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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, v. THE SMOKEHOUSE OF NEW YORK, LLC, BRETT H. PORTIER, and PANAGIOTA SOUBLIS, Defendants.	17 Civ. 4830 **COMPLAINT**

Plaintiff the United States of America, by its attorney, Joon H. Kim, Acting United States Attorney for the Southern District of New York, alleges upon information and belief as follows:

INTRODUCTION

1. Defendants' packaged fish business in Mamaroneck, New York, has repeatedly been contaminated by the bacterium *Listeria monocytogenes* ("*L. mono*"). These outbreaks have been caused by Defendants' persistent failure to operate their business in compliance with health standards set by the Food, Drug, and Cosmetic Act (the "Act") and related regulations.

2. *L. mono* is highly dangerous to human health. In the general population, it can cause severe flu-like symptoms and, in extreme cases, confusion, loss of balance, and

convulsions. For pregnant women, it can cause miscarriage, stillbirth, premature delivery, or life-threatening infection of the newborn.

3. The United States brings this action to enjoin this ongoing public health threat pursuant to 21 U.S.C. § 331(a) and 21 U.S.C. § 331(k).

JURISDICTION AND VENUE

4. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a), and 28 U.S.C. §§ 1331, 1337, and 1345.

5. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

6. Defendant The Smokehouse of New York, LLC ("Smokehouse"), is a New York limited liability company that conducts business at a facility located at 434 Waverly Avenue, Mamaroneck, New York 10543 (the "Facility").

7. Defendant Brett H. Portier ("Portier") is Smokehouse's Director of Operations. Portier is responsible for Smokehouse's day-to-day operations, including product ordering, receiving, packaging, storing, facility maintenance, sanitation, and oversight of employees. He is also responsible for preventing, detecting, and correcting violations of health regulations. He performs his duties at 434 Waverly Avenue, Mamaroneck, New York 10543.

8. Defendant Panagiota Soublis, who is married to Portier, is Smokehouse's President, sole corporate officer, and owner. She performs her duties at 434 Waverly Avenue, Mamaroneck, New York 10543.

DEFENDANTS' BUSINESS

9. Defendants prepare, process, pack, hold, and distribute refrigerated, vacuum-packed, ready-to-eat cold-smoked and hot-smoked fish and fishery products, including but not limited to smoked salmon, trout, whitefish, and sturgeon, as well as other non-fish food products.

10. In addition to processing fish and fishery and other food products, Defendants operate a retail store in the front of the Facility. The retail store distributes Smokehouse's finished products, as well as other products it obtains from other distributors.

11. Smokehouse ships its products in interstate commerce, including to retail stores and restaurants in Florida and New Jersey. Additionally, Smokehouse sells products through its website, www.thesmokehouseny.com, to customers throughout the United States.

12. The raw fish that Defendants use to process their ready-to-eat, smoked fish and fishery products originate from outside of New York, including from British Columbia, Canada.

LEGAL FRAMEWORK

13. All food covered by the Act must be prepared, processed, packed, and otherwise handled according to good manufacturing practices as set forth in 21 C.F.R. Part 110.

14. The seafood Hazard Analysis and Critical Control Point ("HACCP") regulations, 21 C.F.R. Part 123, were implemented to ensure seafood safety in particular. The regulations require seafood processors to protect against any food safety hazards that are reasonably likely to occur in their seafood. The first step under the seafood HACCP regulations is for every fish and fishery product processor to conduct a hazard analysis to determine whether there are food safety

hazards that are reasonably likely to occur during the processing of each kind of fish or fishery product that it produces. 21 C.F.R. § 123.6(a).

15. Whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur during seafood processing, the processor must develop and implement an adequate seafood HACCP plan to control the identified food safety hazards. 21 C.F.R. § 123.6(b). Among other things, a seafood HACCP plan must:

a. Include critical control points ("CCPs"), which are points, steps, or procedures in a food manufacturing process at which controls can be applied to prevent, eliminate, or reduce to an acceptable level a food safety hazard, 21 C.F.R. §§ 123.3(b), 123.6(c)(2); and

b. Include critical limits at each CCP, which are the maximum or minimum values within which a physical, biological, or chemical parameter must be maintained to prevent, eliminate, or reduce to an acceptable level, the occurrence of the identified food safety hazard(s). 21 C.F.R. §§ 123.3(c), 123.6(c)(3).

16. Seafood processors must monitor their CCPs and critical limits for each type of fish or fishery product they manufacture to ensure they are controlling for known food safety hazards such as *L. mono* in their seafood.

17. Seafood processors must also take appropriate corrective actions whenever a deviation occurs, 21 C.F.R. §§ 123.7 and 123.8(a), and monitor, with sufficient frequency, sanitation controls and practices used during processing to ensure that they conform with the

current good manufacturing practice ("CGMP") requirements for food, as specified at 21 C.F.R. Part 110. 21 C.F.R. § 123.11(b).

18. Defendants are subject to the seafood HACCP regulations because they engage in the "processing," as defined at 21 C.F.R. § 123.3(k)(1), of "fish" or "fishery product," as defined at 21 C.F.R. §§ 123.3(d) and (e).

19. A seafood processor's failure to comply with any of the seafood HACCP regulations renders its fish or fishery products adulterated under the Act. *See* 21 U.S.C. § 342(a)(4); 21 C.F.R. § 123.6(g).

PUBLIC HEALTH RISKS PRESENTED BY DEFENDANTS' FOOD

20. *L. mono* is the bacterium that causes listeriosis, a disease commonly contracted by eating food contaminated with *L. mono*. Listeriosis can be serious, even fatal, for vulnerable groups such as newborns and those with impaired immune systems. The most serious forms of listeriosis can result in meningitis and septicemia. Pregnant women may contract flu-like symptoms from listeriosis, and complications from the disease can result in miscarriage or

septicemia in the newborn. *L. mono* is the major pathogen, and one of several bacterium, contained within the *Listeria species* ("*L. spp.*").

21. *L. mono* can survive and grow under many conditions, including refrigeration temperatures and high salt or high acid conditions. *L. mono* can colonize on moist surfaces such as floors, floor drains, wet areas, and processing equipment.

22. The presence of *L. mono* in a facility processing ready-to-eat foods presents a particularly significant public health risk.

DEFENDANTS' VIOLATIONS

23. Items processed, packed, and held in Defendants' facility, including Defendants' ready-to-eat fish , are food within the meaning of the Act, 21 U.S.C. § 321(f).

24. Defendants violate 21 U.S.C. § 331(a) by causing to be introduced or delivered for introduction into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

25. Defendants violate 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 of their components in interstate commerce.

26. Defendants' food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that it has been held in insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health as a result of the presence of *L. mono* because Defendants have failed to operate according to good manufacturing practices as required by 21 C.F.R. Part 110. The fish and fishery products are further adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health because Defendants have failed to comply with

the seafood HACCP regulations, 21 C.F.R. Part 123, by, among other deficiencies, failing to adequately control for all food safety hazards reasonably likely to occur such as *L. mono*, failing to implement effective sanitation controls to minimize the potential for microorganism growth and contamination, and failing to adequately monitor sanitation pursuant to 21 C.F.R. § 123.11(b).

DEFENDANTS' HISTORY OF VIOLATIONS

27. The U.S. Food and Drug Administration ("FDA") has conducted numerous inspections of Defendants' Facility since 2000.

28. Specifically, between 2011 and 2015, FDA conducted five inspections of Defendants' Facility. At the close of each inspection, FDA issued an itemized List of Inspectional Observations ("Form FDA-483"), documenting seafood HACCP and sanitation violations, including but not limited to:

a. Failure to manufacture, package, and store food under conditions and controls necessary to minimize the potential for microorganism growth and contamination, including *L. mono*;

b. Failure to monitor the sanitation conditions with sufficient frequency to assure conformance with CGMP;

c. Failure to monitor employee practices as to assure conformance with CGMP;

d. Failure to implement adequate seafood HACCP plans that control for all food safety hazards reasonably likely to occur; and

e. Failure to adequately implement the seafood HACCP monitoring, recordkeeping, and verification requirements.

29. Additionally, during each of these inspections, FDA found evidence of widespread *L. mono* in the Facility.

a. During the February 23 - March 11, 2011, inspection, FDA sampled a refrigerated, vacuum-packed, ready-to-eat cold-smoked salmon, which tested positive for *L. mono.*

b. During the March 29 - April 1, 2011, inspection, FDA took an environmental sample consisting of 100 subsamples, 6 of which tested positive for *L. mono*. One of the positive *L. mono* samples was found on a food-contact surface (cutting board).

c. During the November 15-21, 2011, inspection, FDA took an environmental sample consisting of 94 subsamples, 25 of which tested positive for *L. mono*.

d. During the December 3-12, 2013, inspection, FDA took an environmental sample consisting of 100 subsamples, 10 of which tested positive for *L. mono*.

e. During the November 18 - December 2, 2015, inspection, FDA took an environmental sample consisting of 99 subsamples, 21 of which tested positive for *L. mono*.

30. After the inspections, Defendants proposed a number of corrective actions that they stated would address the problems found during the inspections, including (a) installing a new floor and replacing drain covers, (b) cleaning and sanitizing the Facility, (c) instituting regular environmental swabbing of the Facility and testing of finished products, (d) revising their

seafood HACCP plans, (e) hiring a seafood HACCP consultant, and (f) retraining employees on sanitation and CGMP.

31. Notwithstanding these proposed corrections, Defendants have been unable to bring their operations into compliance. FDA most recently inspected Defendants' facility between March 8 and April 5, 2017. At the close of that inspection, FDA investigators issued Defendants an 11-item Form FDA-483, listing many of the same observations as in prior inspections. These included, among others:

a. Failure to manufacture, package, and store food under conditions and controls necessary to minimize the potential for microorganism growth and contamination, including *L. mono*;

b. Failure to monitor the sanitation conditions with sufficient frequency to assure conformance with CGMP;

c. Failure to monitor employee practices as to assure conformance with CGMP;

d. Failure to implement adequate seafood HACCP plans that control for all food safety hazards reasonably likely to occur; and

e. Failure to adequately implement the seafood HACCP monitoring, recordkeeping, and verification requirements.

32. During the 2017 inspection, FDA investigators also took an environmental sample consisting of 99 subsamples, 37 of which tested positive for *L. mono*. Two of the positive *L. mono* subsamples were found on food-contact surfaces, namely on a stainless steel table where fish is processed and on a plastic tray used interchangeably to hold raw and finished products.

33. FDA compared the positive *L. mono* samples found during its inspections of the Facility from 2011 to 2017. The laboratory analysis revealed four resident strains of *L. mono* currently in Defendants' Facility, including one *L. mono* strain that has persisted since 2011 despite Defendants' efforts to clean and sanitize the Facility. The laboratory analysis revealed a fifth resident strain of *L. mono* that existed in Defendants' Facility from at least November 2011 to December 2013.

34. On April 28, 2017, Defendants responded to the FDA Form-483. Defendants proposed certain corrective actions, including (a) installing new floors and drains, (b) cleaning and sanitizing the Facility, (c) creating an environmental monitoring program, (d) designating certain days and areas of the Facility for processing raw, fresh fish, (e) revising their seafood HACCP plan, (f) hiring a seafood HACCP consultant, and (e) re-training employees on sanitation and good manufacturing practice. However, Defendants' response does not provide any verification of the corrective actions, and moreover, the response is largely identical to Defendants' previous commitments to correct violations, which have not resulted in compliance. Defendants' response additionally does not provide or promise a root cause analysis to identify the practices, procedures, and harborage sites that led to the resident *L. mono* strains in the Facility.

PRIOR WARNINGS AND CONTINUED THREAT TO PUBLIC HEALTH

35. Defendants have a long history of non-compliance. Since 2000, FDA has conducted sixteen inspections of the Facility, repeatedly observing sanitation and seafood HACCP violations similar to those observed during the most recent inspection. At the close of all but two of these sixteen inspections, FDA investigators issued Forms FDA-483 listing the observed objectionable conditions and practices at the Facility.

36. Additionally, in April 2000, FDA issued a letter to Smokehouse regarding its seafood HACCP violations. In November 2000, FDA issued a Warning Letter to Smokehouse regarding its seafood HACCP violations. In August 2011, FDA issued a second Warning Letter to Smokehouse regarding both its seafood HACCP violations and positive *L. mono* findings.

37. Defendants have repeatedly promised to comply with the statutory and regulatory requirements by, among other things, cleaning and sanitizing the Facility, re-training employees, and revising their seafood HACCP plans. However, their deviations from the seafood HACCP regulations remain systemic and persistent, and FDA has found widespread *L. mono* in the Facility during each inspection over the last six years. Defendants' repeated failure to bring their operations into compliance with the law, despite ample warnings, has resulted in a continued risk to public health and necessitates this injunction. Unless restrained by order of this Court, Defendants are likely to continue to violate the law and threaten the public health.

WHEREFORE, the United States respectfully requests this Court to:

I. Order that Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who have received actual notice of this Court's order by personal service or otherwise, cease receiving, preparing, processing, packing, labeling, holding, and distributing food at or from the Facility or at any other location(s) at or from which Defendants, now or in the future, receive, prepare, process, pack, label, hold, and distribute food, unless and until Defendants bring their operations into compliance with the Act and applicable regulations, to FDA's satisfaction;

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who have received actual notice of this Court's order by personal service or otherwise, from directly or indirectly violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, or the causing thereof, any food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4);

III. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who have received actual notice of this Court's order by personal service or otherwise, from directly or indirectly violating 21 U.S.C. § 331(k) by adulterating, or causing adulteration, within the meaning of 21 U.S.C. § 342(a)(4), of any food while such food is held for sale after shipment of one or more of its components in interstate commerce;

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

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

Dated: New York, New York
June 27, 2017

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