP and cGMP requirements, and *Listeria* Monitoring Program; and

(8) 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) within three (3) business days of retaining such Laboratory or Expert(s);

C. After reviewing all FDA inspectional observations of deficiencies from January 2006 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 seafood and/or seafood product received, prepared, processed, packed, labeled, held, and/or distributed by Defendants, that minimizes the risk of the introduction of *Listeria mono* into Defendants' food, and to ensure that the foods are not adulterated, within the meaning of 21 U.S.C. § 342(a). Such analyses, plans, and controls shall include, but are not limited to, thoroughly cleaning, sanitizing, renovating, and rendering Defendants' facility and all equipment therein suitable for use in receiving, processing, preparing, packing, holding, and distributing articles of food to prevent the articles from becoming adulterated, and instituting such procedures inside the facility to ensure that the facility and equipment therein are continuously maintained in a sanitary condition;

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

(4) Develops, to FDA's satisfaction, written SSOPs with monitoring 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 and 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 *Listeria 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). Such methods, processes, and controls shall include, but shall not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering the facility and all equipment therein suitable for use in receiving, preparing, processing, packing, holding, and/or distributing food to prevent it from becoming adulterated, and ensuring that the facility and all equipment therein are continuously maintained in a sanitary condition;

(b) an effective program for environmental monitoring and testing of the facility to ensure that organisms such as *Listeria* species ("*Listeria spp.*") are systemically

controlled, and harborage sites are identified and eliminated, so that pathogenic organisms such as *Listeria mono* do not occur 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. Environmental monitoring shall include, but shall not be limited to, collecting samples from food-contact surfaces, equipment, and other sites throughout the facility (where the raw ingredients, and in-process and finished products are received, prepared, processed, packed, held, and/or distributed, and common areas that could be reservoirs for cross-contamination), and analyzing samples in a manner acceptable to FDA. Defendants shall ensure that the results of all analyses conducted pursuant to this paragraph are sent to FDA within two (2) calendar days after receipt by Defendants

(c) an adequate written plan for remedial action that Defendants shall implement should *Listeria spp.* or any pathogenic organism, including *Listeria mono*, be detected. The remedial action shall include, at a minimum, product disposition, intensified sanitation, intensified sampling measures, a comprehensive investigation, and a contamination source determination (i.e., root cause analysis), all of which are acceptable to FDA.

(6) Develops and conducts, to FDA's satisfaction, employee training programs (in English and any other language necessary to effectively convey the substance of the training) on the seafood HACCP and cGMP regulations, an FDA-approved HACCP plan, SSOPs with sanitation monitoring records (as required by 21 C.F.R. § 123.11(b)), a *Listeria* Monitoring Program, and any other control strategies specific to Defendants' seafood and seafood products, and documents that Defendants and each of their officers, employees, and any other person(s) who perform duties at Defendants' 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 with sanitation monitoring records, the *Listeria* Monitoring Program, written verification procedures, and training programs developed pursuant to paragraphs (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 Defendants' facility as described in paragraph (C)(6) above;

D. FDA has approved, in writing, the seafood 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 (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 Defendants' facility in a sanitary condition, coordinate with the Laboratory, 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 plan, *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 their facility and equipment followed by environmental sampling as verification of effectiveness therein and make improvements, thereby rendering their 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, remedying inspectional observations from January 2006 to the present, and Defendants ensure that their facility and equipment therein will be continuously maintained in a sanitary condition.

F. The Expert(s) conducts a comprehensive inspection of Defendants' facility and the methods and controls used to receive, prepare, process, pack, label, hold, and distribute food to determine whether Defendants are 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 seafood HACCP and cGMP deficiencies observed by FDA since January 2006, 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) Defendants' facility and the methods and controls used to receive, prepare, process, pack, label, hold, and distribute articles of food are, in the Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations. The comprehensive inspection shall also include, but shall not be limited to, taking environmental samples from Defendants' facility, and testing such samples in accordance with paragraph 4(C)(6)(b), identifying and eliminating harborage sites, and conducting a root cause analysis. 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 report to FDA in writing the actions they have taken to bring their operations into compliance with this Decree, the Act, and its implementing regulations, including, producing documentation that Defendants have cleaned and sanitized the facility and equipment therein and made improvements, thereby rendering the facility and equipment suitable for receiving, manufacturing, preparing, processing, holding, labeling, packing, and distributing articles of food; and identifying specific measures that Defendants have taken to address each of the violations documented by FDA since January 2006;

H. Defendants destroy, under FDA's supervision, and according to a destruction plan submitted in writing by Defendants and approved in writing by FDA prior to implementation, all raw ingredients and all in-processed and finished articles of food currently in their custody, control, or possession at the time this Decree is signed by the parties;

I. Defendants recall, to the retail level, and destroy all fish and fishery products distributed to date.

J. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and its implementing regulations, conducts inspections of Defendants' facility, including the buildings, sanitation-related systems, equipment, utensils, labeling, and all articles of food and relevant records contained therein;

K. Defendants have paid all costs of inspection, analysis, review, investigation, examination, and supervision for FDA's oversight with respect to paragraph 6(A) though (J), at the rates set forth in paragraph 15; and

L. FDA has notified Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 4(A)-(I) of this Decree, the Act, and its implementing regulations. FDA shall endeavor to complete its review of Defendants'

compliance with such requirements and provide such written notification, as appropriate, in a timely manner. In no circumstance shall FDA's silence be construed as a substitution for written notification.

5. After receiving notice from FDA pursuant to paragraph 4(L), Defendants shall not receive, prepare, process, pack, hold, label, or distribute any seafood or seafood product not identified in a written HACCP plan approved by FDA pursuant to paragraph 4(D) until Defendants submit for FDA's review a written HACCP plan for such seafood or seafood product and receive FDA's written approval for such plan. FDA shall endeavor to complete its review of Defendants' written HACCP plan and provide such written notification, as appropriate, in a timely manner. In no circumstance shall FDA's silence be construed as a substitution for written approval.

6. Immediately upon resuming operations after completing the requirements of paragraph 4, Defendants shall, in consultation with the Expert(s), continuously implement the written seafood HACCP plans, SSOPs with sanitation monitoring, *Listeria* Monitoring Program, written verification procedures, and employee training programs approved by FDA pursuant to paragraph 4(D). Defendants further shall comply with the following requirements:

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

(1) A statistically relevant number of finished product samples based on the size of the lot, to be randomly collected, consisting of a representative sample from every lot of seafood or seafood product that they process for the first five (5) consecutive production days;

(2) After the completion of testing under paragraph 6(A)(1), Defendants shall have tested a statistically relevant number of finished product samples based on the size of the

lot, to be randomly collected, consisting of a representative sample from one lot of each type of finished seafood or seafood products that they process each week for the next three (3) months;

(3) After the completion of testing under paragraph 6(A)(2), Defendants shall have tested a statistically relevant number of finished product samples based on the size of the lot, to be randomly collected, consisting of representative sample from at least one lot of each type of finished seafood or seafood products that they process each month for the next twelve (12) months; and

(4) After completion of testing under paragraph 6(A)(3), Defendants shall have tested a randomly collected, representative sample from at least one lot of each type of finished seafood or seafood products that they process every three (3) months thereafter.

B. Defendants shall send copies of the results of all testing conducted pursuant to paragraph 6(A) to FDA within two (2) calendar days after receipt by Defendants. If any laboratory test completed pursuant to paragraph 6(A) shows the presence of *Listeria mono* in any article of food, then Defendants must immediately cease production and notify FDA 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 from the time the laboratory sample(s) testing positive for *Listeria 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. FDA shall endeavor to complete its review of Defendants' compliance with such requirements and provide such written notification, as

appropriate, in a timely manner. After correcting the cause of the contamination, Defendants shall reinstate the complete sequence of testing under paragraph 6(A) anew;

C. Conduct environmental monitoring and testing as set forth in paragraph 4(C)(5) to ensure that the SSOPs effectively control the *Listeria mono* hazard and that the SSOPs with monitoring are consistently implemented. Environmental testing shall be performed by the laboratory in accordance with timetables and methods that Defendants submit in writing to FDA for prior written approval by FDA. Defendants shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) business days after receipt by Defendants;

D. Defendants' environmental testing shall include, at a minimum, all of the following:

(1) If a food or non-food-contact surface tests positive for *Listeria spp.* during routine testing, intensified sampling must be initiated immediately, in conjunction with intensified cleaning and sanitizing. Intensified sampling requires that at least three (3) surrounding areas are sampled during production and analyzed; and

(2) Any *Listeria spp.* isolate from a food-contact surface must initiate a root cause analysis with corrective actions to prevent recurrence, and the isolate must be tested further to determine whether it is *Listeria mono*. In addition, all food products that come in contact with a site that tests positive for *Listeria spp.* since the last cleaning and sanitizing of the affected area occurred must be held pending laboratory test results of those food products and further testing of the *Listeria spp.* isolate from the food-contact surface. Defendants shall submit their sampling plan for product testing to FDA, which must be acceptable to FDA prior to testing. FDA shall endeavor to complete its review of Defendants' written sampling plan and

provide such written notification, as appropriate, in a timely manner. The food products can be released only if laboratory test results for the food products are negative for *Listeria spp*. and the food-contact surface isolate is not *Listeria mono.* If the laboratory test results for the food products or the food-contact surface are positive for *Listeria mono*, Defendants must destroy—at their own expense and under FDA's supervision, and according to a written destruction plan submitted by Defendants and approved in writing by FDA prior to implementation—all food products manufactured from the time of the last cleaning and sanitizing of the affected area occurred, the Defendants shall bear the costs of FDA's supervision of such destruction at the rates specified in Paragraph 15; and

E. In the event that Defendants or their Expert(s) determine that the *Listeria* Monitoring Program that FDA approved pursuant to paragraph 4(C) needs to be revised, Defendants shall provide proposed changes to FDA in writing at least twenty (20) calendar days prior to their 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 *Listeria spp.* and ensure that *Listeria mono* does not occur in finished products.

7. If, after notifying FDA of the name of the laboratory retained to conduct sample collection and analyses pursuant to paragraph 6(D), 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.

8. Within thirty (30) calendar days after Defendants resume their operations after completing the requirements of paragraph 4 and receiving the notice set forth in paragraph 4(L), the Expert(s) shall conduct a comprehensive inspection of the facility, and any other location(s) at or from which Defendants receive, prepare, process, pack, hold, or distribute articles of food, and the methods and controls used to receive, prepare, process, pack, hold 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 4, 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, 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.

9. 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 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.

10. 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.

11. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' facility, and any other location(s) at or from which Defendants receive,

prepare, process, pack, hold, 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, 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.

12. 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, 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 shall be separate and apart from, and in addition to, any other remedy available to FDA.

13. The following process and procedures apply when FDA issues an order under paragraph 12 except as provided under subparagraph D below:

A. Unless a different timeframe is specified by FDA in its order, within five (5) business days after receiving an order under paragraph 12, Defendants shall notify FDA in writing either that: (i) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific actions taken or to be taken and the proposed schedule for completing the actions; or (ii) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in

detail and in writing the basis for their disagreement; in doing so Defendants also may propose specific alternative actions and specific timeframes for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. FDA shall endeavor to review Defendants' notification and provide a written notification, as appropriate, in a timely manner. This written notification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable) and, if they so choose, bring the matter before this Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement FDA's order unless and until the Court stays, reverses, vacates, or modifies FDA's order. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 23.

D. The process and procedures set forth in paragraphs A-C shall not apply to any order issued under paragraph 12 if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief. Any cessation of operations under this paragraph 13(D) shall continue until Defendants receive written notice from FDA that Defendants appear to be in compliance with the Act, its implementing regulations, and this Decree.

14. Any action described in paragraph 12 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. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, supervision, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses to implement and monitor the remedies set forth in paragraph 12, at the rates specified in paragraph 15.

15. 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: $110.59 per hour or fraction thereof per representative for inspection and investigative work; $132.56 per hour or fraction thereof per representative for analytical or review work; $0.65 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.

16. Defendants shall promptly provide any information or records to FDA upon request regarding the receiving, preparing, processing, packing, labeling, holding, 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 location(s) at or from which Defendants receive, prepare, process, pack, hold, 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.

17. 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 ten (10) 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.

18. 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.

19. 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.

20. In the event that any of the Defendants 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.

21. 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 one thousand dollars ($1,000) for each day such violation continues; an additional sum of five hundred dollars ($500) in liquidated damages per day for each violation of this Decree, the Act, or its implementing regulations; and an additional sum equal to twice the retail value of each shipment of adulterated seafood or seafood product. 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.

22. 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.

23. All decisions specified in this Decree shall be vested in the discretion of FDA. Defendants shall abide by the decisions of FDA, and 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 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 of the decision. No discovery shall be taken by either party.

24. Defendants shall address all communications required under this Decree to Stephen Rabe, a Compliance Officer with the FDA Office of Human and Animal Foods. Any and all communication shall be sent via electronic mail to orahafeast5firmresponses@fda.hhs.gov with the email subject "Consent Decree Correspondence – Irvington Seafood – [Topic]," where the topic is a succinct title describing the correspondence. The body of such communications to FDA required by the terms of this Decree shall reference this civil action by case name and civil action number.

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

26. If Defendants have continuously complied with the terms of this Decree, the Act, and all applicable laws and regulations for a period of five (5) years after entry of this Decree, Defendants may petition this Court for relief from this Decree. If, at the time of the petition, in FDA's judgment Defendants have met the foregoing criteria, Plaintiff will not oppose such petition.

27. 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 to any party as may be necessary or appropriate.

SO ORDERED, this 11th day of May, 2023.

s/ Kristi K. DuBose
UNITED STATES DISTRICT JUDGE

Entry consented to:

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HELENE NOU
Individually

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