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

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No.
	)	
FORTUNE FOOD PRODUCT, INC., a corporation, and STEVEN SEETO and TIFFANY JIANG, individuals,	)	
	)	
Defendants.	)	

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin Fortune Food Product, Inc., a corporation, and Steven Seeto and Tiffany Jiang, individuals (collectively, "Defendants"), from:

A. Violating 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;

B. Violating 21 U.S.C. § 331(a), by introducing 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 within the meaning of 21 U.S.C. § 342(a)(4); and

C. Violating 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, to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) while they are held for sale after shipment of one or more of their components in interstate commerce.

Jurisdiction and Venue

2. This court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a), and personal jurisdiction over all parties.

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

Defendants

4. Defendant Fortune Food Product, Inc. ("Fortune Food" or "the company"), is an Illinois company located at 1821 South Canalport Avenue, Chicago, Illinois 60616, within the jurisdiction of this court. The company employs approximately ten employees. The company is a "covered farm," within the meaning of 21 C.F.R. § 112.4, and thus subject to the requirements of the Produce Safety Rule.

5. Defendant Steven Seeto is Fortune Food's president and majority owner. Defendant Seeto has the authority to hire and fire employees, and is responsible for, among other things, the company's daily operations, the production of its soy products, and the growing, harvesting, and packaging of its sprouts.

6. Defendant Tiffany Jiang is a supervisor and accountant for Fortune Food, and the most responsible person at the company when Defendant Seeto is not present. Among other responsibilities, Defendant Jiang oversees raw materials purchasing and sales at the company.

7. Defendants Seeto and Jiang perform their duties at 1821 South Canalport Avenue, Chicago, Illinois 60616, within the jurisdiction of this court.

8. Defendants manufacture, process, grow, harvest, pack, hold for sale, and distribute in the United States, articles of food within the meaning of 21 U.S.C. § 321(f), namely, sprouts and soy products.

9. Defendants sell and ship their sprouts and soy products outside the state of Illinois, including to Wisconsin. Defendants also receive components and ingredients for their sprouts and soy products from outside the state of Illinois. Specifically, the mung bean seeds that Defendants use to grow their sprouts originate in China, and the calcium sulphate that Defendants use in their soy products is shipped from New Jersey.

Produce Safety Rule Requirements

10. In 2011, Congress passed the FDA Food Safety Modernization Act, Pub. L. 111-353, which amended the FDCA to add 21 U.S.C. § 350h. That section required FDA to issue a regulation providing for science-based minimum standards for fruits and vegetables that are raw agricultural commodities based on known safety risks and to set forth procedures, processes, and practices to minimize the risk of serious adverse health consequences or death from consumption of contaminated produce. 21 U.S.C. § 350h. FDA issued the Produce Safety Rule in 2015. *See* 80 Fed. Reg. 74354 (Nov. 27, 2015).

11. The Produce Safety Rule establishes mandatory, science-based minimum standards for the safe growing, harvesting, packing, and holding of covered produce. *See*

generally 21 C.F.R. Part 112. Sprouts are "covered produce" under the Produce Safety Rule, 21 C.F.R. § 112.1(b)(1), and the Rule includes certain requirements that are specifically applicable to sprouts. *See* 21 C.F.R. §§ 112.141–112.150.

12. Violations of the Produce Safety Rule are violations of 21 U.S.C. § 331(vv).

13. Defendants violate the Act, 21 U.S.C. § 331(vv), by failing to comply with Produce Safety Rule requirements in growing, harvesting, packing and holding sprouts. 21 C.F.R. § 112.192(a); *see also* 21 U.S.C. § 350h. FDA inspected Defendants' establishment between January 10 and February 1, 2018 ("the 2018 inspection"), and between August 19 and September 30, 2019 ("the 2019 inspection"), and documented violations of Produce Safety Rule requirements during both of those inspections. Defendants' violations of the Produce Safety Rule include:

A. Failing to adequately maintain all agricultural water distribution systems as necessary and appropriate to prevent the water distribution system from being a source of contamination, in violation of 21 C.F.R. § 112.42(b). For example, in both the 2019 and 2018 inspections, firm representatives stated that the water distribution system had never been checked or modified. FDA investigators also observed a ruptured irrigation hose held together by adhesive tape—a surface that is not capable of being cleaned and to which pathogens can adhere—and water leaking out of the taped hole onto an outer portion of the hose stained with black material, and then dripping onto the sprouts.

B. Failing to use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained, in violation of 21 C.F.R. § 112.123(a). For example, in both the 2019 and 2018 inspections, FDA investigators observed that the belt utilized to transport sprouts had holes, the pieces of metal

used to affix the bar prongs to the belt were detached, and the welding on the hooks attached to the belt and agitators were not smooth, making all of these surfaces difficult to clean and sanitize. In addition, during the 2019 inspection, FDA investigators observed that the welding on the corners of the packaging table was not smooth, making it difficult to clean and sanitize, and that the metal strainer used to handle sprouts was coming apart, creating crevasses that are difficult to clean and sanitize.

C. Failing to maintain and sanitize food contact surfaces of equipment and tools as frequently as reasonably necessary to protect against sprout contamination, in violation of 21 C.F.R. §§ 112.123(d) and 112.143(b). For example, in both the 2019 and 2018 inspections, FDA investigators observed a Fortune Food employee using the same shovel both to harvest sprouts and to collect sprouts from the floor and then to throw them away.

D. Failing to establish and implement a written sampling plan that identifies the number and location of samples, of both spent sprout irrigation water ("SSIW") and sprouts, to be collected for each sprout production batch to test for pathogens, in violation of 21 C.F.R. § 112.147. *See also* 21 C.F.R. §§ 112.143(c) & 122.144(b). For example, in both the 2019 and 2018 inspections, Fortune Food reported that it does not have a written sampling plan for testing the SSIW of each sprout production batch for pathogens, and does not test the SSIW for each sprout production batch. Moreover, during the 2019 inspection, Fortune Food reported that, in October 2018, the SSIW for one of its sprout production batches tested positive for *E. coli* O157:H7, but the company failed to take most of the corrective actions required under 21 C.F.R. §§ 112.148 and 112.142(b)—*e.g.*, treat or discontinue use of the implicated seed lot, report the positive test to the seed supplier, and implement additional cleaning or sanitation measures to eliminate the pathogen from affected surfaces and surrounding areas.

E. Failing to establish and implement a written environmental monitoring plan that is designed to identify *Listeria Monocytogenes* if it is present in the growing, harvesting, packing, or holding environment, in violation of 21 C.F.R. § 112.145(a). *See also* 21 C.F.R. § 112.143(d). During the 2018 inspection, Fortune Food reported that it did not have a written environmental monitoring plan to identify *Listeria. Monocytogenes* and did not test the growing, harvesting, packing, or holding environment for *Listeria* species or *Listeria. Monocytogenes*. During the 2019 inspection, Fortune Food reported that it collects environmental samples for *Listeria* species, but that it still does not have a written environmental monitoring plan. In addition, although environmental samples recently taken from its sprout production room floor had tested positive for *Listeria* species, Defendants failed to take the corrective actions required under 21 C.F.R. § 112.146 after this positive test and did not have any record of corrective actions, in violation of 21 C.F.R. § 112.150(b)(6).

F. Failing to treat seeds used to grow sprouts using a scientifically valid method to reduce microorganisms of public health significance or to rely on prior treatment of the seeds conducted by a grower, distributor, or supplier of the seeds, in violation of 21 C.F.R. § 112.142(e). For example, in both the 2019 and 2018 inspections, Fortune Food reported that it neither applies an antimicrobial treatment to its seeds nor receives pre-treated seeds from its supplier.

G. Failing to establish and keep records of training that document required training of personnel including the training date, topics covered, and the person(s) trained, in violation of 21 C.F.R. § 112.30(b). For example, in both the 2019 and 2018 inspections, FDA investigators observed that Fortune Food did not have any documentation of personnel training for those who handle sprouts.

Food Adulteration

14. Food is adulterated within the meaning of the Act "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 342(a)(4).

15. Sprouts are "covered produce" under the Produce Safety Rule, 21 C.F.R. § 112.1(b)(1). The requirements in the Produce Safety Rule apply in determining whether sprouts are adulterated under 21 U.S.C. § 342(a)(4). *See* 21 C.F.R. § 112.192(b)(1)(ii).

16. Soy products are subject to the requirements of the final rule, *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food*, 80 Fed. Reg. 55908 (Sept. 17, 2015) (hereafter, "cGMP & PC Rule"), codified at 21 C.F.R. Part 117. Like the Produce Safety Rule, the cGMP & PC Rule establishes best practices that must be followed and conditions that must be maintained during food manufacturing, processing, packing, and holding operations. *See* 21 C.F.R. §§ 117.10-117.110. The cGMP & PC Rule requires, among other things, that all operations in the manufacturing, processing, packing, and holding of food be conducted in accordance with adequate sanitation principles. 21 C.F.R. § 117.80(a). The requirements in the cGMP & PC Rule apply in determining whether food is adulterated under 21 U.S.C. § 342(a)(4). *See* 21 C.F.R. § 117.1(a)(1)(ii).

17. Defendants violate the Act, 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).

18. Defendants violate the Act, 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).

19. Defendants' sprouts and soy products are adulterated under 21 U.S.C. § 342(a)(4) because they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health.

20. During the 2019 and 2018 inspections, FDA investigators documented similar types of insanitary conditions and repeated violations of Produce Safety Rule requirements and cGMP & PC Rule requirements, including, but not limited to, the following:

A. Failure to adequately maintain all agricultural water distribution systems as necessary and appropriate to prevent the water distribution system from being a source of contamination, in violation of 21 C.F.R. § 112.42(b). *See supra* ¶ 13.A.

B. Failure to use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained, in violation of 21 C.F.R. § 112.123(a). *See supra* ¶ 13.B.

C. Failure to maintain and sanitize food contact surfaces of equipment and tools as frequently as reasonably necessary to protect against contamination of sprouts, in violation of 21 C.F.R. §§ 112.123(d) and 112.143(b). *See supra* ¶ 13.C.

D. Failure to conduct food manufacturing, processing, packing, and holding operations in accordance with adequate sanitation principles, in violation of 21 C.F.R. § 117.80(a) and 21 C.F.R. § 110.80. For example, during the 2019 inspection, the FDA investigators observed: two employees submerging their uncovered arms into the tofu water tub when transferring tofu from the tub to final packaging. They also observed an employee wearing the same gloves to, interchangeably, move firm tofu from the tofu water tub to final package, and handle non-sanitized production equipment. During the 2018 inspection, the FDA investigators

similarly observed an employee touching garbage and then touching food contact surfaces without changing gloves.

E. Failure to conduct food manufacturing, processing, packing, and holding operations under such conditions and controls as are necessary to minimize the potential for food contamination, in violation of 21 C.F.R. § 117.80(c)(2) and 21 C.F.R. § 110.80(b). *See also* 21 C.F.R. §§ 117.35(a) and 110.35(a). For example, during the 2019 inspection, the FDA investigators observed an employee repeatedly using a knife to cut tofu after the knife had been submerged in pooled wash water previously used by another employee to clean a metal container; an employee splashing dirty, soapy water from the floor toward unprotected tofu on open racks, during cleaning of the production room floor; and employees not using sanitizer to clean equipment food contact surfaces. During the 2018 inspection, the FDA investigators observed practices that similarly risked food contamination when an employee placed trays used to hold tofu directly on the floor after being cleaned.

F. Failure to operate in a plant of suitable design to facilitate maintenance and sanitary operations, and to maintain the plant in repair adequate to prevent food from becoming adulterated, in violation of 21 C.F.R. §§ 117.20(b) & 117.35(a), and 21 C.F.R. §§ 110.20(b) & 110.35(a). For example, during the 2019 inspection, the FDA investigators observed the absence of grouting on the floors in the tofu production room, resulting in water collecting and remaining stagnant directly underneath exposed and handled tofu; grease and dust buildup on the ceiling fans above the area where the exposed tofu is cut and handled; grease and dust buildup on the standing fans used to cool the exposed tofu; and buildup of an unknown substance on the machine used to package the exposed tofu. During the 2018 inspection, the FDA investigators similarly observed the same ceiling and standing fans in the tofu production room were filthy in

appearance. In addition, during the 2019 inspection, the FDA investigators observed employees failing to clean all food-contact surfaces as frequently as necessary to protect against food contamination, in violation of 21 C.F.R. § 117.35(d). In particular, FDA investigators observed that the metal containers that directly contact the tofu products had visible residue after cleaning and before further tofu product processing.

Warnings

21. Defendants have been warned about their ongoing violations. At the close of the 2018 inspection, FDA investigators issued a List of Inspectional Observations ("Form FDA-483") to Defendant Jiang, on behalf of Fortune Food, and, during the closeout meeting for the 2018 inspection, discussed with her each of the objectionable conditions and practices observed. Shortly thereafter, Defendant Jiang, on behalf of Fortune Food, submitted a written response to FDA, promising certain corrective actions. Fortune Food's response, however, did not fully address all the observations cited on the Form FDA-483.

22. Accordingly, on July 19, 2018, FDA issued a Warning Letter to Defendant Seeto, on behalf of Fortune Food, explaining the inadequacy of the company's promised corrective actions, and notifying the company that it violated Produce Safety Rule requirements with respect to its sprouts, and cGMP & PC Rule requirements with respect to its soy products. The Warning Letter cautioned Fortune Food that if it failed to promptly correct its violations, FDA may pursue further regulatory action, including an injunction. Defendants did not respond to the Warning Letter.

23. At the close of the 2019 inspection, FDA investigators issued a Form FDA-483 to Defendant Jiang, on behalf of Fortune Food, and again discussed with her each of the

objectionable conditions and practices observed. Defendants promised to submit a written response to the Form FDA-483, but have not done so.

24. Altogether, Defendants have been generally unresponsive to FDA's warnings, and in the limited instances in which Defendants have responded to FDA's warnings, their actions have been, and continue to be, inadequate to address the insanitary conditions at the establishment.

Request for Relief

25. Despite numerous warnings from FDA, Defendants continue to violate the Act.

26. Based on the foregoing, Plaintiff believes that, unless restrained by this court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the court:

I. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, cease receiving, preparing, processing, growing, harvesting, packing, labeling, holding, and distributing articles of food unless and until Defendants bring their receiving, preparing, processing, growing, harvesting, packing, labeling, holding, and distribution operations into compliance with the Act and applicable regulations, to FDA's satisfaction;

II. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be 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 Produce Safety Rule requirements, as set forth in 21 C.F.R. Part 112, in growing, harvesting, packing and holding covered produce; and

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); and

C. Violating 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 held for sale after shipment of one or more of their components in interstate commerce.

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receiving, preparing, processing, growing, harvesting, packing, labeling, holding, and distribution of food to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Award Plaintiff its costs incurred in pursuing this action, including the costs of investigation to date, and such other equitable relief as the court deems just and proper.

Respectfully submitted,

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