IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

UNITED STATES OF AMERICA, Plaintiff, v. MARY E. PARRISH an individual, doing business as FORT MASSAC FISH MARKET, Defendant.	Civil No.: 17-cv-1005 COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

INTRODUCTION

1. This action is brought by the United States of America pursuant to the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin Mary E. Parrish, an individual doing business as Fort Massac Fish Market ("Defendant"), from violating 21 U.S.C. § 331(a), by causing to be introduced or delivered for introduction into interstate commerce food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4).

JURISDICTION AND VENUE

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

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

DEFENDANT

4. Defendant Mary E. Parrish does business as and is the owner of Fort Massac Fish Market ("Fort Massac").

5. Defendant Parrish operates the business at a facility located at 1117 E 2nd Street, Metropolis, Illinois ("the facility"), within the jurisdiction of this Court.

6. Defendant Parrish is the most responsible person at Fort Massac. She oversees all aspects of the business and is directly responsible for Fort Massac's day-to-day operations, including receiving, processing, storing, packaging, and distributing product. She has accompanied FDA investigators during inspections of the facility and has authority to respond to FDA's inspectional observations and make corrections.

7. Defendant Parrish receives raw fish eggs, also known as shovelnose sturgeon (hackleback) and paddlefish (spoon bill) roe, and prepares, processes, packs, holds, and distributes the roe as salted, ready-to-eat caviar.

8. Defendant distributes most, if not all, of her ready-to-eat caviar to a wholesale customer in New York.

HAZARDS PRESENTED BY DEFENDANT'S FOOD

9. *Clostridium botulinum* ("*C. bot*") is an anaerobic bacterium, meaning that it thrives in oxygen-free environments. All people are susceptible to the potent neurotoxin that *C. bot* spores can produce in food. Ingestion of even a small amount of this neurotoxin can cause botulism, a rare but life-threatening disease.

10. *C. bot* is widely distributed in nature and can be found in any raw fish or fishery product. Certain *C. bot* strains, called proteolytic strains, produce offensive odors and tastes in food products. In contrast, non-proteolytic strains of *C. bot* do not produce the same sensory signals. These non-proteolytic strains are particularly dangerous because they can grow at refrigeration temperatures and render a food toxic without any signs of spoilage. Toxin formation by non-proteolytic *C. bot* can occur at temperatures above 38°F. To inhibit *C. bot*

growth and toxin formation in salted, ready-to-eat caviar, processors must employ adequate salting in conjunction with maintaining appropriate temperature during transit, processing, storage, and distribution.

LEGAL FRAMEWORK

11. Defendant's ready-to-eat caviar is "food" within the meaning of the Act, 21 U.S.C. § 321(f).

12. Food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) "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."

13. A seafood processor's failure to comply with the requirements of the seafood Hazard Analysis and Critical Control Point ("HACCP") regulations, 21 C.F.R. Part 123, renders its fish or fishery products adulterated under the Act. 21 U.S.C. § 342(a)(4); 21 C.F.R. §§ 123.6(g), 123.12(d).

14. The Hazard Analysis and Critical Control Point ("HACCP") regulations for fish and fishery products, 21 C.F.R. Part 123, were implemented to ensure food safety, and they require processors to protect against any food safety hazards that are reasonably likely to occur in their fish and fishery products. The first step under HACCP is for every 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). A food safety hazard is "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." 21 C.F.R. § 123.3(f).

15. Whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur during processing, the processor must develop and implement an

adequate HACCP plan to control the identified food safety hazards. 21 C.F.R. § 123.6(b). Among other things, a HACCP plan must:

a. include critical control points, 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, at each critical control point, critical limits, 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. Processors must monitor their critical control points 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 *C. bot*, in their food.

17. 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 conformance with the current good manufacturing practice requirements for food, 21 C.F.R. Part 110. 21 C.F.R. § 123.11(b).

DEFENDANT'S VIOLATIONS

18. Defendant's ready-to-eat caviar is food within the meaning of the Act, 21 U.S.C. § 321(f).

19. Defendant violates 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).

20. Defendant's food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health.

21. Defendant is subject to the HACCP regulations because she engages 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).

22. Defendant's food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that she fails to comply with the HACCP regulations, 21 C.F.R. Part 123 by, among other deficiencies, failing to adequately control for the hazard of *C. bot* growth and toxin formation in her ready-to-eat caviar and failing to implement effective sanitation controls.

HISTORY OF VIOLATIONS

23. FDA most recently inspected Defendant's facility between December 13 and 14, 2016 ("December 2016 inspection"), and observed HACCP deficiencies that included, but were not limited to, the following:

a. Failure to implement the verification, monitoring, and recordkeeping procedures listed in Defendant's HACCP plan. Specifically, Defendant did not conduct quarterly water phase salt testing, as required by Defendant's HACCP plan, to verify that she was adequately controlling the hazard of *C. bot* growth and toxin formation in her ready-to-eat caviar. In addition, Defendant did not have records showing that the temperature in her facility's cooler was being reviewed and controlled. At a minimum, a daily visual check of the recorded cooler temperature data is needed to ensure the raw roe is maintained below 38°F to control non-proteolytic *C. bot*. *See* 21 C.F.R. §§ 123.6(b) and (c)(7). The FDA investigator also observed during this inspection that Defendant did

not know how to read the continuous temperature recorder chart generated by the monitoring device in her facility's cooler. *See* 21 C.F.R. §§ 123.6(b), 123.8(a)(3)(iii).

b. Failure to list a hazard that is reasonably likely to occur in Defendant's HACCP plan. Specifically, Defendant's HACCP plan did not list the hazard of *C. bot* growth and toxin formation at the "Receiving Raw Roe" critical control point. Roe, when packaged in bulk quantities can become tightly packed, displacing air within the packaging and creating a reduced-oxygen environment in which *C. bot* can grow and form a toxin, a hazard that can be controlled by ensuring that the roe maintains a temperature below 38°F. However, the FDA investigator observed that Defendant accepted four pounds of raw roe in a plastic bag from a supplier without any evidence, such as ice or another cooling media, that the roe was maintained below 38°F during transit. *See* 21 C.F.R. § 123.6(c)(1).

c. Failure to calibrate process monitoring equipment to ensure its accuracy. Specifically, although the Defendant used a continuous temperature chart recorder to monitor the temperature in her facility's cooler, the temperature indicated on the device's digital display did not match the temperature recorded by the device, demonstrating that the recorder was not accurate and must be repaired or calibrated. *See* 21 C.F.R. § 123.8(a)(2)(ii).

d. Failure to monitor, correct, and document sanitation conditions and practices. The FDA investigator observed, among other things, the following:

i. Defendant did not properly clean and sanitize food contact surfaces such as screens and spatulas prior to use; she only rinsed these utensils with water before using them to produce ready-to-eat caviar.

ii. After touching tables and the touchpad of the scale, Defendant made direct bare-hand contact with ready-to-eat caviar without cleaning or sanitizing her hands.

iii. Boxes containing pails used by the Defendant to hold caviar contained what appeared to be dead cockroaches and excreta. In addition, some of these pails had filth and what appeared to be speckles of insect excreta and cockroach egg casings on their exteriors.

iv. Empty pails and lids used to hold ready-to-eat caviar with filthy residue on their surfaces were stacked in the sink in the processing room, making the sink inaccessible to handwashing.

v. The only bathroom in the facility had residue and filth on the floors, walls, and fixtures, including a smashed insect stuck on the wall next to the doorway. A dead cockroach and what appeared to be insect excreta was observed on the sink backsplash, and the sink itself was filled with empty aluminum cans.

vi. The sink in the employee breakroom was not in use and had a cockroach, a used Q-tip swab, a dirty spoon, and what appeared to be insect excreta in or next to it.

vii. The entire building had filth build-up on its floors and walls, and the laundry/storage room had animal fur and feathers accumulating along the floor wall junction and wall studs. Defendant's pet dogs were allowed in the building.

viii. Defendant did not maintain required sanitation control records.

24. At the close of the December 2016 inspection, the FDA investigator issued Defendant a five-item List of Inspectional Observations ("Form FDA-483"), citing the observed deficiencies. Although the investigator informed Defendant that she had 15 days to respond in writing, she did not submit a response.

25. FDA also inspected the facility between April 15 and 18, 2016 ("April 2016 inspection"), and observed essentially the same deficiencies that were observed in the December 2016 inspection, including, but not limited to, the following:

a. Failure to implement the verification, monitoring, and recordkeeping procedures listed in Defendant's HACCP plan;

b. Failure to list a hazard that is reasonably likely to occur and thus must be controlled in Defendant's HACCP plan;

c. Failure to calibrate process monitoring equipment to ensure its accuracy; and

d. Failure to monitor, correct, and document sanitation conditions and practices.

26. At the close of the April 2016 inspection, the FDA investigator issued Defendant a five-item Form FDA-483 citing the observed deficiencies. Although the investigator informed Defendant that she had 15 days to respond in writing, she did not submit a response.

27. Following the April 2016 inspection, the FDA Chicago District Office issued Defendant a Warning Letter dated October 4, 2016, discussing the objectionable conditions that FDA's investigator observed during the April 2016 inspection and warning her that failure to correct violations may result in further regulatory action, including an injunction. Defendant did not respond to this Warning Letter.

28. In addition to the Form FDA-483s issued to Defendant at the end of the 2016 inspections and the October 4, 2016 Warning Letter, FDA also issued Defendant another Warning Letter, dated May 21, 2003, following an inspection of the facility in January 2003, and an Untitled Letter, dated April 9, 2002, following an inspection of the facility in February-March 2002.

29. Both the May 21, 2003 Warning Letter and the April 9, 2002 Untitled Letter discussed deficiencies that were similar to those observed during the 2016 inspections, including, but not limited to, the following: failure to adequately control the *C. bot* hazard, inadequate process monitoring and recordkeeping, failure to calibrate process-monitoring equipment, and failure to monitor and document sanitation conditions and practices.

30. Defendant responded to the May 21, 2003 Warning Letter with promised corrective actions.

31. Defendant did not respond to the April 9, 2002 Untitled Letter.

32. It is clear that, despite ample notice, Defendant is ignoring her obligation to bring her operations into compliance with the law, and unless restrained by order of this Court, Defendant is likely to continue to violate 21 U.S.C. § 331(a).

WHEREFORE, the United States respectfully requests this Court to:

I. Order that Defendant and each and all of her 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 the 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 Defendant,

now or in the future, receives, prepares, processes, packs, labels, holds, and distributes food, unless and until Defendant brings her 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), Defendant, and each and all of her 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 the 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 causing the introduction or delivery for introduction into interstate commerce, any food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4);

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

IV. Award the United States 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 this 20th day of September, 2017.

Respectfully submitted,

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