IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. FORTUNE FOOD PRODUCT, INC., a corporation, and STEVEN SEETO and TIFFANY JIANG, individuals, Defendants.	)	Case No. 20 C 5356 Judge John Robert Blakey

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint for Permanent Injunction against Fortune Food Product, Inc., a corporation, and Steven Seeto and Tiffany Jiang, individuals (collectively, "Defendants"), and Defendants having consented to entry of this 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 as follows:

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

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. Defendants violate 21 U.S.C. § 331(vv) by failing to comply with the requirements established under 21 U.S.C. § 350h, as set forth in 21 C.F.R. Part 112 ("Produce Safety Rule") for growing, harvesting, packing, and holding covered produce within the meaning of 21 C.F.R. § 112.3, specifically sprouts.

4. Defendants violate 21 U.S.C. § 331(a) by introducing and/or delivering for introduction into interstate commerce articles of food within the meaning of 21 U.S.C. § 321(f), specifically sprouts and soy products, that are adulterated under 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 violate 21 U.S.C. § 331(k) by causing articles of food within the meaning of 21 U.S.C. § 321(f), specifically sprouts and soy products, that are held for sale after shipment of one or more of their components in interstate commerce, to become adulterated under 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.

6. For the purposes of this decree:

A. "Associated Persons" refers to Defendants' 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).

B. "Sprout Safety Plan" refers to the collective documentation, which may include processes, procedures, training materials, and other supporting records, to ensure that Defendants' sprout operations adhere to the Act and the Produce Safety Rule. *See infra* ¶ 8.B.i.

C. "Other Food Products" refers to products that meet the definition of "food" at 21 C.F.R. § 117.3, but do not meet the definition of "covered produce" at 21 C.F.R. § 112.3. This term includes, but is not limited to, soy products manufactured by Defendants—*e.g.*, tofu products and soy noodle products.

D. "Defendants' Establishment" refers to 1821 South Canalport Avenue, Chicago, Illinois 60616, and any other location(s) at which Defendants now or in the future directly or indirectly receive, prepare, process, label, grow, harvest, pack, label, hold, and/or distribute articles of food, as defined at 21 U.S.C. § 321(f).

7. Defendants represent to the Court that, at the time of entry of this decree, they are engaged in receiving, preparing, processing, labeling, growing, harvesting, packing, holding, and/or distributing only sprouts, and not any other articles of food, at or from Defendants' Establishment. If Defendants or any of their Associated Persons later intend to resume receiving, preparing, processing, labeling, growing, harvesting, packing, holding, or distributing any Other Food Products at or from Defendants' Establishment, they first must comply with paragraph 10 of this decree. If Defendants or any of their Associated Persons later intend to resume receiving, preparing, processing, labeling, growing, harvesting, packing, holding, or distributing any covered produce (other than sprouts), as defined at 21 C.F.R. § 112.3, at or from Defendants' Establishment, they must first comply with paragraph 11 of this decree.

8. Upon entry of this decree, Defendants and each and all of their Associated Persons, who have received actual notice of this decree by personal service or otherwise, 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, preparing, processing, labeling, growing, harvesting, packing, holding, and/or distributing sprouts at or from Defendants' Establishment, unless and until:

A. Defendants retain, at Defendants' expense, an independent person or persons (the "Sprout Safety Expert(s)") who is without any personal or financial ties (other than a retention agreement) to Defendants or their families, who has completed specific training that is

related to the growing, harvesting, packing, and holding of sprouts and is at least equivalent to that received under standardized curriculum recognized as adequate by FDA, who meets the requirements of a preventive controls qualified individual as defined in 21 C.F.R. § 117.3, and who, by reason of background, education, training, or experience is qualified to: develop and implement, in accordance with paragraph 8B of this decree, a written Sprout Safety Plan for Defendants' sprouts to comply with the Act and the Produce Safety Rule; inspect Defendants' Establishment; and determine whether Defendants' methods, processes, and controls are continuously operated and administered in conformity with this decree, the Act, and its implementing regulations. Defendants shall notify the United States Food and Drug Administration (FDA) in writing of the identity and qualifications of the Sprout Safety Expert(s) within three (3) business days after retaining such expert(s);

B. The Sprout Safety Expert(s) shall:

(1) Establish, to FDA's satisfaction, a Sprout Safety Plan to ensure that Defendants' sprout operations adhere to the Act and the Produce Safety Rule. The Sprout Safety Plan shall:

(a) Include a written sampling plan that identifies the number and location of samples of spent sprout irrigation water ("SSIW") or sprouts to be collected and tested for pathogens for each sprout production batch, and that meets all the criteria in 21 C.F.R. § 112.147, including, as required by 21 C.F.R. § 112.147(b), ensuring that Defendants do not allow any sprout production batch to enter into commerce unless the results of the testing of SSIW or sprouts from that batch are negative for *E. coli* O157:H7, *Salmonella* species, and if applicable, any other pathogen that meets the criteria in 21 C.F.R. § 112.144(c);

(b) Ensure that Defendants, as required by 21 C.F.R § 112.142(e), either treat seeds used to grow sprouts using a scientifically valid method to reduce microorganisms of public health significance, or rely on prior treatment of the seeds conducted by a grower, distributor, or seed supplier and obtain appropriate documentation of such treatment from the grower, distributor, or supplier;

(c) Include a written environmental monitoring plan that is designed to identify *Listeria Monocytogenes* if it is present in the growing, harvesting, packing or holding environment for Defendants' sprouts, and that meets all the criteria in 21 C.F.R. § 112.145. As provided at 21 C.F.R. § 112.145(b), the written environmental monitoring plan must be directed to sampling and testing for either *Listeria* species or *Listeria Monocytogenes;*

(d) Include a written integrated pest management program that, among other things, ensures that Defendants, as required by 21 C.F.R. § 112.128, take measures to exclude pests from their fully-enclosed buildings, take measures to prevent pests from becoming established in their partially-enclosed buildings (as applicable), and take measures reasonably necessary to protect their sprouts, food contact surfaces, and food-packing materials from contamination by pests in the Establishment, including routine pest monitoring as necessary;

(e) Include a written sanitation plan which ensures that Defendants' sprout operations satisfy the sanitation requirements in 21 C.F.R. Part 112, and that Defendants' growing, harvesting, packing, and holding processes, cleaning and sanitizing operations, corrective actions, employee health and hygiene precautions, and Establishment construction and maintenance (including, but not limited to, the Establishment's buildings and sanitation-related systems, *e.g.*, plumbing and sewage disposal, equipment, and utensils contained

therein) protect against the contamination of their sprouts and food contact surfaces and prevent insanitary conditions at Defendants' Establishment; and

(f) Establish a written employee training program in English and any other language necessary to convey the substance of the training, that includes instruction in the Produce Safety Rule and the Sprout Safety Plan; and, after receiving FDA's approval of the Sprout Safety Plan in accordance with paragraph 8C of this decree, ensure that Defendants and their officers, employees, and all other persons who perform duties at Defendants' Establishment are trained in accordance with such program to ensure that individuals who handle sprouts or food contact surfaces are qualified to perform their assigned duties, consistent with 21 C.F.R. § 112.21.

(2) Submit to FDA documentation demonstrating that the Sprout Safety Expert(s) has adequately trained Defendants, their officers, and their employees;

C. FDA has approved, in writing, the Sprout Safety Plan developed by the Sprout Safety Expert(s), as specified in paragraph 8B of this decree;

D. Defendants:

(1) Assign continuing responsibility for implementing and monitoring the Sprout Safety Plan to a person who has successfully completed food safety training related to the growing, harvesting, packing, and holding of sprouts that is at least equivalent to that received under standardized curriculum recognized by FDA, as required by 21 C.F.R. § 112.22(c), and who, by reason of background, education, training, or experience, is qualified to maintain Defendants' Establishment in a sanitary condition, implement any necessary corrective action, and ensure compliance with the Sprout Safety Plan. Defendants shall provide such person with the authority and resources to achieve any necessary corrective action;

(2) Ensure that the FDA-approved Sprout Safety Plan is available and accessible (in English and any other language necessary to convey the substance of such documents) to Defendants' officers, employees, and all other persons who perform duties at Defendants' Establishment;

(3) Ensure that Defendants and their employees successfully complete the trainings as required under the FDA-approved Sprout Safety Plan;

(4) Destroy, under FDA's supervision, and in accordance with the procedures provided in paragraph 9 of this decree, all articles of food and food ingredients (including but not limited to in-process and finished articles of food) in Defendants' custody, control, or possession as of the date this decree is signed by the parties;

(5) At their expense, further clean and sanitize Defendants' Establishment and equipment therein and make improvements (including, but not limited to, improvements to allow for the adequate cleaning and proper maintenance of equipment) to render Defendants' Establishment and equipment suitable for receiving, preparing, processing, labeling, growing, harvesting, packing, holding, and distributing articles of food in accordance with this decree, the Act, and its implementing regulations, and ensure that Defendants' Establishment and equipment therein will be continuously maintained in a sanitary condition;

E. The Sprout Safety Expert(s) conducts a comprehensive inspection of Defendants' Establishment and the methods and controls used to receive, prepare, process, label, grow, harvest, pack, hold, and distribute sprouts to determine whether Defendants are operating in compliance with this decree (including the Sprout Safety Plan developed pursuant to paragraph 8B of this decree and approved by FDA pursuant to paragraph 8C of this decree), the Act, and its implementing regulations, including the Produce Safety Rule. Defendants shall ensure that the

Sanitation and Sprout Safety Expert(s) shall submit, in writing, all findings and supporting documentation to Defendants and FDA concurrently, within ten (10) business days after completing the inspection;

F. The Sprout Safety Expert(s) certifies in writing to FDA that Defendants:

(1) Have adequately established and implemented the FDA-approved Sprout Safety Plan; and

(2) Have adequately addressed the inspectional observations that directly or indirectly relate to their receiving, preparing, processing, labeling, growing, harvesting, packing, holding, and/or distributing sprouts listed on every Form FDA-483 issued to Defendants since January 2018; and

(3) Are in compliance with the Produce Safety Rule and the terms of this decree;

G. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this decree, the Act, and its implementing regulations, inspect of Defendants' Establishment, including the buildings, equipment, utensils, labeling, and all articles of food and relevant records contained therein;

H. Defendants have paid all costs of inspection, analysis, review, investigation, examination, and supervision for FDA's oversight with respect to paragraph 8 of this decree, at the rates set forth in paragraph 18 of this decree; and

I. FDA has notified Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 8A–8F and 8H 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. Within thirty (30) days after entry of this decree, Defendants shall, under FDA's supervision and pursuant to a written destruction plan approved in writing by FDA prior to implementation, destroy all articles of food and food ingredients (including but not limited to in-process and finished articles of food) in Defendants' custody, control, or possession as of the date this decree is signed by the parties. Defendants shall bear the costs of destruction and the costs of FDA's supervision incurred under this paragraph. Defendants shall not dispose of any products in a manner contrary to the provisions of the Act, any other federal law, or the laws or any State or Territory, as defined in the Act, in which the products are disposed.

10. Upon entry of this decree, Defendants and each and all of their Associated Persons, who have received actual notice of this decree by personal service or otherwise, 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, preparing, processing, labeling, growing, harvesting, packing, holding, and/or distributing any Other Food Products at or from Defendants' Establishment, unless and until:

A. Defendants notify FDA in writing at least ninety (90) calendar days in advance of resuming operations for such products;

B. Defendants retain, at Defendants' expense, an independent person or persons (the "Food Safety Expert(s)"), who may be the same person(s) as the Sprout Safety Expert(s) described in paragraph 8A of this decree, is without any personal or financial ties (other than a retention agreement) to Defendants or their families, who meets the requirements of a preventive controls qualified individual as defined in 21 C.F.R. § 117.3, and who, by reason of background, education, training, or experience is qualified to: develop and implement, in accordance with paragraph 10C of this decree, a written Food Safety Plan for Defendants' Other

Food Products to comply with the Act and the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule ("cGMP & PC Rule"), 21 C.F.R. Part 117; and determine whether Defendants' methods, processes, and controls are continuously operated and administered in conformity with this decree, the Act, and its implementing regulations. Defendants shall notify FDA in writing of the identity and qualifications of the Food Safety Expert(s) within three (3) business days after retaining such expert(s);

C. The Food Safety Expert(s) shall:

(1) Establish, to FDA's satisfaction, a written plan to ensure that Defendants' Other Food Products operations adhere to the Act and the cGMP & PC Rule ("Food Safety Plan"). The Food Safety Plan shall:

(a) Ensure that Defendants conduct a hazard analysis and establish a preventive controls implementation plan (to include preventive control management components, such as procedures and records for monitoring, verification, and validation) as defined at 21 C.F.R. §§ 117.130 and 117.135, to effectively and continuously control the risk of pathogenic organisms, such as the genus *Listeria* and *Bacillus Cereus* or chemical hazards, such as mycotoxins/natural toxins, in their facility and products;

(b) Ensure that, as required by 21 C.F.R. § 117.80, Defendants conduct all operations in the manufacturing, processing, packing, and holding of all Other Food Products in accordance with adequate sanitation principles and under such conditions and controls as necessary to minimize the potential for food contamination;

(c) Ensure that, as required by 21 C.F.R. §§ 117.20(b) and 117.35(a), Defendants' Establishment is of suitable design to facilitate maintenance and sanitary

operations, and maintained in repair adequate to prevent their Other Food Products from becoming adulterated;

(d) Include a written integrated pest management program which, among other things, ensures that Defendants, as required by 21 C.F.R. § 117.35(c), take effective measures to exclude pests from the manufacturing, processing, packing, and holding areas for their Other Food Products operations, and to protect against the contamination of their Other Food Products by pests; and

(e) Include a written sanitation plan which ensures that Defendants' Other Food Products operations satisfy the sanitation requirements in 21 C.F.R. Part 117, and that Defendants' growing, harvesting, packing, and holding processes, cleaning and sanitizing operations, corrective actions, employee health and hygiene precautions, and Establishment construction and maintenance (including, but not limited to, the Establishment's buildings and sanitation-related systems, *e.g.*, plumbing and sewage disposal, equipment, and utensils contained therein) protect against the contamination of their Other Food Products and food contact surfaces and prevent insanitary conditions at Defendants' Establishment; and

(f) Establish a written employee training program in English and any other language necessary to convey the substance of the training, that includes instruction in the cGMP & PC Rule and the Food Safety Plan; and, after receiving FDA's approval of the Food Safety Plan in accordance with paragraph 10D of this decree, ensure that Defendants and their officers, employees, and all other people who perform duties at Defendants' Establishment are trained in accordance with such program to ensure that individuals who handle Other Food Products or food contact surfaces are qualified to perform their assigned duties, consistent with 21 C.F.R § 117.4(b).

(2) Submit to FDA documentation demonstrating that the Food Safety Expert(s) has adequately trained Defendants, their officers, and their employees;

D. FDA has approved, in writing, the Food Safety Plan developed by the Food Safety Expert(s), as specified in paragraph 10C of this decree;

E. Defendants assign continuing responsibility for implementing and monitoring the Food Safety Plan to a person who meets the requirements of a preventive controls qualified individual as defined in 21 C.F.R. § 117.3, and who, by reason of background, education, training, or experience, is qualified to maintain Defendants' Establishment in a sanitary condition, implement any necessary corrective action, and ensure compliance with the requirements at 21 C.F.R. § 117.180(a)). Defendants shall provide such person with the authority and resources to achieve any necessary corrective action;

F. Defendants ensure that the FDA-approved Food Safety Plan is available and accessible (in English and any other language necessary to convey the substance of such documents) to Defendants' officers, employees, and all other persons who perform duties at Defendants' Establishment;

G. Defendants ensure that Defendants and their employees successfully complete the trainings as required under the FDA-approved Food Safety Plan;

H. The Food Safety Expert(s) conducts a comprehensive inspection of Defendants' Establishment and the methods and controls used to receive, prepare, process, label, grow, harvest, pack, hold, and distribute Other Food Products to determine whether Defendants are operating in compliance with this Decree (including the Food Safety Plan developed pursuant to paragraph 10C of this decree and approved by FDA pursuant to paragraph 10D of this decree), the Act, and its implementing regulations, including the cGMP & PC Rule. Defendants shall

ensure that the Food Safety Expert(s) shall submit, in writing, all findings and supporting documentation to Defendants and FDA concurrently, within ten (10) business days after completing the inspection;

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

(1) Have adequately established and implemented the FDA-approved Food Safety Plan; and

(2) Have adequately addressed the inspectional observations that directly or indirectly relate to their receiving, preparing, processing, labeling, growing, harvesting, packing, holding, and/or distributing Other Food Products listed on every Form FDA-483 issued to Defendants since January 2018; and

(3) Are in compliance with the cGMP & PC Rule and the terms of this decree;

J. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and its implementing regulations, inspects Defendants' Establishment, including the buildings, 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 10 of this decree, at the rates set forth in paragraph 18 of this decree; and

L. FDA has notified Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 10A–10G and 10I of this decree, the Act, and its implementing regulations. In no circumstance shall FDA's silence be construed as a substitution for written notification.

11. Upon entry of this decree, Defendants and each and all of their Associated Persons, who have received actual notice of this decree by personal service or otherwise, 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, preparing, processing, labeling, growing, harvesting, packing, holding, and/or distributing any covered produce (other than sprouts) at or from Defendants' Establishment, unless and until:

A. Defendants notify FDA in writing at least ninety (90) calendar days in advance of resuming operations for such products;

B. Defendants establish, to FDA's satisfaction, that their receiving, preparing, processing, labeling, growing, harvesting, packing, holding, and/or distributing of such products is in compliance with this Decree, the Act, and its implementing regulations;

C. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this decree, the Act, and its implementing regulations, inspects Defendants' Establishment, including the buildings, equipment, utensils, labeling, and all articles of food and relevant records contained therein;

D. Defendants have paid all costs of inspection, analysis, review, investigation, examination, and supervision for FDA's oversight with respect to paragraph 10 of this decree, at the rates set forth in paragraph 18 of this decree; and

E. FDA has notified Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 11A, 11B, and 11D of this decree, the Act, and its implementing regulations. In no circumstance shall FDA's silence be construed as a substitution for written notification.

12. Upon resuming operations:

A. After complying with paragraph 8 of this decree and receiving FDA's written notification pursuant to paragraph 8I of this decree, Defendants shall meet the following requirements for the receiving, preparing, processing, labeling, growing, harvesting, packing, holding, and distributing of sprouts:

(1) Defendants shall continuously and effectively implement, on an ongoing basis, the Sprout Safety Plan developed pursuant to paragraph 8B of this decree and approved by FDA pursuant to paragraph 8C of this decree, which training programs shall be completed by each new employee within five (5) business days after the new employee commences work at Defendants' Establishment; and

(2) Defendants shall retain an independent person or persons (the "Sprout Safety Auditor") who shall meet the criteria for, and may be the same person(s) as, the Sprout Safety Expert(s) described in paragraph 8A of this decree, to conduct audit inspections of Defendants' Establishment and the methods, processes, and controls used to receive, prepare, process, label, grow, harvest, pack, hold, or distribute sprouts, as follows:

(a) Within three (3) months after Defendants resume operations after completing the requirements in paragraph 8 of this decree, the Sprout Safety Auditor shall conduct an audit of Defendants' Establishment and the methods and controls used to receive, prepare, process, label, grow, harvest, pack, hold, and distribute sprouts, to determine whether Defendants are operating in compliance with this Decree, the Act, and its implementing regulations, and to identify any deviations from such requirements. Defendants shall ensure that the Sprout Safety Auditor submits an Audit Report documenting all findings to Defendants and FDA concurrently, within seven (7) business days after completing the audit. As a part of every Audit Report (except the first one), the Sprout Safety Auditor shall assess the adequacy of actions

taken by Defendants to correct all previous audit observations indicating that Defendants are not in compliance with this Decree, the Act, or its implementing regulations. If the Audit Report contains any audit observations indicating that Defendants are not in compliance with this Decree, the Act, or its implementing regulations ("Audit Report Observations"), Defendants shall make all necessary corrections within ten (10) business days after receipt of the Audit Report, unless FDA notifies Defendants in writing that a shorter time period is necessary; and

(b) Thereafter, the Sprout Safety Auditor shall conduct audits no less frequently than once every three (3) months for a period of no less than one (1) year, and then at least once every six (6) months for the next two (2) years. If an Audit Report contains any Audit Report Observations, FDA may, in its discretion, require that the three-year auditing cycle be extended by one year or until such Audit Report Observations have been corrected. Absent such an FDA requirement, beginning in the fourth year after Defendants resume their operations after completing the requirements of paragraph 8 of this decree, the Sprout Safety Auditor shall conduct audits at least annually unless FDA informs Defendants in writing that more frequent audit inspections and reporting are required.

B. After complying with paragraph 10 of this decree and receiving FDA's written notification pursuant to paragraph 10J of this decree, Defendants shall meet the following requirements for the receiving, preparing, processing, labeling, growing, harvesting, packing, holding, or distributing of Other Food Products:

(1) Defendants shall continuously and effectively implement, on an ongoing basis, the Food Safety Plan developed pursuant to paragraph 10C of this decree and approved by FDA pursuant to paragraph 10D of this decree, which training programs shall be

completed by each new employee within five (5) business days after the new employee commences work at Defendants' Establishment; and

(2) Defendants shall retain an independent person or persons (the "Food Safety Auditor") who shall meet the criteria for, and may be the same person(s) as, the Food Safety Expert(s) described in paragraph 10B of this decree (who also, per paragraph 10B of this decree, may be the same person(s) as the Sprout Safety Expert(s) described in paragraph 8A of this decree), to conduct audit inspections of Defendants' Establishment and the methods, processes, and controls used to receive, prepare, process, label, grow, harvest, pack, hold, or distribute Other Food Products, as follows:

(a) Within three (3) months after Defendants resume operations for such products after completing the requirements in paragraph 10 of this decree, the Food Safety Auditor shall conduct an audit of Defendants' Establishment and the methods and controls used to receive, prepare, process, label, grow, harvest, pack, hold, and distribute Other Food Products, to determine whether Defendants are operating in compliance with this decree, the Act, and its implementing regulations, and to identify any deviations from such requirements. Defendants shall ensure that the Food Safety Auditor submits an Audit Report documenting all findings to Defendants and FDA concurrently, within seven (7) business days after completing the audit. As a part of every Audit Report (except the first one), the Food Safety Auditor shall assess the adequacy of actions taken by Defendants to correct all previous audit observations indicating that Defendants are not in compliance with this decree, the Act, or its implementing regulations. If the Audit Report contains any audit observations indicating that Defendants are not in compliance with this decree, the Act, or its implementing regulations ("Audit Report Observations"), Defendants shall make all necessary corrections within ten (10) business days after receipt of the

Audit Report, unless FDA notifies Defendants in writing that a shorter time period is necessary; and

(b) Thereafter, the Food Safety Auditor shall conduct audits no less frequently than once every three (3) months for a period of no less than one (1) year, and then at least once every six (6) months for the next two (2) years. If an Audit Report contains any Audit Report Observations, FDA may, in its discretion, require that the three-year auditing cycle be extended by one year or until such Audit Report Observations have been corrected. Absent such an FDA requirement, beginning in the fourth year after Defendants resume their operations after completing the requirements of paragraph 10 of this decree, the Food Safety Auditor shall conduct audits at least annually unless FDA informs Defendants in writing that more frequent audit inspections and reporting are required.

C. After complying with paragraph 11 of this decree and receiving FDA's written notification pursuant to paragraph 11C of this decree, Defendants shall meet the following requirements for the receiving, preparing, processing, labeling, growing, harvesting, packing, holding, or distributing of covered produce (other than sprouts):

(1) Defendants shall retain an independent person or persons (the "Covered Produce (Other than Sprouts) Safety Auditor") who shall meet the criteria for, and may be the same person(s) as, the Food Safety Auditor described in paragraph 12B(2) of this decree, to conduct audit inspections of Defendants' Establishment and the methods, processes, and controls used to receive, prepare, process, label, grow, harvest, pack, hold, or distribute covered produce (other than sprouts), as follows:

(a) Within three (3) months after Defendants resume operations for such products after completing the requirements in paragraph 11 of this decree, the Covered

Produce (Other than Sprouts) Safety Auditor shall conduct an audit of Defendants' Establishment and the methods and controls used to receive, prepare, process, label, grow, harvest, pack, hold, and distribute such products, to determine whether Defendants are operating in compliance with this decree, the Act, and its implementing regulations, and to identify any deviations from such requirements. Defendants shall ensure that the Covered Produce (Other than Sprouts) Safety Auditor submits an Audit Report documenting all findings to Defendants and FDA concurrently, within seven (7) business days after completing the audit. As a part of every Audit Report (except the first one), the Covered Produce (Other than Sprouts) Safety Auditor shall assess the adequacy of actions taken by Defendants to correct all previous audit observations indicating that Defendants are not in compliance with this decree, the Act, or its implementing regulations. If the Audit Report contains any audit observations indicating that Defendants are not in compliance with this decree, the Act, or its implementing regulations ("Audit Report Observations"), Defendants shall make all necessary corrections within ten (10) business days after receipt of the Audit Report, unless FDA notifies Defendants in writing that a shorter time period is necessary; and

(b) Thereafter, the Covered Produce (Other than Sprouts) Safety Auditor shall conduct audits no less frequently than once every three (3) months for a period of no less than one (1) year, and then at least once every six (6) months for the next two (2) years. If an Audit Report contains any Audit Report Observations, FDA may, in its discretion, require that the three-year auditing cycle be extended by one year or until such Audit Report Observations have been corrected. Absent such an FDA requirement, beginning in the fourth year after Defendants resume their operations after completing the requirements of paragraph 10 of this decree, the Covered Produce (Other than Sprouts) Safety Auditor shall conduct audits at least annually unless

FDA informs Defendants in writing that more frequent audit inspections and reporting are required.

13. Upon entry of this decree, Defendants and their Associated Persons are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(vv) by failing to comply with the requirements established under 21 U.S.C. § 350h, which are set forth in the Produce Safety Rule, 21 C.F.R. Part 112, for growing, harvesting, packing, and holding covered produce;

B. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4);

C. Violating 21 U.S.C. § 331(k) by causing articles of food that are held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4); and

D. Failing to implement and continuously maintain the requirements of this decree.

14. If, at any time after entry of this decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report, or data prepared or submitted by Defendants, the Sprout Safety Expert(s), the Food Safety Expert(s), the Sprout Safety Auditor, the Food Safety Auditor, the Covered Produce (Other than Sprouts) Safety Auditor , or any other information, that Defendants have failed to comply with any provision of this decree, Defendants have violated the Act or its implementing regulations, or 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, labeling, growing, harvesting, packing, holding, or distributing any and all 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 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.

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

15. Upon receipt of any order issued by FDA pursuant to paragraph 14 of this decree, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 14 of this decree 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.

16. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' operations and, without prior notice, 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 representatives shall be permitted to: have immediate access to Defendants' places of business including, but not limited to all buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material therein; take photographs and make video recordings; take samples of Defendants' raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material; and examine and copy all records relating to the receipt, preparing, processing, labeling, growing, harvesting, packing, holding, and distribution of any and all of Defendants' products 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 separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

17. Defendants shall immediately provide any information or records to FDA upon request regarding the receipt, preparing, processing, labeling, growing, harvesting, packing, holding, and distribution of Defendants' food products. Defendants shall maintain copies of their Sprout Safety Plan and the Food Safety Plan, along with copies of all records required by such plans and this decree, at Defendants' Establishment, and any other location(s) at or from which Defendants receive, prepare, process, label, grow, harvest, pack, hold, and/or distribute articles of food, in a location where the 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.

18. 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, including all transportation and associated costs for FDA investigators and experts, 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 after receiving written notification from FDA of the costs. As of the date that this decree is signed by the parties, these rates are: $101.00 per hour or fraction thereof per representative for inspection and investigative work; $121.06 per hour or fraction thereof per representative for analytical or review work; $0.575 per mile (plus tolls) 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.

19. Within five (5) business days after entry of this decree, Defendants shall prominently post a copy of this decree (in English and any other language necessary to convey the substance of the decree) in a conspicuous location in an employee common area at Defendants' Establishment 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.

20. Within ten (10) business 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 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.

21. Within ten (10) business 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. Within twenty (20) 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, identifying the names, addresses, and positions of all Associated Persons who have received a copy of this decree, and attaching a copy of the executed certified mail return receipts.

22. In the event that any of the Defendants becomes associated with any additional Associated Person(s) 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 Associated Person(s). Within five (5) business days after each time that any of the Defendants becomes associated with any additional Associated 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 Associated Persons who received a copy of this decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts.

23. 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 Fortune Food Product, 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.

24. 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: five thousand dollars ($5,000) in liquidated damages for each day such violation continues; an additional sum of four thousand dollars ($4,000) in liquidated damages per day per violation, 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

product distributed 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, or the Court to impose, additional civil or criminal penalties to be paid by Defendants, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

25. Should the United States bring and prevail in an 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.

26. 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, 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 the decision was made. No discovery shall be taken by either party.

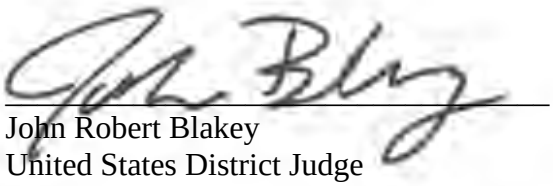
27. All notifications, correspondence, and communications to FDA required by the terms of this decree shall be prominently marked "Decree Correspondence" and addressed to the District Director, Chicago District Office, 550 West Jackson Blvd., 15th Floor, Chicago, Illinois 60661, and shall reference this civil action by case name and civil action number.

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

29. 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 15th day of September, 2020.

Entered:



John Robert Blakey
United States District Judge

Entry consented to:

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TIFFANY JIANG, in her individual capacity

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