UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA, Plaintiff, v. KWONG TUNG FOODS, INC., a corporation, and VIETA "VICTOR" C. WANG, and JUNEY H. WANG, individuals, Defendants.	CIVIL ACTION NO. 16-cv-2412 (RHK/KMM) CONSENT DECREE OF PERMANENT INJUNCTION

CONSENT DECREE

Plaintiff, the United States of America, by its undersigned attorneys, having filed a complaint for permanent injunction against Kwong Tung Foods, Inc., a corporation, and Vieta "Victor" C. Wang, and Juney H. Wang, individuals (collectively, "Defendants"), and Defendants having appeared and consented to the 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 over all parties to this action.

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

3. Defendants do not contest that they violated the Act, 21 U.S.C. § 331(k), by causing articles of food to become adulterated, within the meaning of 21 U.S.C. § 342(a)(4), while such articles were held for sale after shipment of one or more of their components in interstate commerce. The articles of food were adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they were prepared, packed, and/or held under insanitary conditions whereby they may have become contaminated with filth or may have been rendered injurious to health.

4. Defendants represent to the Court that, as of June 30, 2016, they are not directly or indirectly engaged in receiving, processing, manufacturing, preparing, packing, holding, and/or distributing any type of food and have terminated all employees engaged in any of the forgoing activities.

5. If Defendants intend to resume, directly or indirectly, receiving, processing, manufacturing, preparing, packing, holding, and/or distributing food, Defendants (a) shall first notify the United States Food and Drug Administration ("FDA") in writing at the address specified in paragraph 20 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, process, manufacture, prepare, pack, hold and/or distribute any food until and unless the Defendants fully comply with all of the requirements set forth in paragraphs 6(A) through 6(K) of this Decree. Defendants' notice shall identify the type(s) of food that Defendants intend to receive, process, manufacture, prepare, pack, hold, and/or distribute, and the location at which Defendants desire to commence or resume operations. Defendants 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), Defendants have paid the costs of such inspections as required by paragraph 6(J), and Defendants have 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. Upon entry of this Decree, Defendants and each and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive notice of this Decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly receiving, processing, manufacturing, preparing, packing, holding, and/or distributing any article of food at or from their facility located at 1840 East 38th Street, Minneapolis, Minnesota 55407, or any other or new location at or from which Defendants directly or indirectly receive, process, manufacture, prepare, pack, hold, or distribute food ("Defendants' facility"), unless and until:

A. Defendants select and retain, at Defendants' expense, an independent expert or experts (the "Food Safety Expert(s)") having no personal or financial ties other than the retention agreement to Defendants or their families, and who, by reason of background, education, training, and experience, is qualified to develop, and ensure adequate implementation of, a written Sanitation Control Program, as defined in paragraphs 6(C) and 6(D), covering Defendants' manufacturing processes, including cleaning and sanitizing operations, pest control, employee health and hygiene, and plant construction and maintenance (including the plant's buildings and sanitation-related systems (i.e., plumbing, sewage disposal), equipment, and utensils contained therein), to protect against contamination of food, food-contact surfaces, and food-packaging materials with chemicals, toxins, microorganisms, vermin, and filth. Defendants

shall notify the FDA in writing of the name(s) and qualifications of the Food Safety Expert(s) as soon as they retain such expert(s);

B. Defendants select and retain, at Defendants' expense, an independent laboratory (the "Laboratory") that has no personal or financial ties other than the retention agreement to Defendants or their families, that is qualified to collect product, spent irrigation water, and environmental samples from within the Defendants' facility and analyze those samples for the presence of pathogens using a method that is acceptable to the FDA. Defendants shall notify FDA in writing immediately upon retaining such a Laboratory and shall provide FDA with a copy of the service contract. Such service contract shall contain provisions, deemed acceptable to FDA, for regular environmental and finished product sample collection and analysis, including how and where to sample, the number and frequency of samples to be collected, and the methods of analyses, in accordance with the Sanitation Control Program discussed in paragraph 6(C) below;

C. Defendants' Food Safety Expert(s), in consultation with the Laboratory and after reviewing all FDA observations since December 2012, develops a written Sanitation Control Program, acceptable to FDA, as discussed in paragraph 6(D), which shall, at a minimum:

(i) Establish adequate methods, facilities, and controls for receiving, processing, manufacturing, preparing, packing, holding, and distributing articles of food to minimize the risk of contamination of food, food-contact surfaces, and/or food-packaging materials, and to ensure that food is not adulterated, within the meaning of 21 U.S.C. § 342(a)(4). Such methods, facilities, and controls shall include, but not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering Defendants' facilities and all equipment therein suitable for use in receiving, processing, manufacturing, preparing, packing, holding, and/or distributing

articles of food to prevent the articles of food from becoming adulterated, and instituting procedures to ensure that the plant and equipment therein are continuously maintained in a sanitary condition;

(ii) Require that seeds and beans that are used for sprouting are conditioned, stored, and transported in a manner that minimizes the likelihood that the seeds and beans will be contaminated with pathogens. Seeds and beans must be stored in closed or covered containers in a clean, dry area dedicated to seed and bean storage. Containers must be positioned off the floor and away from walls to reduce the possibility of contamination by rodents or other pests and to facilitate regular monitoring for pests;

(iii) Ensure that Defendants adhere to the requirements of 21 C.F.R. Part 110, which sets forth current good manufacturing practice ("cGMP") in manufacturing, packaging, and holding food;

(iv) Require that seeds and beans for sprouting are treated with one or more scientifically valid treatments per FDA guidance for the reduction of pathogens in seeds, sprouts, or beans, and that Defendants carefully follow and comply with all labeling when mixing and using antimicrobial chemicals;

(v) Require that the adequacy of cleaning and sanitizing be established through targeted environmental swabbing and appropriate microbial testing;

(vi) Require that Defendants conduct microbiological testing of spent irrigation water from every batch/lot of sprouts for *Salmonella* and *Escherichia coli* O157:H7 in order to detect contamination in sufficient time to determine whether to ship product. Sampling must occur between 48 to 56 hours from the start of the sprouting process. Defendants must obtain the test results before shipping product and shall not ship any product from a lot where

contamination is found. Such testing, whether performed by Defendants or a contractor, must be done by trained personnel, in a qualified laboratory, using appropriate sampling procedures and validated testing methods. Defendants must retain records and reports related to this testing for two (2) years and make such records and reports available to FDA upon request;

(vii) Require an effective program for environmental monitoring and testing of Defendants' facility to ensure that pathogenic organisms, including, but not limited to, *Salmonella* and *Listeria* species *(*"spp."), are adequately controlled within the facility. Environmental monitoring shall include, but not be limited to, developing: (a) a schedule for regularly collecting swab samples from food-contact and non-food-contact surfaces, equipment, and other environmental sites throughout the facility where in-process and finished articles of food are received, processed, manufactured, prepared, packed, held, and/or distributed, and a facility map designating the locations for collecting swab samples; (b) a plan for testing all environmental samples for S*almonella* spp. and *Listeria* spp., including *Listeria monocytogenes*; (c) a corrective action plan for responding to samples that yield pathogens; and (d) a plan to report the results of all positive test analyses conducted pursuant to this paragraph to FDA within two (2) calendar days of receiving such results and to retain all other test results conducted pursuant to this paragraph for FDA inspection;

(viii) Require that production of foods which do not contain any allergens is performed using equipment that does not contain residue (visible or otherwise) of products that do include allergens, or ensure that labeling accurately reflects potential allergens; and

(ix) Establish a plan for remedial action should any pathogenic organism be detected;

D. FDA approves, in writing, the Sanitation Control Program developed by the Food Safety Expert(s);

E. Defendants make written copies of the Sanitation Control Program available and accessible to all their employees in a language they understand;

F. Defendants assign responsibility and authority for implementing and monitoring the Sanitation Control Program on a continuing basis to an employee who is trained in sanitation control requirements;

G. The Food Safety Expert(s) conducts a comprehensive inspection of Defendants' facility, including the buildings, sanitation-related systems, equipment, utensils, articles of food, and relevant records contained therein, to determine whether Defendants have adequately established and implemented the FDA-approved Sanitation Control Program, whether Defendants have adequately addressed the FDA investigators' inspectional observations listed on the Forms FDA 483 provided to Defendants on October 26, 2015, December 18, 2014, and December 21, 2012, and whether Defendants comply with 21 C.F.R. Part 110;

H. The Food Safety Expert(s) certifies in writing to FDA that Defendants:

(i) Have adequately established and implemented the FDA-approved Sanitation Control Program;

(ii) Have adequately addressed the Form FDA 483 observations and any other violations noted by the Food Safety Expert(s) or others; and

(iii) Comply with 21 C.F.R. Part 110;

I. FDA, as it deems necessary to evaluate Defendants' compliance with this Decree, the Act, and all applicable regulations, conducts inspections of Defendants' facility,

including the buildings, sanitation-related systems, equipment, utensils, all articles of food, and relevant records contained therein;

J. Defendants have paid all costs of inspection, analysis, review, investigations, examination, and supervision for FDA's oversight with respect to paragraph 6, at the rates set forth in paragraph 10 below; and

K. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 6(A) through 6(J) of this Decree, the Act, and FDA regulations.

7. Upon resuming operations after completing the requirements of paragraph 6, Defendants shall, in consultation with the Food Safety Expert(s) and the Laboratory, continuously and effectively implement, on an ongoing basis, the Sanitation Control Program, unless Defendants submit, and FDA approves in writing an alternative program, consisting of validated methods and controls that are shown to FDA's satisfaction to eliminate potential contamination of food, and otherwise ensure compliance with the requirements of this Decree, the Act, and its implementing regulations. In the event that Defendants or their Food Safety Expert(s) determine that the Sanitation Control Program needs to be revised, Defendants shall provide suggested changes to FDA in writing at least thirty (30) days prior to their planned implementation, and shall not implement their suggested changes until FDA approves those changes in writing.

8. If, after receiving FDA's paragraph 6(K) notification, Defendants terminate or in any way alter their service contract with the Laboratory retained to conduct sample collection and analyses identified in paragraph 6(B) and described in their Sanitation Control Program, Defendants shall notify FDA within five (5) calendar days. If Defendants terminate their service

contract, Defendants shall retain a new independent laboratory in accordance with paragraph 6(B) as soon as practicable and provide FDA a copy of the service contract with the new laboratory within five (5) calendar days of execution.

9. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' 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 Defendants' raw ingredients, 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 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.

10. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $90.65 per hour or fraction thereof per representative for inspection work; $108.63 per hour or fraction thereof per representative for analytical or review work; $0.54 cents per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and 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 applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

11. Defendants and each and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive 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 articles of food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), while such articles are held for sale after shipment of one or more components in interstate commerce; or

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

12. If, at any time after entry of this Decree, FDA determines based on the results of an inspection, sample analysis, or other information, that Defendants have failed to comply with any provision of this Decree, 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, issue a directive notifying Defendants in writing of the noncompliance and ordering Defendants to take appropriate action immediately, including, but not limited to, one or more of the following actions:

A. Cease receiving, processing, manufacturing, preparing, packing, holding, and/or distributing articles of food;

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

C. Submit samples of raw ingredients, in-process or finished articles of food, containers, and packaging materials to a qualified laboratory to determine whether they are contaminated with chemicals, toxins, microorganisms, or filth;

D. Take any other corrective actions as FDA deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, and its implementing regulations, including, but not limited to, requiring that Defendants re-implement or re-institute any of the requirements of this Decree; and/or

E. Pay liquidated damages as specified in paragraph 15 of this Decree.

13. The provisions of paragraph 12 shall be apart from, and in addition to, all other remedies 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, and reviews to implement and monitor recalls and other corrective actions, at the rates specified in paragraph 10 of this Decree.

14. Upon receipt of an FDA directive described in paragraph 12, Defendants shall immediately and fully comply with the terms of the directive. In the event that Defendants disagree with the terms of the directive, they may appeal to this Court and shall continue to immediately and fully comply with the terms of the directive unless and until the Court modifies or overturns the directive.

15. If any Defendant fails to comply with the provisions of this Decree, the Act, and/or its implementing regulations, Defendants shall pay to the United States of America liquidated damages in the sum of one thousand dollars ($1,000.00) for each day that a Defendant

fails to comply; an additional sum of five hundred dollars ($500.00) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree; and an additional sum equal to twice the retail value of each shipment of adulterated food. 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 criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

16. If any Defendant violates this Decree and is found in civil or criminal contempt thereof, Defendants shall, in addition to other remedies, reimburse Plaintiff 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.

17. 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.

18. Defendants shall provide notice of this Decree in the following manner.

A. Within ten (10) calendar days after entry of this Decree, Defendants shall:

(i) Provide a copy of this Decree, personally or, when necessary, by certified mail, return receipt requested, to each and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or

participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates);

(ii) If Defendants then have any employees who will engage in receiving, processing, manufacturing, preparing, packing, holding, and/or distributing food, post a copy of this Decree on a bulletin board in the employee common area at Defendants' facility, and ensure that the Decree remains posted there for as long as it remains in effect; and

(iii) If Defendants then have any employees who will engage in receiving, processing, manufacturing, preparing, packing, holding, and/or distributing food, hold a general meeting or series of smaller meetings for their employees, at which they shall describe the terms and obligations of this Decree.

B. Within twenty (20) calendar days after entry of this Decree, Defendants shall provide FDA with an affidavit signed by Defendants attesting to their compliance with subparagraph A of this paragraph, stating the fact and manner of compliance, and identifying the names and positions of all persons who were notified under the requirements in subparagraph A.

C. Within ten (10) calendar days from the date of employment of any new employee who will engage in receiving, processing, manufacturing, preparing, packing, holding, and/or distributing food, Defendants shall provide the new employee with a copy of this Decree, personally or, when necessary, by certified mail, return receipt requested.

19. Defendants shall notify FDA in writing at least thirty (30) calendar days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including reorganization, relocation, dissolution, assignment, or lease or sale of the business or any assets of the business, such as buildings, equipment, or inventory. Defendants shall notify FDA in writing at least thirty (30) calendar days before any subsequent 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, if that activity relates to receiving, processing, manufacturing, preparing, packing, holding, and/or distributing food. Defendants shall provide any prospective successor or assign with a copy of this Decree at least twenty (20) calendar days before the assignment or change in business, and shall provide FDA with an affidavit of compliance with this paragraph within fifteen (15) calendar days of providing a copy of this Decree to a prospective successor or assign.

20. Defendants shall address all communications with FDA required under this Decree to Director, Minneapolis District Office, Food and Drug Administration, 250 Marquette Avenue, Suite 600, Minneapolis, MN 55401, shall prominently mark the envelope as "DECREE CORRESPONDENCE," and shall reference this civil action by case name and civil action number in such communications.

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

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

SO ORDERED this 15th day of July, 2016.

s/ Richard H. Kyle
Richard H. Kyle
United States District Judge

We hereby consent to the entry of the forgoing Decree:

FOR DEFENDANTS

/s/ Victor Wang
VIETA "VICTOR" C. WANG, individually, and on behalf of KWONG TUNG FOODS, INC.

s/ Juney Wang
JUNEY H. WANG, individually

/s/ John S. Watson
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