UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	Civil No._____
	)	
v.	)	
	)	
S. SERRA CHEESE COMPANY, a corporation,	)	COMPLAINT FOR PERMANENT INJUNCTION
	)	
and	)	
	)	
FINA SERRA and STEFANO SERRA, individuals,	)	
	)	
Defendants.	)	
	)	

Plaintiff, the United States of America, by its undersigned attorneys, 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), and the equitable authority of this Court, to enjoin and restrain S. Serra Cheese Company ("Serra Cheese"), a corporation, and Fina Serra and Stefano Serra, individuals, (collectively, "Defendants"), from violating: (a) 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, articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4); and (b) 21 U.S.C. § 331(k) by causing articles of food that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

2. This Court has jurisdiction over this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

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

THE DEFENDANTS

4. Serra Cheese was incorporated in the state of Michigan in 1997. The firm prepares, processes, packs, holds, and distributes several varieties of pasteurized, ready-to-eat cheese, including ricotta, provolone, mozzarella, and primo sale. All of these products are manufactured at Serra Cheese's facility located at 19717 15 Mile Road, Clinton Township, Michigan 48035, within the jurisdiction of this Court.

5. Fina Serra is co-owner and manager of Serra Cheese. She is also the firm's Secretary and Treasurer. Ms. Serra is responsible for the firm's day-to-day operations, including purchasing, receiving, storage, production, packaging, labeling, and shipping. Ms. Serra performs her duties at 19717 15 Mile Road, Clinton Township, Michigan 48035, within the jurisdiction of this Court.

6. Stefano Serra is co-owner of Serra Cheese. He is also the firm's President and Vice President, and he trains employees on how to make cheese. Mr. Serra performs his duties at 19717 15 Mile Road, Clinton Township, Michigan 48035, within the jurisdiction of this Court.

7. Defendants have been and are now engaged, at 19717 15 Mile Road, Clinton Township, Michigan 48035, in preparing, processing, packing, holding, and distributing various articles of food—namely, ready-to-eat cheese. Defendants' ready-to-eat cheese is food within the meaning of 21 U.S.C. § 321(f).

8. Defendants' cheese is sold to retail and wholesale customers, including restaurants and supermarkets in Michigan and Illinois. The firm also produces cheese for two companies located in Pennsylvania and New York, which sell it under their own private labels.

Serra Cheese receives in interstate commerce one or more components used to manufacture its cheese, including rennet from Wisconsin.

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9. *Escherichia coli* ("*E. coli*") are a diverse group of bacteria that include pathogenic and non-pathogenic strains. Non-pathogenic strains of *E. coli* (*e.g.*, generic, non-pathogenic *E. coli*) in food, which were found in samples of cheese from Defendants' facility, are not associated with human illness, but are an indicator of insanitation during processing and contamination with filth. Because *E. coli* are not inherently present in the milk of dairy animals, the presence of *E. coli* in milk or other dairy products indicates that the milk or dairy product was exposed either directly or indirectly to feces. Insanitary conditions, including poor employee hygiene practices, improperly sanitized utensils and equipment, or contaminated raw materials, may also be a source of *E. coli* in milk and other dairy products.

10. *Listeria innocua* ("*L. innocua*") is one of ten species of *Listeria*. *L. innocua* is non-pathogenic, but it is not a normal bacterial flora of milk. *L. innocua* was found in Defendants' facility and is indicative of insanitary conditions. *L. innocua* is often found in environments that also support the growth of *L. monocytogenes*, a pathogenic organism that poses an acute, life-threatening hazard to human health because it is the causal agent for the disease listeriosis. The presence *of L. innocua* in Defendants' facility demonstrates the potential for the presence of *L. monocytogenes* in the same processing environment.

DEFENDANTS' CONDUCT AND VIOLATIONS

11. FDA most recently inspected Defendants' facility between October 22 and November 8, 2013 (the "November 2013 Inspection"). This inspection established that the ready-to-eat cheese products that Defendants manufacture, process, pack, label, hold, and

distribute are 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 become contaminated with filth or rendered injurious to health. The insanitary conditions include the presence of generic, non-pathogenic *E. coli* and *L. innocua* and Defendants' failure to implement effective monitoring and sanitation controls in accordance with the current Good Manufacturing Practice ("CGMP") requirements for food. See 21 C.F.R. Part 110. FDA investigators documented many significant deviations from CGMP, including, but not limited to, the following:

A. Failure to perform filling and assembling in a manner that protects food from becoming contaminated, as required by 21 C.F.R. § 110.80(b)(13). Specifically, FDA investigators observed an employee drop a piece of plastic wrapping on the wet processing room floor. Without washing or sanitizing it, the employee picked the plastic wrapping up off the floor and placed it directly on ready-to-eat provolone cheese. In addition, FDA investigators observed an employee washing perforated plastic trays on the floor of the firm's processing area immediately before filling the trays with mozzarella cheese;

B. Failure to take effective measures to protect finished food from contamination by raw materials, as required by 21 C.F.R. § 110.80(b)(6). Specifically, FDA investigators observed an employee use the same centrifugal pump to transfer raw and pasteurized milk without adequately washing and sanitizing the pump and associated hoses between such uses. In addition, FDA investigators observed employees dump raw milk onto the floor in a high-traffic area of the processing room;

C. Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food and food contact surfaces, as

required by 21 C.F.R. § 110.35(a). Specifically, FDA investigators observed an employee using a hose to clean a table in a manner that caused water from the table and floor to splatter onto ready-to-eat provolone cheese. In addition, Defendants do not have separate cleaning and sanitizing steps for utensils and equipment;

D. Failure to construct the facility in such a manner as to allow floors to be adequately cleaned and kept clean and in good repair, as required by 21 C.F.R. § 110.20(b)(4). Specifically, FDA investigators observed that the concrete floor in the manufacturing area was pitted and porous. In addition, some areas of the floor had layers of paint and/or sealant that were cracked, peeling, and chipped. The FDA investigators also observed standing water in all areas of the walk-in cooler; and

E. Failure to store raw materials in a manner that protects against contamination, as required by 21 C.F.R. § 110.80(a)(1). Specifically, FDA investigators observed that employees used salt from a fifty-pound bag that had a wet bottom to make ready-to-eat mozzarella cheese.

12. During the November 2013 Inspection, FDA investigators collected numerous environmental and finished product samples from Defendants' facility. FDA analyzed 71 environmental subsamples for *Listeria*. Thirty of these subsamples tested positive for *L. innocua*, including 11 subsamples from locations in close proximity to food. In addition, FDA found excessive levels of generic, non-pathogenic *E. coli* in Serra Cheese's primo sale cheese, fresh cherry mozzarella cheese, sundried tomato cheese, and hot red pepper cheese.

13. At the close of the November 2013 Inspection, FDA investigators issued a seven-item List of Inspectional Observations ("Form FDA-483") to, and discussed each of the observed deviations with, Defendant Fina Serra.

14. In an undated letter received by FDA on January 22, 2014, Defendant Fina Serra responded to the November 2013 Form FDA-483, representing that actions had been and were being taken to correct the CGMP violations identified during the November 2013 Inspection. After reviewing Defendants' submission, FDA determined that the proposed corrections are inadequate to fully address Defendants' CGMP violations. For example, Defendants' response did not address how they would clean and sanitize the centrifugal pumps between uses.

15. Defendants violate 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), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or rendered injurious to health.

16. Defendants violate 21 U.S.C. § 331(k) by causing the adulteration, within the meaning of 21 U.S.C. § 342(a)(4), of articles of food while such articles are held for sale after shipment of one or more of their components in interstate commerce.

HISTORY

17. FDA previously inspected Defendants' facility between January 8-23, 2013 (the "January 2013 Inspection"). Several of the CGMP deviations observed during the November 2013 Inspection, discussed in paragraph 11, are the same as, or similar to, those observed by FDA during the January 2013 Inspection. For example, during the January 2013 Inspection, FDA documented Defendants' failure to: (a) conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials (similar to paragraph 11(C) above); (b) construct the facility in such a manner as to allow floors to be adequately cleaned and kept clean and in good

repair (similar to paragraph 11(D) above); and (c) store raw materials in a manner that protects against contamination (similar to paragraph 11(E) above). At the close of the January 2013 Inspection, FDA investigators issued an eight-item Form FDA-483 to Defendant Fina Serra and discussed each of the observations with her. Defendants did not respond to the January 2013 Form FDA-483.

18. FDA issued a Warning Letter to Defendants on June 6, 2013, detailing violations of the CGMP regulations observed during FDA's January 2013 Inspection. The Warning Letter also informed Defendants that FDA found *L. innocua* in their facility and generic, non-pathogenic *E. coli* in their cheese, and that the presence of these microorganisms was indicative of insanitary conditions. The Warning Letter emphasized the serious nature of the deficiencies, stated that it was not intended to be an all-inclusive review of Defendants' products, and stated that it was Defendants' responsibility to ensure that their products comply with the Act and its implementing regulations.

19. Defendant Fina Serra responded to the Warning Letter by letter dated July 23, 2013, promising numerous corrections. Although Defendants made some corrections in response to FDA's inspectional observations, they either did not follow through on their attempts to correct or failed to sustain the corrections they made, because the FDA Investigators observed and documented ongoing, significant CGMP violations during the November 2013 Inspection, and FDA's laboratory analyses confirmed the presence of *L. innocua* and generic, non-pathogenic *E. coli* in Defendants' facility and cheese, respectively.

20. 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, the United States respectfully requests that this Court:

I. Permanently and perpetually restrain and enjoin Defendants S. Serra Cheese Company, a corporation, and Fina Serra and Stefano Serra, individuals, and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of the Court's Order, from doing or causing to be done, directly or indirectly, any of the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, or the causing thereof, any article of food that is adulterated; and

B. Violating 21 U.S.C. § 331(k) by causing the adulteration of any article of food while such article of food is held for sale after shipment of one or more of its components in interstate commerce.

II. Permanently and perpetually restrain and enjoin, under 21 U.S.C. § 332(a) and the equitable authority of this Court, Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships), from doing or causing to be done, directly or indirectly, any act that adulterates food within the meaning of 21 U.S.C. § 342(a)(4).

III. Order Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of the Court's Order, to cease receiving, preparing, processing, packing, holding, and distributing all food at or from their facility, or at any other location(s) from which Defendants receive, prepare, process, pack, hold, or distribute

food, unless and until Defendants bring their receiving, preparing, processing, packing, holding, and distribution operations into compliance with the Act and its implementing regulations to FDA's satisfaction.

IV. Grant the United States its costs and such other and further relief as the Court deems just and proper.

Dated this 8th day of August, 2014.

Respectfully submitted,

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